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VKM Report 2026:06

Risk assessment of contaminants in sewage sludge used as fertilising product in Norway – fate and effects in the food chain and the environment

Trine Eggen, Carl Einar Amundsen, Robert Barneveld, Aksel Bernhoft, Barbara Bukhvalova, Gunnar Eriksen, Belinda Flem, Christiane Kruse Fæste, Tron Øystein Gifstad, Merete Grung, Veronika Sele, Kaja Skjærven, Øystein Sæle, Stefan Trapp, Christian Vogelsang, Håvard Steinshamn

Scientific Opinion of the Panel on Animal Feed of the Norwegian Scientific Committee for Food and Environment

This report presents a risk assessment of organic contaminants in sewage sludge and sewage-sludge-based products used on agricultural land in Norway, under current and alternative fertiliser regulations and management practices. It identifies a limited number of substances of concern for soil health, aquatic organisms, animal health, and human health, and provides a scientific basis for evaluating circular economy, organic fertilisers, and the safe recycling of bioresources in agriculture.

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Norwegian Scientific Committee for Food and Environment (VKM)
Postboks 222 Skøyen
0213 Oslo
Norway

Email: vkm@vkm.no

vkm.no

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Preparation of the opinion

The Norwegian Scientific Committee for Food and Environment (Vitenskapskomiteen for mat og miljø, VKM) appointed a project group to draft the opinion. The project group consisted of 7 VKM members, 3 VKM staff and 5 external experts. Two referees commented on and reviewed the draft opinion. The Committee, by the Panel on Animal Feed, assessed, and approved the final opinion.

Authors of the opinion

The authors have contributed to the opinion in a way that fulfils the authorship principles of VKM (VKM, 2023). The principles reflect the collaborative nature of the work, and the authors have contributed as members of the project group and/or the VKM Panel on Animal Feed.

Members of the project group

Trine Eggen – Chair of the project group. Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) NIBIO

Carl Einar Amundsen – External expert. Affiliation: Former researcher in The Norwegian Defence Estates Agency

Robert Barneveld – External expert. Affiliation: NIBIO

Aksel Bernhoft – Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) Norwegian Veterinary Institute

Barbara Bukhvalova – VKM staff. Affiliation: VKM

Gunnar Sundstøl Eriksen – External expert. Affiliation: Norwegian Veterinary Institute

Belinda Flem – Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) The Geological Survey of Norway (NGU)

Christiane Kruse Fæste – Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) Norwegian Veterinary Institute

Tron Øystein Gifstad – Project leader, VKM staff. Affiliation: VKM.

Merete Grung – External expert. Affiliation: The Research Institute for Water and the Environment (NIVA)

Veronika Sele – Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) Institute of Marine Research

Stefan Trapp – External expert. Affiliation: Department of Environmental Engineering, Technical University of Denmark (DTU)

Christian Vogelsang – Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) The Research Institute for Water and the Environment (NIVA)

Håvard Steinshamn – Chair of the Panel on Animal Feed. Affiliation: 1) VKM; 2) NIBIO

Members of the Panel on Animal Feed

Aksel Bernhoft – Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) Norwegian Veterinary Institute

Trine Eggen – Chair of the project group. Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) NIBIO

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Veronika Sele – Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) Institute of Marine Research

Kaja Skjærven – Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) Institute of Marine Research

Øystein Sæle – Member of the Panel on Animal Feed. Affiliation: 1) VKM; 2) Institute of Marine Research

Håvard Steinshamn – Chair of the Panel on Animal Feed. Affiliation: 1) VKM; 2) NIBIO

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VKM would like to thank the referees Dries Huygens (JRC, European Commission, Seville, Spain) and Marciel Alvarez Marote (Consultant, self-employed) and Roland Kallenborn (Norwegian Institute of Life Sciences) for their valuable comments through critical review of the draft opinion. VKM emphasises that the referees are not responsible for the content of the final opinion. In accordance with VKM's routines for approval of a risk assessment (VKM,

2024), VKM received their comments before evaluation and approval by VKM Panel on Animal Feed and before the opinion was finalised for publication.

Expertise of VKM experts

Persons working for VKM, either as appointed members of the Committee or as external experts, do this by virtue of their scientific expertise, not as representatives for their employers or third-party interests. The provisions on impartiality in the Norwegian Public Administration Act apply to all work carried out by VKM.

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Summary

Background and purpose

The Norwegian fertiliser regulations was revised in 2025 to support reduced pollution, better utilisation of nutrients, fulfilment of international obligations, simplification, and facilitation of nutrient recycling. In Norway, 50 to 60 per cent of sewage sludge is used on agricultural land, compared with around 40 per cent in the EU. Norway has many small wastewater treatment plants and a long tradition of using treated sludge in agriculture. At the same time, incineration is less common in Norway than in many other European countries, partly because Norwegian wastewater treatment largely relies on chemical phosphorus precipitation (chemical separation of phosphorus).

In recent years, new products based on sewage sludge have been developed, such as pellets, biochar and struvite (a fertiliser product recovered from wastewater that makes it possible to recycle phosphorus and nitrogen for agricultural use).

At the same time, knowledge about organic contaminants in sewage sludge has increased. On this basis, the Norwegian Food Safety Authority asked VKM to assess the risks associated with organic contaminants in sewage sludge and sludge-based products.

Terms of reference and scope

VKM was tasked with identifying organic contaminants in sewage sludge and assessing which substances were relevant to include in the risk assessment. The assignment also covered products made from sludge, such as biochar, ash and struvite.

Risks were to be assessed for the use of sludge on agricultural land over a period of up to 100 years. If current practice could lead to undesirable effects, alternative application rates and uses were also to be evaluated. In addition, less stringent rules for use in the cultivation of vegetables and on grassland used for mowing and grazing were to be assessed.

The assessment covered possible effects on soil-dwelling organisms, aquatic organisms, livestock and humans. Combined effects of multiple substances were not assessed in detail.

Methods and scenarios

The risk assessment was based on data for more than 1,000 organic contaminants measured in Norwegian sewage sludge. For some pharmaceuticals that had not been analysed, levels were estimated using consumption data and modelling. Substances were prioritised based on occurrence, properties, degradation, mobility and toxicity.

A model was developed to calculate how organic contaminants may accumulate and spread in soil, water and plants over time. The calculations were used to assess exposure for soil- and water-dwelling organisms, livestock and humans. The model accounted for climate and soil conditions in five regions in Norway.

A wide range of scenarios for the use of sewage sludge and sludge-based products in the cultivation of cereals, potatoes, vegetables and grass were assessed. These included current practice, reduced application rates, use every ten years and annually, different intervals between application and cultivation or grazing, and the use of pellets, biochar, struvite and liquid digestate from sewage sludge. The effects of thermal hydrolysis were also assessed.

Summary of main findings

Norwegian monitoring data show that municipal sewage sludge contains many different organic contaminants, but levels vary widely between treatment plants and regions. The levels of several legacy pollutants, such as PCBs, PAHs and PBDEs, have decreased over time but are still present in sludge and remain relevant because they degrade slowly and can accumulate in the environment. PFAS are regularly detected, particularly PFOS and other long-chain PFAS. Pharmaceuticals and newer industrial chemicals often occur at low levels but with large variation. Several substances found at the highest concentrations are linked to cosmetics and personal care products.

The different sludge-based products have different risk profiles. Pellets are expected to pose roughly the same or slightly lower risk than dewatered sludge. Struvite contains very low levels of organic contaminants and was consistently associated with low risk. Biochar is distinctive in that pyrolysis reduces many organic contaminants, but there is still uncertainty related to the possible formation of new compounds and how residues may be bound or released over time.

For soil-dwelling organisms, the assessment showed that current practice may pose a long-term risk for some substances. After quality assessment of the data, 19 organic substances showed potential risk, including certain pharmaceuticals, cosmetic-related substances, plastic-related compounds, PAHs and PFOS.

Lower application rates reduced risk but did not eliminate it. For some persistent substances, annual application could result in a higher cumulative load than application every ten years.

For aquatic organisms, under current practice one substance exceeded the risk threshold, the pharmaceutical fenbendazole, but the assessment is uncertain. In scenarios with less stringent conditions or alternative uses, several substances were considered capable of posing a risk to the aquatic environment.

For livestock, the calculations generally showed low levels of individual substances in feed rations. Risk was highest for grazing animals, as soil ingestion is an important exposure pathway, and with the use of liquid digestate from sewage sludge, direct intake may also contribute. Delayed grazing after application of products was found to reduce exposure. At the same time, some substances, particularly bisphenols and certain pharmaceuticals, are highlighted as relevant to animal health, and combined effects cannot be ruled out.

For humans, current use of sewage sludge is generally assessed to pose relatively low risk to food safety for most of the substances examined. At the same time, an increase in organic contaminants in agricultural soil is undesirable. The report highlights PFAS, PCBs, dioxins, PAHs, PBDEs, siloxanes, bisphenol A, octocrylene and several pharmaceuticals as important for food safety, because dietary exposure to some of these substances is already considered undesirable or of concern. For individuals with high consumption of locally caught freshwater fish, exposure is generally assumed to be limited, but for some individuals it may be relevant.

Main conclusion

Norwegian data show that sewage sludge contains many organic contaminants, but levels vary widely. Most substances appear to pose low risk to soil-dwelling and aquatic organisms, and low health risk to livestock and humans. Some persistent substances may give rise to concern over time.

Struvite was consistently associated with low risk, while pellets, biochar, sewage sludge and liquid digestate from sewage sludge have more complex risk profiles. For humans and livestock, risk is generally low under current practice, but certain groups of substances are undesirable because the overall burden is already high or of concern.

The report concludes that some substances should be prioritised for further investigation and follow-up.

In summary: VKM concludes that most organic contaminants in sewage sludge pose low risk, but that some organic contaminants may give rise to concern over time. This particularly applies to persistent substances that can accumulate in soil. The report therefore highlights the need for further investigation through the collection of more data and knowledge to support future risk assessments.

Sammendrag på norsk

Bakgrunn og formål

Den norske gjødselforskriften ble revidert i 2025, for å legge til rette for redusert forurensning, bedre utnyttelse av næringsstoffer, internasjonale forpliktelser og forenkling, samt tilrettelegging for resirkulering av næringsstoffer. I Norge brukes 50 til 60 prosent av avløpsslammet på jordbruksarealer, mot rundt 40 prosent i EU. Norge har mange små renseanlegg og lang tradisjon for å bruke renset slam i landbruket. Samtidig er forbrenning mindre vanlig i Norge enn i mange andre europeiske land, blant annet fordi norsk avløpsrensing i stor grad bygger på kjemisk fosforfelling (kjemisk separasjon av fosfor).

De siste årene er det utviklet nye produkter basert på avløpsslam, som pellets, biokull og struvitt (gjødselprodukt som utvinnes fra avløpsvann, som gjør det mulig å gjenvinne fosfor og nitrogen til bruk i landbruket).

Samtidig har kunnskapen om organiske forurensninger i avløpsslam økt. På denne bakgrunn ba Mattilsynet VKM om å vurdere risikoen ved organiske forurensninger i avløpsslam og slamprodukter.

Oppdrag og avgrensning

VKM fikk i oppdrag å kartlegge organiske forurensninger i avløpsslam, og vurdere hvilke stoffer som var relevante å ta med i risikovurderingen. Oppdraget omfattet også produkter laget av slam, som biokull, aske og struvitt.

Risiko skulle vurderes for bruk av slam på jordbruksarealer opptil 100 år. Dersom dagens praksis kan gi uønskede effekter, skulle også alternative mengder og bruksformer vurderes. Videre skulle også mindre strenge bruksregler ved dyrking av grønnsaker og for grasarealer brukt til slått og beite vurderes.

Vurderingen omfattet mulige virkninger for jordlevende organismer, vannlevende organismer, husdyr og mennesker. Kombinasjonseffekter av mange stoffer samtidig ble ikke vurdert i detalj.

Metode og scenarier

Risikovurderingen bygget på data for over 1000 organiske forurensinger målt i norsk avløpsslam. For noen legemidler som ikke var analysert, ble nivåene beregnet ved hjelp av forbrukstall og modellering. Stoffene ble prioritert ut fra forekomst, egenskaper, nedbrytning, mobilitet og giftighet.

Det ble utviklet en modell for å beregne hvordan organiske forurensinger kan hope seg opp og spre seg i jord, vann og planter over tid. Beregningene ble brukt til å vurdere eksponering for jord- og vannlevende organismer, husdyr og mennesker. Modellen tok hensyn til klima og jordforhold i fem områder i Norge.

En lang rekke scenarier for bruk av avløpsslam og produkter basert på avløpsslam til dyrking av korn, potet, grønnsaker og gras ble vurdert. Disse omfattet dagens praksis, redusert spredningsmengder, 10-årig og årlig bruk, ulike intervaller mellom spredning og dyrking eller beiting, samt bruk av pellets, biokull, struvitt og flytende biorest fra avløpsslam. Effekten av termisk hydrolyse ble også vurdert.

Sammendrag av hovedfunn

Norske overvåkingsdata viser at kommunalt avløpsslam inneholder mange ulike organiske forurensninger, men nivåene varierer mye mellom renseanlegg og regioner. Innholdet av flere eldre miljøgifter, som PCB, PAH og PBDE, har gått ned over tid, men finnes fortsatt i slam og er fortsatt relevante fordi de brytes langsomt ned og kan hope seg opp i miljøet. PFAS påvises jevnlig, og særlig PFOS og andre langkjedede PFAS går igjen. Legemidler og nyere industrikjemikalier forekommer ofte i lave nivåer, men med stor variasjon. Flere av stoffene som finnes i høyest konsentrasjon er knyttet til kosmetikk og personlig pleie.

De ulike slamproduktene har forskjellige risikoprofiler. Pellets forventes å ha om lag samme eller noe lavere risiko enn avvannet slam. Struvitt inneholder svært lave nivåer av organiske forurensninger og ga gjennomgående lav risiko. Biokull skiller seg ut ved at pyrolyse reduserer mange organiske forurensninger, men det er fortsatt usikkerhet knyttet til om nye forbindelser kan dannes, og hvordan rester eventuelt kan bindes eller frigjøres over tid.

For jordlevende organismer viste vurderingen at dagens praksis kan gi langsiktig risiko for en del stoffer. Etter kvalitetsvurdering av datagrunnlaget var det 19 organiske stoffer som viste potensiell risiko, blant annet enkelte legemidler, kosmetikkrelaterte stoffer, plastrelaterte forbindelser, PAH og PFOS.

Lavere spredningsmengder reduserte risikoen, men fjernet den ikke. For noen persistente stoffer kunne årlig tilførsel gi høyere samlet belastning enn spredning hvert tiende år.

For vannlevende organismer ble det ved dagens praksis identifisert ett stoff med beregnet risiko over terskelen, legemidlet fenbendazol, men vurderingen er usikker. I scenarier med mindre strenge vilkår eller andre bruksmåter, ble flere stoffer vurdert å kunne gi risiko for vannmiljøet.

For husdyr viste beregningene gjennomgående lave nivåer av enkeltstoffer i fôrrasjonen. Risikoen var størst for beitedyr, fordi jordinntak er en viktig eksponeringsvei, og ved bruk av flytende biorest av avløpsslam kan også direkte inntak bidra. Vi fant at utsatt beiting etter spredning av produktet vil redusere eksponeringen. Samtidig trekkes enkelte stoffer, særlig bisfenoler og noen legemidler, fram som relevante for dyrehelse, og kombinasjonseffekter kan ikke utelukkes.

For mennesker vurderes dagens bruk av avløpsslam generelt å gi relativt lav risiko for mattrygghet for de fleste av stoffene som er undersøkt. Samtidig er det uønsket at innholdet av organiske forurensninger i jordbruksjord øker. Rapporten peker særlig på PFAS, PCB, dioksiner, PAH, PBDE, siloksaner, bisfenol A, octocrylene og flere legemidler som viktige for mattrygghet, fordi kostinntaket av noen av disse stoffene allerede er vurdert som uønsket eller bekymringsfullt. For personer med høyt inntak av lokalt fanget ferskvannsfisk, antas eksponeringen generelt å være begrenset, men for enkelte kan den være relevant.

Hovedkonklusjon

Norske data viser at avløpsslam inneholder mange organiske forurensninger, men nivåene varierer mye. De fleste stoffene ser ut til å gi liten risiko for jordlevende og vannlevende organismer, og liten helserisiko for husdyr og mennesker. Noen tungt nedbrytbare stoffer kan gi grunn til bekymring over tid.

Struvitt ga gjennomgående lav risiko, mens pellets, biokull, avløpsslam og flytende biorest fra avløpsslam har mer sammensatte risikoprofiler. For mennesker og husdyr er risikoen generelt lav ved dagens praksis, men enkelte stoffgrupper er uønsket fordi belastningen allerede er høy, eller har en bekymring.

Rapporten konkluderer med at noen stoffer bør prioriteres for nærmere undersøkelser og videre oppfølging.

Oppsummert: VKM konkluderer med at de fleste organiske forurensningene i avløpsslam gir liten risiko, men at noen organiske forurensninger kan gi grunn til bekymring over tid. Dette gjelder særlig stoffer som er tungt nedbrytbare og kan hope seg opp i jord. Rapporten peker derfor på behov for videre undersøkelser gjennom innhenting av flere data, mer data og kunnskap for gjennomføringer av kommende risikovurderinger.

Abbreviations

ATC	Anatomical Therapeutic Chemical Classification System
ADI	Acceptable Daily Intake
AF	Assessment Factor
AI	Artificial Intelligence
BAF	Bioaccumulation Factor. See glossary for explanation
BCF	Bioconcentration Factor. See glossary for explanation
BCF_{carrot}	Bioconcentration Factor, for root vegetables, e.g. carrot and radish
BCF_{cereal}	Bioconcentration Factor, for cereals
BCF_{fish}	Bioconcentration Factor, for fish, under steady-state conditions
BCF_{leaf}	Bioconcentration Factor, for plant leaves
BCF_{potato}	Bioconcentration Factor, for potato
BCF_{plant}	Bioconcentration Factor, for plant
BMDL	Benchmark Dose Level
BMF	Biomagnification Factor. See glossary for explanation
BSAF	Biota-to-soil accumulation factor. See glossary for explanation
DM	Dry matter
DNEL	Derived No Effect Level
Dw	Dry weight
ECHA	European Chemical Agency
EFSA	European Food Safety Authority
ERA	Environmental Risk Assessment
EPM	Equilibrium partitioning method
EU	European Union
EQS	Environmental Quality Standards
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FPR	Fertiliser Product Regulation
Ha	Hectar
HBGV	Health-Based Guidance Value
K_d	Soil-water (or soil-pore water) distribution coefficient
K_{oc}	Organic carbon-water partition coefficient
K_{ow}	Octanol-water partitioning coefficient
$K_{p/sed}$	Sediment-water partition coefficient
$K_{p/soil}$	Soil-water partition coefficient
$K_{p/susp}$	Suspended particulate matter-water partition coefficient

LO(A)EL	Lowest Observed (Adverse) Effect Level
Log D	Distribution coefficient (log scale), distribution of a compound between octanol and water phase at a specific pH
MEC	Measured Environmental Concentration
MEC_{sludge}	Measured Environmental Concentration, in sludge
ML	Maximum Level, for contaminants in food and feed
MOE	Margin of Exposure
MRL	Maximum Residue Level, limit for residues of pesticides and veterinary medicines
NEA	Norwegian Environmental Agency
NER	Non-Extractable Residue. See glossary for explanation
NFSA	Norwegian Food Safety Authority
NLR	Norwegian Agricultural Advisory Service (Norsk Landbruksrådgiving)
NO(A)EL	No Observed (Adverse) Effect Level
NOEC	No Observed Effect Concentration
OECD	The Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic compounds. See glossary for explanation
PMT	Persistent, Mobile and Toxic compound. See glossary for explanation
PEC	Predicted Environmental Concentrations
$PEC_{soil/yr}$	Predicted Environmental Concentrations, soil
$PEC_{soil/background}$	Predicted Environmental Concentrations, soil - last months before 6th application in scenarios application dewatered sewage sludge every 10th year
$PEC_{soil/peak/100yr}$	Predicted Environmental Concentrations, soil - average of first months after application of sewage sludge product last time within a 100 year perspective
PEC_{plant}	Predicted Environmental Concentrations, plants
PEC_{sw}	Predicted Environmental Concentrations, surface water
$PEC_{sw/peak}$	Predicted Environmental Concentrations, surface water - average of first months after application of sewage sludge product
PNEC	Predicted No Effect Concentration
$PNEC_{aqua}$	Predicted No Effect Concentration, aquatic organisms
$PNEC_{aqua/exp}$	Predicted No Effect Concentration, aquatic organisms, based on experimental studies
$PNEC_{aqua/QSAR}$	Predicted No Effect Concentration, aquatic organisms, based on QSAR
$PNEC_{soil}$	Predicted No Effect Concentration, soil organisms

$PNEC_{soil/est/100yr}$	Predicted No Effect Concentration, estimated for long-time perspective up to 100 years
$PNEC_{soil/exp}$	Predicted No Effect Concentration, soil experimental data
$PNEC_{acute}$	Predicted No Effect Concentration, acute toxicity
$PNEC_{chronic}$	Predicted No Effect Concentration, chronic toxicity
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RCR	Risk Characterisation Ratio. See glossary for explanation
RCR_{soil}	Risk Characterisation Ratio, calculated for soil
$RCR_{soil/peak}$	Risk Characterisation Ratio, calculated for soil - average of first months after application of sewage sludge product
$RCR_{soil/peak/100yr}$	Risks to soil-living organisms from all contaminants with RCR > 1 were characterised for the time immediately after application of sewage sludge (in a 30 day-period after the application) and in a 100-year perspective
RCR_{sw}	Risk Characterisation Ratio, calculated for surface water
SML	Specific migration limit
TDI	Tolerable Daily Intake
TEQ	Toxicity Equivalence Factors
ToR	Terms of Reference
TDLo	Toxic Dose Low. See glossary for explanation
TGD	Technical Guidance Document, EU
Tonne	Tonne = 1000 Kg (= 1 Mg)
TWI	Tolerable Weekly Intake
VKM	Norwegian Scientific Committee for Food and Environment
QSAR	Quantitative Structure-Activity Relationship models

Glossary

BAF: Bioaccumulation factor is the accumulation of a chemical in an organism compared to concentration in the surrounding environment (water, food)

BCF: Bioconcentration factor is the ratio of the concentration of a chemical in a plant/organism to its concentration in the surrounding water medium under steady-state conditions.

BMF: Biomagnification Factor, concentration of a substance in a predator relative to its concentration in the prey. A BMF greater than 1 indicates that a chemical becomes more concentrated in the food chain.

BSAF: Biota-to-soil accumulation factor is the ratio of the concentration of a chemical in an organism (biota) to its concentration in the associated sediment/soil, typically normalized to lipid and organic carbon content, reflecting the extent of bioaccumulation under equilibrium or near-equilibrium conditions.

Chemical list: Complete chemical list is given in Supplementary Materials 4

Hygienisation: Hygienisation in this report refers to processes applied to sewage sludge to achieve a significant reduction of pathogens (including bacteria, viruses, and parasites), commonly accomplished through controlled treatment conditions, particularly defined time–temperature combinations, as recognised in EU practice under Directive 86/278/EEC and related national guidelines.

Non-Extractable-Residue: NER in soils and sediments are defined as chemical species originating from chemicals that remain un-extracted by methods which do not significantly change the chemical nature of these residues (IUPAC definition, Roberts 1984). The extraction method must not substantially change the compounds themselves or the structure of the matrix. The total amount of NER is the sum of strongly adsorbed or entrapped (type I) and covalently bound residues (type II) both either derived from the parent substance or from transformation or degradation products; a third type (III) refers to biogenic NER that are derived from biotic degradation (Kaestner et al. 2014; Schaeffer et al. 2018). NER can be detected and quantified by using isotope-labeled chemicals.

Persistent, Bioaccumulative and Toxic (PBT) chemicals: substances characterized by high environmental persistence (resistance to degradation), significant bioaccumulation in biota (via uptake and slow elimination), and inherent toxicity, leading to adverse effects in organisms and potential biomagnification through trophic levels.

Persistent, Mobile and Toxic (PMT) chemicals: substances characterized by high resistance to degradation, high mobility in the aquatic environment (allowing widespread distribution, particularly in groundwater and drinking water resources), and intrinsic toxicity to organisms, posing long-term risks to human health and ecosystems.

K_d: Soil-water (or soil-pore water) distribution coefficient. Partition coefficient specifically for non-ionised compounds and distribution coefficient for sum non-ionised and ionised compounds

$K_{p,sed}$: The K_p sediment coefficient, also known as the sediment-water partition coefficient, is a measure of how a chemical substance distributes between sediment and water in an aquatic environment

$K_{p,susp}$: Suspended particulate matter-Water partition Coefficient water/suspended solids. Suspended particulate matter is the link of pollutants transport from dissolved phase to the sediment.

RCR: Risk Characterisation Ratio, is a quantitative metric used in chemical risk assessment to evaluate whether exposure to a substance is likely to cause adverse effects. Within EU frameworks (e.g. REACH/ECHA and EFSA-related methodologies), the RCR is used consistently as a formal decision metric, typically defined as PEC/PNEC. Risk Quotient (RQ) also expresses ratio between exposure and effect threshold, but in contrast to RCR, RQ is primarily a screening-level indicator, often based on measured concentrations, and is intended for preliminary risk identification and different toxicity endpoint rather than final risk characterization. RQ is a more generic term used internationally (e.g. US EPA, Canada). RCR was chosen over the RQ.

Liquid fraction of sewage sludge digestate (Reject water)**:** The aqueous fraction separated from anaerobically digested sewage sludge, containing dissolved nutrients, organic matter, and residual contaminants, typically recycled within treatment processes or applied as a liquid fertiliser.

TDLo: Toxic Dose Low, the lowest dose of a substance introduced by any route, other than inhalation, over any given period of time, and reported to produce any toxic effect in humans or to produce tumorigenic or reproductive effects in animals.

Background as provided by the Norwegian Food Safety Authority

In 2009, VKM published a risk assessment of sewage sludge. This assessment has been widely referred to both in Norway and internationally. It's been more than ten years since the assessment was published and new relevant knowledge is available. VKM has in recent years published relevant assessments of potentially toxic elements and antimicrobial resistance (2014 Copper and zinc, 2019 Cadmium and 2022 Heavy metals), so issues covered in these assessments are not included in this assignment.

Regulation 4 July 2003 no. 951 on fertilising products of organic origin regulates the use of sewage sludge as fertilising product. The EU sewage sludge directive is implemented in this regulation. Among other things, the regulation has limit values for heavy metals, a duty of care for contaminants and rules for which crops sewage sludge can be used on.

In Norway, between 50 and 60% of sewage sludge is applied on agricultural land, but the regional differences are large (based on Statistics Norway's annual data on sludge disposal, StatBank table 11788). In Østfold, Oslo, Akershus and Vestfold > 95% of the sewage sludge was applied on agricultural areas in 2018, while in areas with grass production a very small proportion of the sludge is used for agricultural purposes. The proportion of sewage sludge used as fertilising product is high in Norway, compared to many other countries. Norwegian treatment methods differ some from what is usual in in other European countries, and this can also affect the content of contaminants. Furthermore, Norwegian soil and climate conditions can influence the breakdown and binding of contaminants. We need to ensure that the use of sewage sludge as fertilising material in Norway is safe, and that the agricultural soil is kept sound in a long-term perspective. Norwegian conditions should therefore be used as a basis where this is possible.

In 2009, the VKM assessment was made based on average levels of contaminants in sewage sludge. The Norwegian Food Safety Authority (NFSA) believes it is also important to have a realistic "worst case scenario" assessed. Experience shows that treatment plants that stand out with a high content of certain contaminants tend to do so over time, as this is due to regular inputs of for example leachate from airports or old waste sites. Often the same agricultural plots will be fertilised with sludge from the same sewage treatment plant every ten years.

The sludge composition may change in the future due to stricter treatment requirements under the revised directive. This may lead to an increased concentration of contaminants in the sewage sludge.

The NFSA has receives several inquiries from companies that want to use fertilising products based on sewage sludge, which have been treated in new ways, with less strict restrictions than those given in the national regulation. This applies to companies that treat sludge with thermal hydrolysis, companies that dry and pelletize sludge, companies that separate the digestate to a solid and a liquid part and companies that consider making struvite, ashes or biochar from the sludge. Biochar, ashes and struvite may have a different content of contaminants than the starting material.

According to the national regulation sewage sludge can be used before sowing a new meadow, but not on a meadow. The EU sludge directive is less strict and allows grazing and harvesting of

fodder three weeks after the application of sewage sludge on meadows/pastures. The NFSA therefore wants VKM to include an assessment of shorter prohibition periods than today. Different application methods and forms (liquid, solid etc) can affect the risk, such as residual amounts on the culture after application, and the NFSA therefore wants this aspect to be included in the assessment. In addition to normal surface application, sewage sludge can, for example, be applied to grassland in pelletized form or as a solid or liquid part of a separated digestate. The application methods can also vary between different forms of surface spreading or using equipment for intrusion into the field. There are also some companies that want to use sewage sludge where vegetables and fruit are to be grown. The EU sludge directive has a minimum requirement of ten months from the use of sewage sludge to harvesting. In the national regulation, the minimum requirement is three years, except for sludge sold under the trade name sewage sludge-based fertilising product, which has a minimum requirement of ten months. The term sewage sludge-based fertilising product may only be used following approval by the NFSA. There are several requirements for using this designation, among other things for the treatment and spreading quantity. There is only one such product on the market today.

The NFSA assesses relevant contaminants as part of the work with environmental monitoring. In addition, the Norwegian Environment Agency and Norsk Vann collaborate to test sewage sludge from a selection of treatment plants approximately every five years. In the selection of these contaminants, properties that are particularly relevant for uptake in the food chain through uptake by plants or grazing animals have not been assessed. The Norwegian Food Safety Authority considers that it is relevant for VKM to take as a starting point the Norwegian Environment Agency's list of contaminants, to limit the scope of VKM's mission. However, inclusion of other contaminants that are particularly relevant for uptake and adverse effects in the food chain should also be assessed.

In VKM's risk assessment from 2009, there were several contaminants that were not part of the final assessments due to lack of data. Furthermore, negative effects due to exposure to several different contaminants at the same time (the cocktail effect) couldn't be assessed due to a lack of knowledge. It is important to get an overview of relevant data gaps that limit the possibility of making a complete risk assessment.

VKM assessed microplastics in 2019. There is new knowledge about microplastic since then. However, because of the already large scope of this assessment it will not be extended to cover this.

Terms of reference as provided by the Norwegian Food Safety Authority

The NFSA wants VKM's assessment of several questions related to the use of sewage sludge as fertilising products and possible negative effects for health and the environment.

1. Mapping of relevant contaminants in sewage sludge

a) Which contaminants in sewage sludge are relevant and possible to carry out a risk assessment of and what do we know about the level of these in sewage sludge today? The Norwegian Food Safety Authority wants VKM to use the Environmental Protection Agency's list of relevant contaminants.
b) Which other contaminants, then those mentioned in point a) should also be assessed due to their potential for uptake and possible negative effects in the food chain? This point includes possible negative effects on grazing animals.
c) Which contaminants are relevant to investigate in biochar, ashes and struvite based on sewage sludge and what conditions (for example temperature and residence time) are needed for pyrolysis/combustion to break down and/or remove contaminants in the process that converts sludge into biochar/ash?

2. Risk of current practice

a) Describe the mobility of the relevant contaminants in agricultural soil and the immediate vicinity of agricultural soil after the application of sewage sludge, as well as transfer to the target organisms in table 1 for selected scenarios.
b) What levels of the relevant contaminants in agricultural soil poses a risk of harmful effects on the selected target organisms in **Table 1**?
c) What do we know about the current and future exposure (up to 100 years) of the relevant target organisms in **Table 1**, both in terms of average input and a realistic worst-case scenario?
d) If the average scenario described in 2c) shows a risk of adverse effects, will there still be a risk of such effects by reducing the dosage quantity to 8 tons per hectare per 10 years or 1 ton per hectare per year?
e) Give a comment on how the "cocktail effect" is expected to affect the risk to the target organisms in Table 1?

3. Risk when using sewage sludge in new ways

a) If it is permitted to use of sewage sludge in areas where vegetables are grown, ten months before the vegetables are grown, how will this affect human health risks? How will the treatment method and amount applied affect the risk?
b) If the use of sewage sludge is permitted three weeks before grazing or harvesting fodder, how will this affect the risk to grazing animals and animals that eat harvested fodder? How will this affect human health when consuming animal products? How will the product's condition, spreading method and amount of use affect risk?
c) How will using the hygenisation method thermal hydrolysis affect the breakdown of contaminants and possibly reduce the risk in the scenarios mentioned in points a and b, compared to other common sludge treatment methods?
d) How will surface spreading of sewage sludge as mentioned in points b affect the risk to the environment?

Table 1: Target organisms

Target organisms	Adverse effects
Plants • Agricultural and horticultural plants for food and feed [2]	Reduced germination and growth and thus reduced yield
Animals • Soil-living organisms • Aquatic organisms • Production animals that eat feed from cultivated land and/or pasture that has been fertilised Fish (freshwater)	Ecotoxicology Impaired animal health Transfer to animal products
Humans • The whole population and relevant subgroups, people who eat a high proportion of crops gro	Exposure/intake

2Horticultural plants are vegetables.

The need for an assessment of exposure to humans depends on the result of the assessment for plants and animals and may be excluded based on that.

1 Introduction

1.1 Framework for the assessment

1.1.1 Reason for a new risk assessment of organic contaminants in sewage sludge and lessons learned from previous evaluations

In 2009, VKM published the "Risk assessment of contaminants in sewage sludge applied on Norwegian soils", which included heavy metals and selected organic contaminants such as phthalates (DEHP, DBP), octylphenols and octylphenol ethoxylates, nonylphenols and nonylphenol ethoxylates, linear alkylbenzenesulfonate (LAS), polychlorinated biphenyls (PCB7), polycyclic aromatic hydrocarbons (PAH15) and drugs (VKM, 2009).

Since analytical data of measured concentrations in sludge were scarce for the latter group, predicted environmental concentrations (PEC) in sludge were calculated from the predicted transfer from sewage water to sludge for all drugs marketed in Norway with the exclusion of drugs in the groups B, D, S and V of the Anatomical Therapeutic Chemical Classification System (ATC), which were considered as less toxic, and veterinary medicinal products. Applying a tiered approach, drugs that had PEC values corresponding to <100 µg/kg in soil were excluded from further evaluation. For highly potent drugs like hormones and anticancer drugs, an additional safety factor of 10 was applied, setting the cut-off concentration in soil to 10 µg/kg. In the next tier, the recalculation of PEC under consideration of physicochemical properties such as water solubility resulted in the exclusion of less relevant drugs. Subsequently, the PEC calculations were further refined by taking *in vivo* pharmacokinetic properties (biotransformation) into account, leading to another reduction of the number of drugs of interest. Finally, biodegradation during sludge treatment was considered, resulting in the final number of 14 drugs that were evaluated in the 2009 risk assessment.

The overall conclusion of the risk assessment in 2009 was that the use of sewage sludge as agricultural fertiliser would constitute a low risk to the soil ecosystem. Although the estimated concentrations in soil for octylphenols, nonylphenols and LAS exceeded the predicted no effect concentration (PNEC), it was considered that these compounds are highly degradable in soil. There was, however, a potential increase of the metals cadmium (Cd), mercury (Hg), copper (Cu) and zinc (Zn) identified. It was further concluded that the use of sewage sludge in agriculture would not constitute a significant risk to the aquatic environment or to livestock receiving feed produced on sludge-treated fields. Human risk from the consumption of agricultural produce was also considered as low with exception of a potential increased dietary intake of Cd and Cu if only vegetables grown on sludge-treated soil were consumed. The risks had been assessed chemical by chemical, since no methodology for the risk assessment of the mixture occurring in sewage sludge was available. Most of the estimated exposures were well below any predicted effect concentration, making any interaction less likely, unless the contaminants have the same mode of action.

Since 2009, considerably more data on the occurrence of organic contaminants in sewage sludge have become available, including data for drugs, personal care products and per- and polyfluoroalkyl substances (PFAS). In addition, expanded hazard information, including PNEC values for a broad spectrum of chemicals, is now accessible. Therefore, a new risk assessment is needed, with a stronger emphasis on analytical data, where the Norwegian Food Safety

Authority (NFSA) is requesting VKM to assess risks to the environment, livestock, and humans from exposure to organic chemicals in sewage sludge used as fertiliser.

The Terms of Reference (ToR) provided by NFSA addressed the identification of relevant organic chemicals (ToR1), risks arising from current practices of sewage sludge application (ToR2) and risks connected to the use of sludge-derived products such as ash, struvite, biochar, pellets and the liquid fraction of digested sewage sludge (ToR3). Moreover, different scenarios including new ways of applying sewage sludge and sewage sludge products, increased frequencies of applications of sewage sludge or sewage sludge products before cultivation (carrot) or harvest, and the direct use of sewage sludge on pastures without mechanical soil mixing were to be evaluated. Biochar was specifically addressed, including how process conditions determine which organic contaminants that are likely to occur as residues in the final product as well as the potential formation of PAHs or dioxins. Potential impact from thermal hydrolysis applied to improve biogas production during anaerobic digestion on the expected final concentrations and potential degradation of organic contaminants was also assessed. The risk assessment also addresses agricultural practices; application methods – surface application and soil incorporation, period from application to start cultivating or harvesting crops.

The methodology and approach for screening and selection of organic contaminants for the priority list for further risk assessment (ToR 1) have been adapted from previous reports such as the JRC Science for policy report "Screening risk assessment of organic pollutants and environmental impact from sewage sludge management" (JRC, 2022).

The current risk assessment is based on methodologies described in REACH Chapter R.16 Environmental Exposure Estimation (ECHA, 2008) and is similar to the methods used in VKM's previous risk assessments on sewage sludge (VKM 2009) and other fertilisers and soil improvers (VKM 2009, 2014, 2022) (**Chapter 3**).

The methodology chapter (Chapter 3) includes the description of hazard identification and characterisation steps of organic compounds identified through a prioritisation process that was performed based on compound specific properties, occurrence data in sewage sludge and background concentrations in soil and surface water. Predicted Environmental Concentration in soil (PECsoil), surface water (PECsw) and different plant parts (root, leaf, seed; PECplant) were modelled for different sludge application frequencies and in different agricultural areas of Norway. The predicted concentration in soil after 50 years of sludge application (application of 11.2 tons/ha of dewatered sewage sludge every 10 year) was used as an estimate of "background concentration" reflecting previous use of sewage sludge.

The equations applied are presented in **Appendix I , Chapter 7**. Finally, four defined endpoints (organisms in soil and surface water, livestock, humans) were assessed.

Since the prioritisation of the organic contaminants of relevance for risk assessment was a major task, the selection process is illustrated in more detail in **Chapter 6**, including the selection of compounds that might occur in notable concentrations in biochar, struvite, bottom ash and the liquid fraction of digested sewage sludge.

Results of the hazard identification and characterisation, including considerations of compound potencies and toxicities, are presented in **Chapter 8**. The calculated PEC in soil, plants and surface water are shown in **Chapter 7**. Finally, potential environmental, farm

animals health risks of organic contaminants occurring in sewage sludge that were evaluated based on the compiled data are presented in **Chapter 9**.

The toxicity of contaminant mixtures is shortly discussed in **Chapter 9.5**.

Risk assessments are conducted in conjunction with uncertainties connected to analytical bias, prediction methods, parameters applied, decisions taken. Important uncertainties and sensitivities of the current assessment are given in **Chapter 10**. Knowledge gaps that were identified during the preparation of the risk assessment are described in **Chapter 13**.

The answers to the ToRs provided by NFSA are given in **Chapter 11**, and conclusions are provided in **Chapter 12**.

1.2 Legislation for the use of sewage sludge and derived products as fertilising products with relevance for the risk assessment

The Terms of Reference (ToR) submitted to VKM by the NFSA are related to the Norwegian Fertiliser Regulation, EU Sludge Directive, and the EU Fertiliser Product Regulation (FPR). In addition, the EU Urban Wastewater Treatment Directive are of interest since there is a list of specific drugs to be used as indicators for the quaternary treatment performance surveillance.

Regulations for the application of sewage sludge and derived products as fertilising products in agriculture have been implemented for several reasons: 1) to ensure that the treatment will have a positive effect on crop production or soil quality/health, 2) to protect the environment against adverse effects, e.g. prevent eutrophication problems and reduced water quality, 3) to protect environmental organisms, animals and humans against health risks arising from chemical and biological contaminants (organic substances, metals, pathogens) in these type of fertilisers, and 4) to ensure that pathogens, which are harmful to crops, animals and humans, are not spread in the environment.

The ToRs provided by NFSA include questions intended to acquire data for an evaluation of sewage sludge applications in line with the Norwegian Fertiliser Regulation, and the possibilities or need of adjusting practices to recent European legislation, which is less strict than the Norwegian legislation.

The regulations are described shortly below, and in more detail in **Appendix I, Chapter 10**.

1.2.1 Norwegian fertiliser regulation

The Norwegian fertiliser regulation (FOR-2003-07-04-951) has been revised and divided into two parts; the Fertilising Product Regulation (FOR-2025-01-29-116) for production, sales and import of fertilising products of organic origin and certain inorganic fertilising products and the Fertiliser Use Regulations (FOR-2025-01-29-115) for storage and use of fertilisers (Feb. 1. 2025).

The chapters and paragraphs with the most relevance for the present risk assessments below.

Fertiliser Product Regulation
Chapter II (General requirement for the enterprises) **§11** - Use of the product names ‘sterilised sewage sludge’ and ‘sewage sludge-based fertilising products with special conditions of use,

representing e.g. hygiensation by thermal hydrolysis, and pellets, respectively (FOR-2025-01-29-116).

Chapter III (Product requirements) **§15** raw materials accepted for production of fertilising products (positive list), **§25** - Specific maximum limit values (ML) for the content of organic pollutants in raw sludge, **§26** - Specific additional requirements for the production of ash and **§27** - Specific additional requirements for the production of biochar (MLs shown **in A-Table 10.1.1-1**).

Fertiliser Use Regulations
Chapter 3 (Requirements for the application of fertilisers) **§15** The permission of which period in the year spreading of organic fertilisers varies between regions, **§16** Requirements for spreading (Organic fertilisers spread on open ground have to be moulded within 18 hours. Exceptions are e.g. organic-mineral fertilisers that are pelletised, granulated or similar processes, **§19** Restriction on nitrogen application in animal manure (170 kg N/ha/yr) to agricultural land located in the watershed of the Oslofjord **§20** Restrictions on phosphorus application to agricultural land. Products with a low P content may contribute substantially to the input of organic matter, e.g. 40 tonnes/ha/10 yrs for worst-case scenario.

Chapter 4 (Special rules on the use of fertilisers with sewage sludge) **§22** i) Not permitted to apply unhygienised sewage sludge, ii) Use of fertilising products containing sewage sludge is not permitted in grassland, nurseries or where vegetables, potatoes, berries or fruit are grown. Where fertilising products containing sewage sludge have been used, vegetables, potatoes, berries and fruit may be grown and harvested at the earliest three years after the last date of application, iii) Where sewage sludge-based fertilising products with special conditions of use or sterilised sewage sludge have been applied, such crops may nevertheless be cultivated ten months after the last date of application. The areas may be used for grazing or harvesting fodder crops at the earliest in the growing season after fertilising products containing sewage sludge has been used, iv) Fertilisers containing sewage sludge must be mixed into soil within 18 hours after spreading. However, this requirement does not apply to the use of sewage sludge-based fertilising products with special terms of use, v) Fertilising products containing sewage sludge may not be spread on agricultural land with a phosphorus content measured as a P-AL value of 14 or higher. This is not taking into consideration in the risk assessment (not considered in this risk assessment). When spreading fertilising products with sewage sludge on agricultural land, sewage sludge may be applied in quantities containing a maximum of 25 kg P/daa over a ten-year period (250 kg P/ha/10 yrs or 2.5 kg P/ha/yr) (§22f). However, no larger quantities of plant-available phosphorus may be used than corresponds to the maximum permitted phosphorus application under section 20.

Chapter 5 (Special rules on the use of fertilising products (not only sewage sludge) based on the heavy metal content. The present risk assessment does not consider heavy metals, and this are not taking into consideration.

The links between different regulations and requests from NFSA are summarised in **Table 2.3.2-1**.

1.2.2 European Sludge Directive

Council Directive 86/278/EEC (the Sewage Sludge Directive) establishes EU-level requirements for the use of sewage sludge in agriculture, with the primary objective of preventing harmful effects on soil, vegetation, animals and human health. The Directive focuses in particular on

controlling the accumulation of heavy metals in soil and sludge, while allowing the agricultural use of sewage sludge under defined conditions.

The EU Sewage Sludge Directive (86/278/EEC) regulates the agricultural use of sewage sludge mainly through limit values for heavy metals but does not cover organic micro-contaminants or other emerging pollutants.

The Norwegian fertiliser legislation explicitly refers to the EU Sewage Sludge Directive through the European Economic Area Agreement; however, national rules implement and extend this framework through more detailed and, in several respects, stricter requirements, particularly for grassland (10 months versus 3 weeks) and vegetable (3 years versus 10 months) production (ToR 3a and b).

1.2.3 European Fertilising Product Regulation (FPR)

The European Fertilising Product Regulation (EC 2019/1009) was adopted the 5th of June 2019 and fully implemented on the 16th of July 2022 and replaced the old Regulation (EC 2003/2003).

The FPF establishes harmonised EU rules for fertilising products placed on the market, with a focus on product safety, quality, contaminant limits and free movement within the internal market. The Regulation applies to CE-marked fertilising products and regulates product composition and conformity but does not govern how fertilising products are used in agriculture or their conditions of application.

The FPR divides all permitted raw materials into different Component Material Categories (CMC) based on origin and processing. Each category has specific requirements for quality, safety and maximum allowed levels (ML) of contaminants.

Certain CMC allow EU fertilising products to be derived from sewage sludge following advanced treatment and purification. This applies in particular to CMC 12 (precipitated phosphate salts and derivatives), CMC 13 (thermal oxidation materials and derivatives, including sewage sludge ash), and CMC 15 (high purity recovered materials), provided that strict requirements for contaminant levels, material purity and conformity are met.

While biochar based on sewage sludge is not allowed in FPR, this is allowed in Norway but regulated for process conditions and MLs for organic contaminants (A-**Table 10.1.1-1**).

1.2.4 European Urban Wastewater Treatment Directive

The EU Urban Wastewater Treatment Directive was adopted on the 21st of May 1991 (Directive - 91/271 - EN - EUR-Lex). A revised Urban Wastewater Treatment Directive was enforced on the 1st of January 2025 (Directive - EU - 2024/3019 - EN - EUR-Lex) with the aim "to protect human health and the environment from the effects of untreated urban wastewater". Regarding the description of quaternary treatment performance indicators (Annex I, Table 3, EU 2024/3019), a list of relevant substances is presented. These are used to verify ≥80% removal of micropollutants at large WWTPs. On this list, there are 11 drugs and two benzotriazole derivates.

1.2.5 The requested ToRs in relation to the regulations

The ToRs stated by the NFSA are intended to evaluate the Norwegian Fertilising Product Regulation and the EU directive. Summary and information about the fertilising products and the parameters deciding application rate used in the present risk assessment are presented in **Table 2.3.2-1** More information about the ToRs, when considered in an agricultural practice perspective, is given in **Chapter 5**.

Since agricultural practices were part of the ToRs, the first approach for the modelling of exposure levels also included several practical factors, which were, however, later omitted in the risk assessment due to the significantly increased complexity in the modelling and the amount of work.

1.3 Sewage sludge and sewage-based products in Norway

1.3.1 Sewage sludge in the circular economy

In Norway, sewage sludge has been a part of the biological cycle of nutrients since the 1970's and has been considered as a safe contribution to this cycle, improving the physical, chemical and biological properties of soil with the aim of increasing crop production.

Today, Norwegian sewage sludge, following the mandatory requirement of hygenisation and stabilisation, are applied to agricultural soils (60 %), green areas (5 %) and soil products (15 %) (**Figure 1.4-1**). This high utilization volume of sewage sludge has been approved based on the relatively low content of contaminants in Norwegian sewage sludge**.** The mean value of phosphorous in sewage sludge in Norway is 2.2 % per dry matter (dm) (**Appendix I, 2.7-1)**. The total amount of phosphorous in 60 000 tonnes dm (amount of sewage sludge applied to agriculture) of sewage sludge is thus 1320 tonnes of phosphorous, i.e. about 6 % of the amount applied annually through mineral fertilisers and manure to agricultural soils (20 700 tonnes; SSB 2025). The sewage system is considered as a vulnerable recipient implying that only substances that WWTP can actively remove should be permitted to be discharged into the sewer network. Such upstream control approach benefits both the sludge quality and the receiving waters. The high confidence in sewage sludge quality in Norway is partly a result of this approach. However, no WWTPs can fully remove all unwanted substances.

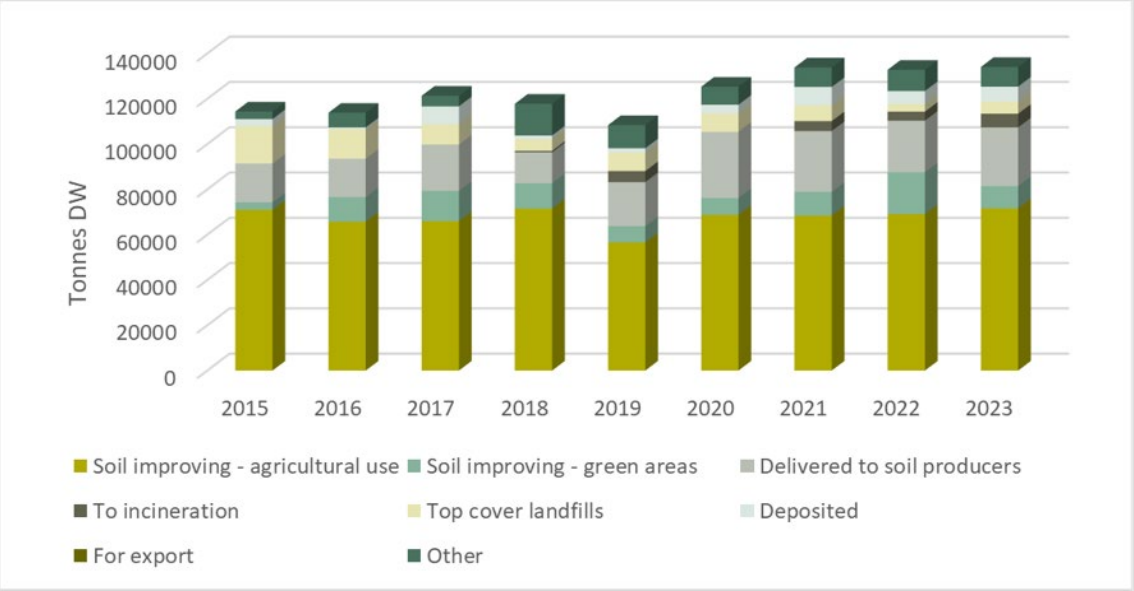


Figure 1.4-1: Utilisation of Norwegian sewage sludge (tonnes dry matter (dm)) in the period 2015 – 2023 (SSB 2025).

1.3.2 Concentrations of organic contaminants in Norwegian sewage sludge

During the 1990s, the focus on organic contaminants in sewage sludge increased in Norway, and more frequent screening for contaminants was initiated in 1996-97 (Paulsrud et al, 1997). Since then, regular screening programmes with primary focus on organic contaminants have been performed every 5th year (Nedland 2002, Blytt 2007, 2013, 2018, Henninge and Blytt 2023). Through these screening programmes, authorities and regulators have gained important data to support risk assessment and regulation. The new Fertilising Product Regulation introduced in Norway (FOR-2025-01-29-116) in 2025 includes maximum allowed levels (ML) for DEHP, the sum of PFOS + PFOA, and PCB7 for sewage sludge and for PAH16 and dioxins/furans/dl-PCB in biochar and ash.

An overview of existing data on organic contaminants in Norwegian sewage sludge is provided in **Chapter 6.1.**

1.3.3 Sewage sludge legislation to ensure safe and sustainable use in accordance with circular economy strategies

The revised Urban Wastewater Treatment Directive (Directive 2024/3019) introduces stricter standards for the collection, treatment and discharge of urban wastewater and increases the amount of sewage sludge that has to be handled (Feasibility study in support of future policy developments of the Sewage Sludge Directive (86/278/EEC). In Norway, more stringent rules for removing nitrogen from wastewater have initiated a remodelling of sewage treatment plants, which probably also will influence the numbers and levels of organic contaminants present in sludge.

New products of sewage sludge (e.g. ash, struvite and biochar), new application technology and treatment methods for wastewater and sewage sludge will increase the versatility of sewage sludge applications. This is in accordance with the circular economy strategy. While

sewage sludge products as ash and P-salts are allowed to be used in agriculture in EU's fertilisers regulation FPR (EU 2019/1009), biochar from sewage sludge is not permitted (**Chapter 1.2.3**).

From a regulatory perspective, the revised regulations call for more knowledge about potential risks of organic contaminants in sewage sludge and in products based on sewage sludge for organisms, farm animals or humans. This science-based risk assessment has the purpose to evaluate the effects of different scenarios concerning application frequencies and methods but also to help the regulatory authorities to establish MLs for the organic contaminants in sewage sludge.

1.4 Literature

Due to the complexity of this risk assessment and the large amount of information needed, different search strategies for data and information were applied, including combined systematic elements with targeted searches to ensure adequate coverage, as well as collecting data from multiple databases, and information gathered based on expert judgements.

1.4.1 Literature search

Several targeted, non-systematic literature searches were conducted to support different aspects of this work. Search was carried out iteratively, with search terms refined as understanding of the topic/research questions. The literature searches focused on different topics, described in **Appendix (A-Table 1.1-1)**.

Systematic literature searches were initially planned, and in the early phase of the project, systematic bibliographic literature searches were performed by an experienced research librarian at the Norwegian Institute of Public Health in cooperation with the project group. However, due to the complexity of the request and the ToRs, the searches were adjusted to fit the project´s objectives and limited time. The requirements set for a systematic review, including use of PRISMA, dual screening, and full risk-of-bias assessment, were not fulfilled with the limited time, and literature searches therefore contain several systematic elements (structured search strategy), but the evidence synthesis should be regarded as a structured, non-systematic review rather than a full systematic review.

Relevant literature was identified primarily through Web of Science, Scopus, and Google Scholar using combinations of keywords (**Appendix I, A-Tables 1.1-1**). Studies were selected based on their relevance to the research questions through screening titles, abstracts, and, where necessary, full texts. Reference lists of key publications were also screened to identify additional sources.

For the topic on biochar and ash, a broad search for literature review studies was conducted to identify data on the occurrence of organic contaminants in these products. An overview of the inclusion criteria for the review studies is shown in **Appendix I, A-Tables 1.2-1; A-Tables 1.2-2**.

For the other topics, searches for primary research articles were conducted. In the initial phase of the project, several literature searches regarding the uptake of contaminants in plants and breakdown of contaminants were conducted. An overview of search strings and hits are presented in the **Appendix I, A-Tables 1.3-1**. Finally complementary literature searches for the oral toxicity in farm and experimental animals were conducted for compounds without any

identified HBGV in Pubmed, Google scholar and WebofScience as well as toxicological dossiers in ECHA and different governmental websites were identified by Google searches.

As the searches were not systematic, the results should be interpreted as indicative rather than exhaustive.

1.4.2 Databases other than bibliographic databases

Data were retrieved from several open access databases, selected based on their relevance to the assessment questions. These included national monitoring databases, international registries, and publicly available datasets from regulatory authorities. An overview of databases used is shown in **Table 1.4.2-1**.

Table 1.4.2-1. Overview of databases used for retrieving the necessary parameters/data for the risk assessment.

Parameters	Name of database	Date of download	Link/source
MEC_{sludge}	Vannmiljø (the Norwegian environment agency)	01.12.2024	https://vannmiljo.miljodirektoratet.no/
MEC_{fish}in reference rivers	Vannmiljø (the Norwegian Environment agency)		https://vannmiljo.miljodirektoratet.no/
PNEC	US EPA ECOTOX knowledgebase		https://cfpub.epa.gov/ecotox/
PNEC for drugs	FASS		https://fass.se/felleskatalogen.no
Koc estimations	Comptox		https://comptox.epa.gov/dashboard/
Koc	Literature		
Ecotoxicity data and QSAR-derived PNECs	Norman network	10.01.2023	https://www.norman-network.com/nds/ecotox/
Properties of drugs	Drugbank	01.12.2025-15.02.2026	https://go.drugbank.com/
Properties of drugs	PubChem	01.12.2025-15.02.2026	https://pubchem.ncbi.nlm.nih.gov/
Properties of drugs	DrugCentral2023	01.12.2025-15.02.2026	https://drugcentral.org/
Properties of drugs	World Health Organization, Evaluations of JECFA	01.12.2025-15.02.2026	https://apps.who.int/food-additives-contaminants-jecfa-database/
Koc	US EPA		Comptox https://comptox.epa.gov/dashboard/
DT50	BIOWIN		SMILES from Comptox
BCF_{fish}	OPERA and test-values	31.10.2025	Comptox https://comptox.epa.gov/dashboard/
Precipitation	Senorge.no	23.09.2025	https://senorge.no/
Temperature	Senorge.no	23.09.2025	https://senorge.no/

1.4.3 Expert knowledge elicitation

In addition to information retrieved from databases and the scientific literature, expert judgement was used to supplement data gaps and to interpret findings. Expert input was obtained from external specialists with relevant subject-matter expertise. Expert judgements were collected via meetings and/or e-mail. Expert assessments were documented, discussed

within the group, and applied in a transparent manner. An overview of the expert's knowledge elicitation for this risk assessment is shown in Appendix I (**Table A-1.4-1**).

1.4.4 Artificial intelligence, mathematical models and predictions

Artificial intelligence tools were used to support parts of the information-process, including retrieving background information, structuring text, formulating search terms, and summarising contents of this risk assessment. All outputs generated by AI were reviewed and verified by the project group.

Copilot (Microsoft 365) was used to develop a semi-mechanistic, mass-balanced model to estimate concentrations of organic contaminants in biochar derived from sewage sludge. The model integrates compound-specific input data (e.g. initial concentrations, physicochemical properties, and structural descriptors) with simplified representations of key pyrolysis processes, including thermal degradation, volatilisation and phase partitioning, secondary formation of compounds such as PAHs, and catalytic formation of PCDD/Fs and PCBs. By combining structure-based degradation functions with system-level mass flows and temperature-dependent biochar yields, the model provides first-order predictions of contaminant fate and resulting concentrations in biochar, primarily intended for screening-level assessments and scenario comparisons rather than precise quantitative prediction. The model is described in detail in **Appendix I, Chapter 4,** and the results are described in **Chapter 6.5.3.**

In the risk assessment, measured and/or experimental data were used as the primary data source, however, for most of the organic contaminants, experimental data were not available and predicted concentrations (PEC and PNEC) were applied. The predictions methodology is described in **Chapter 3.3**.

1.5 Overview of exposure routes for target organisms

Figure 1.5-1 summarises the exposure routes and target organism which organic contaminants in sewage sludge and sludge-based products following application to agricultural land. The target organisms included in this risk assessment are soil-living and aquatic organisms, farm animals and humans (**Table 1**). Negative effects on plants are addressed and discussed in general terms and not based on a risk assessment.

The crop forage and food relevant to animal and human exposure pathways are illustrated and described in Figures and Tables below (**Figures 1.5-1 – 1.5-5, Tables 1.5-1 – 1.5-3**).

Atmospheric deposition may represent a source for some of the same organic contaminants present in sewage sludge or sludge-based products but are not included. Drinking water may an exposure pathway for some contaminants, as visualized in **Figure 1.5-1** and **Figure 1.5-2**, but not included in this risk assessment. Target organisms, relevant matrixes, crop and food items evaluated in this risk assessment, as well as relevant factors and chemical properties, are also described in **Figure 1.5-1** and **Figure 1.5-2**.

In this risk assessment, 0.15 m was used as the default soil mixing depth, but surface spreading and injection (e.g. liquid fraction of digested sewage sludge) into soil were also evaluated in selected scenarios. All PEC calculations were performed on a depth dependent soil volume. This means that assessment of the effects of surface application without mixing or infiltration

is not possible. A minimum soil depth of 0.05 m was applied in the PEC calculations to mimic a situation with minimal mixing.

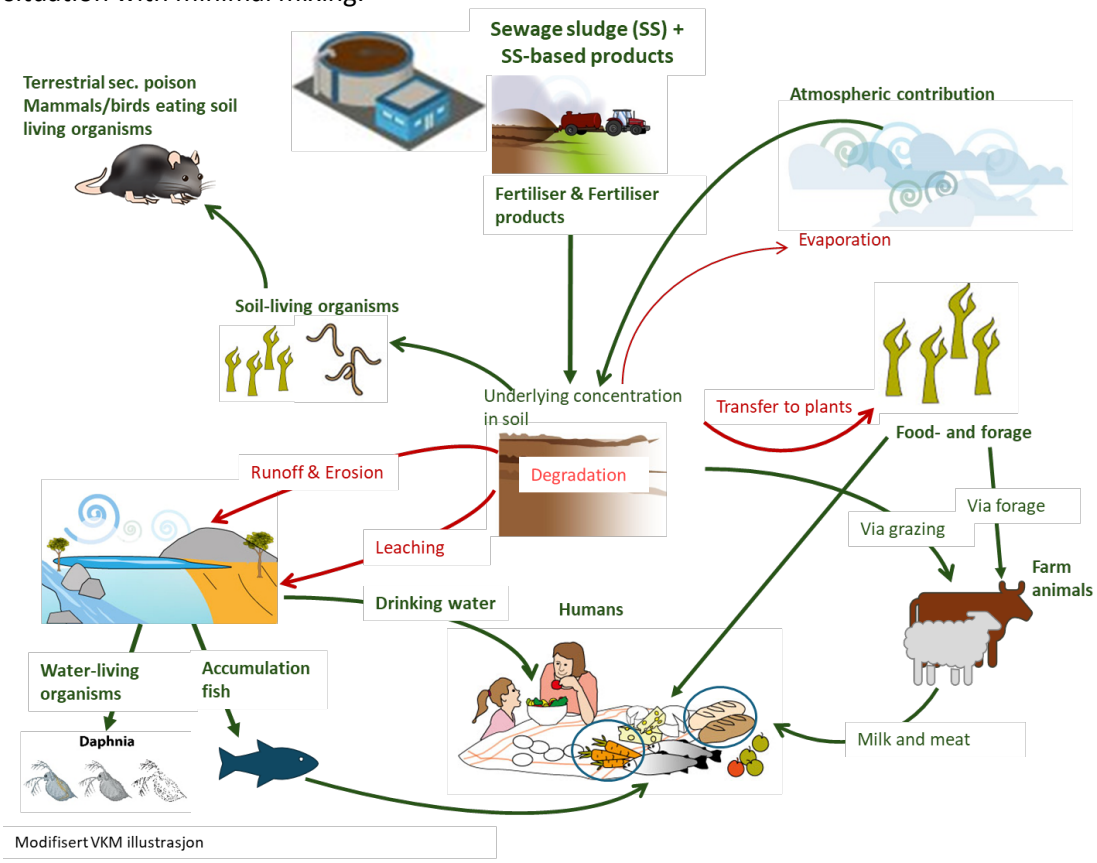


Figure 1.5-1. An overall overview of exposure routes and target organisms considered in this risk assessment with regard to the Terms of References (ToRs).

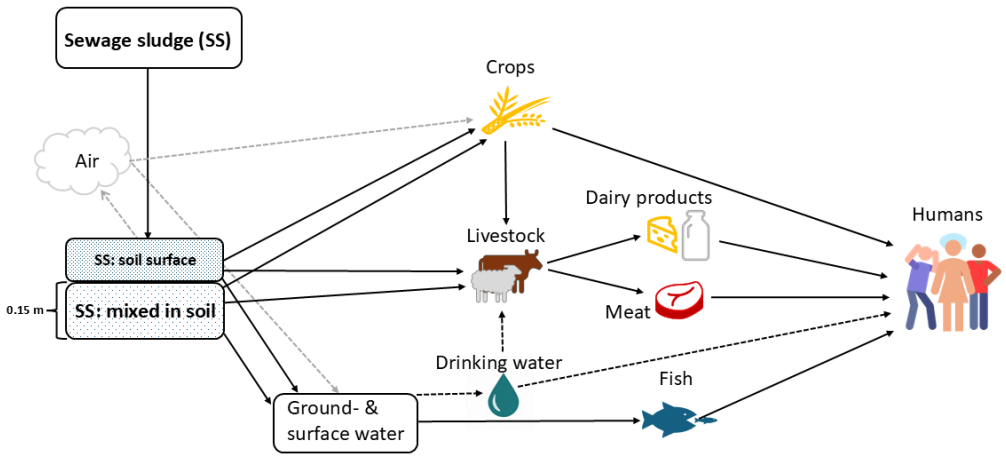


Figure 1.5-2. Exposure pathways for farm animals and humans include exposure matrixes, and associated crop and food items. Atmospheric contribution and drinking water (ground- and surface water) are shown with dotted lines but were not included in the assessment.

An overview of exposure pathways to livestock and humans are shown in **Figure 1.5-2**, and **Table 1.5-1** summarises information on exposure, relevant crops and food items, including soil

ingestion by grazing animals, as well as parameters and chemical properties influencing transfer. Using the predicted environmental concentrations (PEC) of contaminants in soil after sewage sludge application (PEC_{soil}) as starting point, transfer and bioaccumulation in different plant parts were estimated, taking into account compound-specific bioconcentration factors (BCF), for plants (BCF_{plant}) and normalised organic carbon-water partition coefficients (K_{OC}), which reflect the binding affinity of chemicals to organic matter. However, PEC_{soil} values are influenced by several additional factors (e.g. degradation half-lives, DT50, and region-depended factors) that have not been included in this overview (**Table 1.5-1**).

K_{OC} also influences the bioaccessibility of organic contaminants in feed. Compounds with low K_{OC} are more readily absorbed by livestock, whereas compounds with high K_{OC} tend to remain bound to organic matter and show limited transfer. Consequently, K_{OC} is a key parameter governing the transfer from feed to animal products as it affects the bioaccessibility, in combination with other physicochemical properties such as lipophilicity and compound stability.

Table 1.5-1. Overview of crop and food items included in the risk assessment, chemical properties and factors influencing the exposure to livestock and humans.

Farm animals		**Human – general population & sub-groups eating a high portion of locally- grown crops/-caught fish**
Target org. & crops	**Relevance**	**Target org. & crops**
Grazing animals		General population Cereals + vegetables (potato + carrot) + leaves (lettuce ++?)
Grass (↑BCF_{grass})	Ley: All regions	Cereals (↑ BCF_{cereal})
Cereals (↑ BCF_{cereal})	Cereals: All except Målselv	Leafy vegetables (- BCF_{grass})
Soil (↑Koc)		Root vegetables & potato (- BCF_{carrot}/BCF_{potato})
«Indoor»		Milk (exposure based on intake in animals) (↑Koc)
Gras (↑BCF_{grass})	All but particularly Time, Melhus	Meat (exposure based on intake in animals) (↑ Koc)
Cereals (↑BCF_{cereal})	All but particularly Time, Melhus	Sub-population – eating high portion of locally grown crops
		Leafy vegetables (↑ BCF_{grass})
		Root vegetables & potato (↑BCF_{carrot}/BCF_{potato})
		Fish (freshwater fish) (↑BCF_{fish})

The relationships between the exposure matrices (soil, surface water, plants) and target organisms are illustrated in **Figure 1.5-3** (via soil to livestock pathways, including grazing and indoor systems), **Figure 1.5-4** (surface water pathways to aquatic organisms and fish consumed by the local population) and **Figure 1.5-5** (via soil-mediated secondary poising in terrestrial mammals and birds).

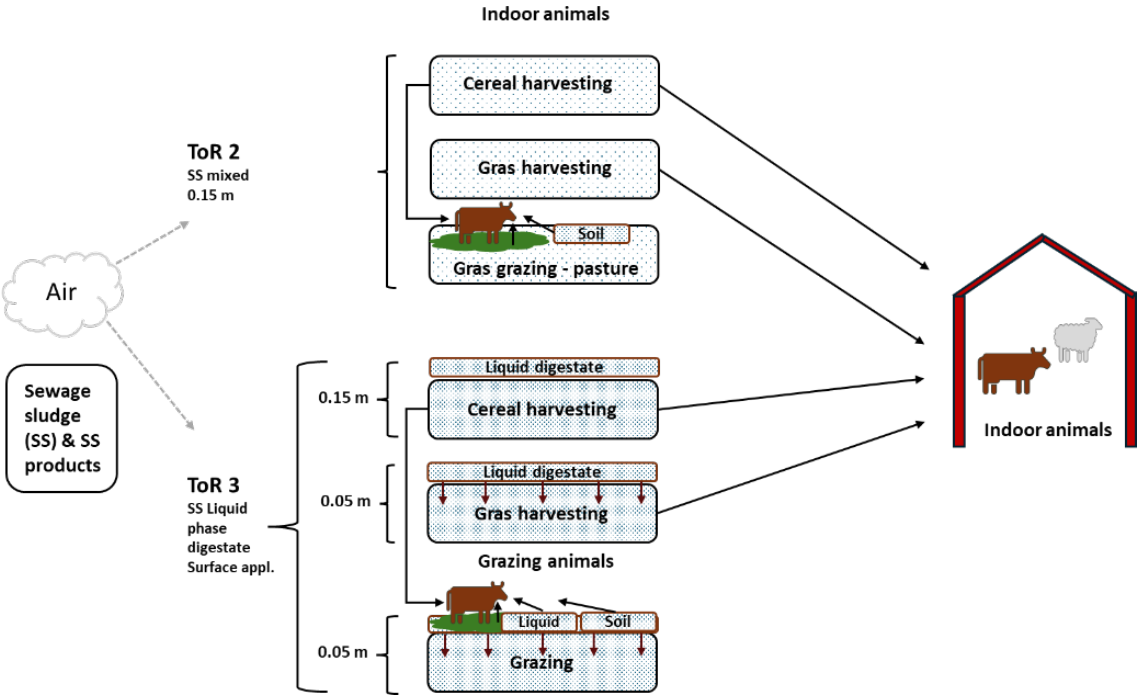


Fig. 1.5-3: Different exposure scenarios for grazing and indoor farmed animals.

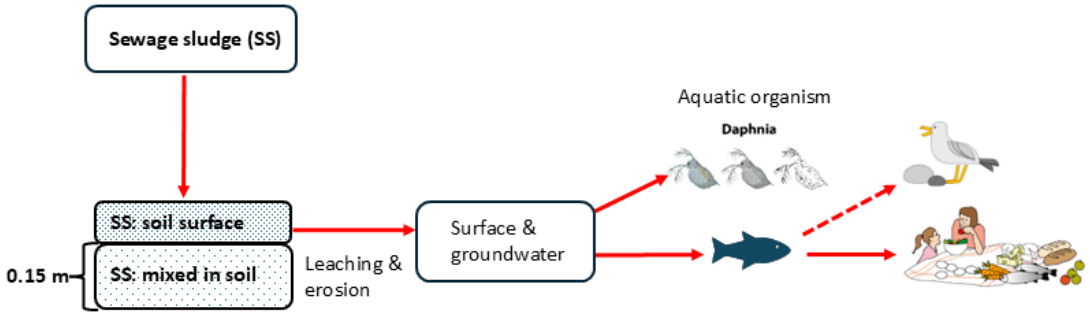


Fig. 1.5-4: Exposure pathways to surface water, aquatic organisms and freshwater fish, with subsequent human exposure via consumption of locally caught fish. Secondary poising of fish-eating birds is also included (dashed line), although it is not included in the risk assessment. Sedentary predator birds in freshwater ecosystems may be particularly exposed to contaminants originating from sewage sludge.

Table 1.5-2. An overview of the target organisms exposed to contaminants after contaminant transfer to surface water via leaching and erosion. Arrows indicate the direction of a low/high number, which results in increased exposure and risk towards farm animals and humans.

Aquatic organisms	Human – Sub population eating high portion locally freshwater fish
Aquatic organisms (↓ Predicted No Effect Concentration in water $PNEC_{aq}$)	Fish (freshwater fish) (↑ BCF_{fish})

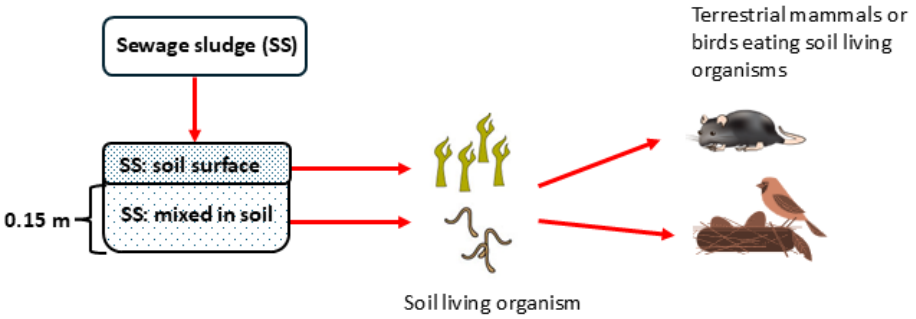


Figure 1.5-5 **Exposure of soil-living organisms and plants to contaminants in sewage sludge, and transfer to terrestrial mammals and birds via consumption of soil-living organisms (secondary poising).**

Table 1.5-3. An overview of target organisms exposed to contaminants in soil or via eating soil living organisms (secondary poising terrestrial mammals).

Soil living organism	Terrestrial mammals/birds – eating soil living organisms
Soil-**living organisms as e.g. earthworms - birds**	Mammals, e.g. mouse, rats,
Plants	Birds

2 Selected agricultural regions and municipalities

Soil and climatic conditions, and thereby agricultural practices, vary considerably throughout Norway. To account for these regional differences, the risk assessment has been performed considering five major agricultural regions, the same that had been used in previous VKM-risk assessments (**Figure 2-1**), which include from North to South:

- Northern Norway, represented regionally by Troms County and by Målselv municipality as a case area (Region 1)
- Central Norway, represented regionally by Trøndelag County and by Melhus municipality as a case area (Region 2)
- Eastern Norway, represented regionally by the Hedmark region and by Stange municipality as a case area (Region 3)
- Southeastern Norway, represented regionally by Akershus County, Vestfold County, and Østfold County. Ås municipality is chosen as case area in this agricultural region (Region 4)
- Southwestern Norway, represented regionally by Rogaland County and by Time municipality as case area (Region 5)

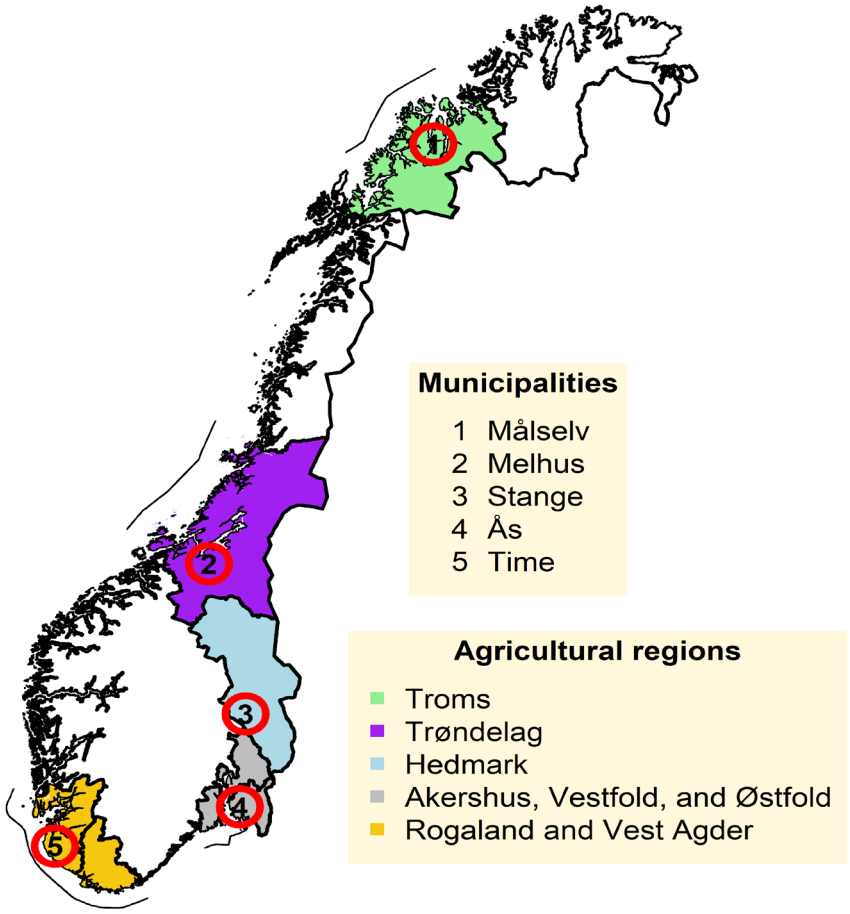


Figure 2-1. Overview of agricultural regions and municipalities included in the risk assessment.

2.1 Agricultural production in selected municipalities

Information about agricultural areas and crop production has been extracted from NIBIO's geospatial data repository (kilden.nibio.no) and from applications for agricultural direct payments from the Norwegian government in 2024 (Produksjons- og avløsertilskudd til jordbruksforetak – søknadsår 2024).

2.1.1 Northern Norway – County of Troms – Målselv municipality

Agriculture in Northern Norway consists primarily of ruminant milk and meat production on grassland, with only small areas dedicated to arable crops. However, in the municipality of Målselv, there is commercial potato cultivation on alluvial soils along the Målselv River. According to the records from the 2024 application for direct agricultural payments from the government (Produksjons- og avløsertilskudd til jordbruksforetak – søknadsår 2024), 83% of the total agricultural area were used for grassland on arable land, 3% for annual forage crops, and 6% for potato. The remaining 8% comprise permanent grassland used for cutting or grazing (**Table 2.1.5-1**).

2.1.2 Central Norway – County of Trøndelag – Melhus municipality

Agriculture plays a major role in Trøndelag County, accounting for approximately 8-9% of the county's economy. The sector is diverse, with dairy milk production representing the largest share of agriculture income (46%), followed by other ruminant production (17%), pig and poultry production (20%), cereal and potatoes production (11%), and horticulture, including greenhouse cultivation, accounting for the remaining 6% (Sand et al 2023). The municipality of Melhus largely reflects the overall agricultural profile of the county. In 2024, 51% of the total agricultural land was devoted to grassland, while 47% was used for cereal cultivation. Barley dominated cereal production, accounting for 80% of the cereal area, whereas oats and wheat constituted 15% and 5%, respectively (**Table 2.1.5-1**).

2.1.3 Eastern Norway – County of Innlandet – Stange municipality

Stange municipality in Eastern Norway, located in the Hedmark region of Innlandet county, represents the agriculture around Lake Mjøsa, where arable cropping on high quality soils dominates. In 2024, 21% of the total agricultural area were used for grassland, 70% for cereals, 3% for potatoes, and 3% for other vegetables. Barley is the dominant cereal and accounts for 63% of the area used for cereals, while wheat comprises 25%, oat 8%, and pulses 2% (**Table 2.1.5-1**).

2.1.4 Southwestern Norway – County of Rogaland - Time municipality

Southwestern Norway is represented by Time municipality in the Jæren landscape, Rogaland County. Agriculture in Rogaland is intensive, with high livestock density consisting mainly of dairy cattle production (Steffenstorpet and Rasmussen 2025). The importance of dairy production is reflected in agricultural area land use in Time, where 95 % of agricultural area was used as grassland and approximately 4 % for cereal cultivation in 2024. Of the total grassland area, 48 % consisted of permanent pastures that cannot be improved or renewed through soil tillage (**Table 2.1.5-1**).

2.1.5 Southeastern Norway – County of Akershus – Ås municipality

Ås municipality in southeastern Norway represents agriculture in the Follo landscape, which consists mainly of arable cropping. Of the total agricultural area, 12 % was used for grassland and 83 % for the production of cereals, including pulses and oil seed crops in 2024. Of the total area used for cereals, barley occupied 40%, wheat 25 %, oats 20 %, pulses (mainly peas) 10 %, and rye 4 % (**Table 2.1.5-1**).

Table 2.1.5-1. Land use within agricultural areas across five selected municipalities representing counties in Northern (Målselv), Central (Melhus), Eastern (Stange), South-Eastern (Ås) and Southwestern (Time) Norway.

Agricultural land use	Units	Målselv	Melhus	Stange	Ås	Time
Total	ha	3023	7098	9005	4175	8275
Permanent grassland and pastures[1]	ha	188	478	386	74	3792
Grassland and forage crops	ha	2598	3164	1626	429	4068
Cereals	ha	0	3326	6345	3530	384
Potato	ha	182	44	276	8	7
Vegetables	ha	12	9	263	15	9
Permanent grassland and pastures	% of total	6.2	6.7	4.3	1.8	45.8
Grassland and forage crops	% of total	85.9	44.6	18.1	10.3	49.2
Cereals	% of total	0.0	46.9	70.5	84.6	4.6
Potatoes	% of total	6.0	0.6	3.1	0.2	0.1
Vegetables	% of total	0.4	0.1	2.9	0.4	0.1

[1]Agricultural areas that cannot be ploughed or tilled, but cover agricultural land, primarily grassland, that can be cut, and permanent pastures that can be grazed but not cut.

2.2 Regional differences

Soil quality and climate factors such as precipitation and temperature influence the fate of organic contaminants in the environment. In Norway, there are regional variations, which might influence the outcome of the risk assessment.

2.2.1 Soil quality

Soil physical and chemical properties are an important parameter for the calculation of risks related to the fate of chemicals in soil and the transfer of chemicals from soil to surface water and to plants.

In previous VKM risk assessments (VKM, 2009, 2014, 2019, 2022), soil properties such as pH, soil organic matter (SOM) and clay content were derived from the NIBIO soil data bank. For the present risk assessment, these values were collected from relevant previous VKM publications. The Norwegian Agricultural Advisory Service (NLR) located in each of the selected municipalities has verified or adjusted the suggested values. The values for soil density were similar to values used in a previous VKM risk assessment (2022) (**Table 2.2.2-1**).

Table 2.2.2-1: Soil properties in the different municipalities. All variables, except clay contenct, were used in for modelling predicted environmental concentrations in soil (PECsoil) (SOM-soil organic matter).

Municipalities	pH (CaCl2)	SOM %	Clay %	Bulk density kg/m3
Målselv	5.2	5.6	10.0	1,181
Melhus	5.7	6.4	17.5	1,194
Stange	5.7	6.5	17.5	1,253
Ås	5.8	5.5	22.5	1,254
Time	5.3	4.1	8.2	809

2.2.2 Precipitation and temperature data for selected environmental regions

The main regional differences in climate drivers relevant for exposure modelling relate to temperature and precipitation, and their magnitudes and temporal patterns. Some important characteristics of the five Norwegian agricultural regions included in this risk assessment are summarised in (**Table 2.2.2-2**).

The annual mean precipitation and mean air temperature are from the periode 1991-2020. The exposure modelling of the contaminants in this risk assessment is based on the monthly average temperature and cumulative precipitation. This further differentiates the effect of these climatic drivers between the regions. **Appendix I, Chapter 3** gives more detailed information about temperature and precipitation in the selected agricultural regions, important for the modelling of the fate of organic contaminants.

Table 2.2.2-2. Annual climate characteristics for the five Norwegian agricultural regions considered in this risk assessment

Region / Municipality	Annual Precipi-tation	Precipi-tation / rain day	Days with precipi-tation	Av. Annual maximum nr days w/o rain	Annual infiltration	Air temp.	Soil temp.	Days frost in soil
	mm	mm	-	-	mm	°C	°C	-
Målselv	794	4.0	148	20	511	1.6	5.4	110
Melhus	981	4.53	162	21	490	5.9	6.1	75
Stange	720	4.32	120	23	322	5.2	6.6	86
Ås	997	5.91	130	22	459	6.4	7.1	85
Time	1507	6.74	184	18	501	8.1	8.4	5

2.3 Agricultural scenarios evaluated in the risk assessment

In the ToR given by NFSA, the impact of agricultural practices on the evaluation of risks from the use of sewage sludge as fertiliser is an important factor to be considered. Information on agricultural practices, including equipment and methods used for the application of sewage sludge in different cropping systems, as well as crop production in the selected regions, is presented in **Appendix I, Chapter 2**.

2.3.1 Selected cropping systems and crop rotations

Based on the information in **Table 2.3.1-1** and judgment by experts working for the Norwegian Agricultural Advisory Service (NLR) and NIBIO in the regions covering the selected locations, standard cropping systems and crop rotations were selected for the calculation of typical scenarios in this risk assessment (**Table 2.3.1-1**).

The cropping systems and crop rotations include the major crops cultivated in the various regions. The crop sequence and their proportion in the rotation are as far as possible in accordance with their proportion of the total area use (**Table 2.3.1-1**). The cropping systems and crop rotations include the major crops cultivated in the various regions. The crop sequence and their proportion in the rotation are as far as possible in accordance with their proportion of the total area use **(Table 2.1.5-1).** Due to modelling limitations, crop rotations were simplified and fixed to 5-year sequences. Available background information was insufficient to distinguish between different cereal species. For root vegetable crops, carrot was used as a representative example.

Table 2.3.1-1. Overview of today's cropping systems and crop rotations and the models used in the five selected municipalities representing counties in Northern, Central, Eastern, Southeastern- and Southwestern Norway.

Region	Cropping system	Crop rotation	Modelled rotation
Målselv	Ley-potato	Grass-grass-grass-potato-potato-potato-barley[1]	Potato-grass established[1]-grass-grass-grass
	Ley	Grass-grass-grass-grass-grass-barley[1]	Grass est.[1]–grass–grass-grass-grass
Melhus	Ley-cereals	Grass-grass-grass-grass-barley[1]	Grass est.[1]-grass-grass-grass-grass
	Cereals	Barley-oat-barley-barley-barley-wheat	Cereal-cereal-cereal-cereal-cereal
Stange	Cereals	Barley-oat-wheat-barley-barley-wheat	Cereal-cereal-cereal-cereal-cereal
	Ley-Cereals	Grass-grass-grass-barley[1]	Grass-grass-grass-cereal-cereal[1]
	Potato-Cereals	Barley-oat-barley-potato	Cereal-cereal-cereal-potato-cereal
	Cereals-Vegetables	Barley-barley-barley-carrot/onion-potato	Cereal-cereal-cereal-carrot-potato
Ås	Cereals	Barley-oat-wheat-barley- pulses	Cereal-cereal-cereal-potato-cereal
	Ley-Cereals	Grass-grass-grass-wheat-oat-barley[1]	Grass-grass-grass-cereal-cereal[1]
Time	Ley	Grass-grass-grass-barley[1]	Grass est.[1] -grass-grass-grass-grass
	Permanent pasture	Permanent grassland used for grazing	Grass-grass-grass-grass-grass

[1]Grass establishment either without cover crop or under a cover of a cereal crop such as barley, either as whole crop silage or for cereals. In Målselv, the barley cover crop is only used as whole crop silage. Alternatively, grass is established after the cereal crop is harvested in late summer

2.3.2 Selection and description of scenarios

In the Terms of References, several scenarios are outlined that have to be considered for assessing the risks. The scenarios cover the evaluation of today's common practices of sewage

sludge applications in accordance with the present fertilising product regulations, including a worst-case scenario (ToR2). In addition, scenarios of using sewage sludge and sewage sludge products in new ways are included (ToR3). An overview of the different scenarios and information with relevance to the Norwegian Fertiliser Use Regulations (FOR-2025-01-29-115) and the Norwegian Fertilising Product Regulation (FOR-2025-01-29-116) are presented in **Table 2.3.2-1**.

For **ToR 3**, risk assessments with regard to the application of sewage sludge and different sewage sludge products such as biochar, ash and struvite, different application methods, and application regimes were conducted. The respective scenarios included also the evaluation of shortened time periods between the application of sewage sludge/sewage sludge products and the cultivation and harvesting of certain produces, such as vegetables and grass. A full overview of the scenarios included in this risk assessment is given in (**Table 2.3.2-1**). Factors included in these scenarios are shortly addressed bellow and more thoroughly presented in **Appendix I Chapter 2**.

Sewage sludge products addressed in the **ToR 3** in the risk assessment include ash, biochar and struvite. A description of their production and material properties used for the characterisation of connected hazards in this risk assessment is given in **Chapters 6.4, 6.5 and 6.6, respectively**. On request from the NFSA, pellets produced from sewage sludge and the liquid fraction of digested sewage sludge were also included.

Application rates (kg DM sewage sludge or sewage sludge products/ha/yrs), **and frequency** (per yr or 10^{th} yrs) used in the different scenarios were chosen according to the Norwegian Fertiliser Regulations (**Appendix I, Chapter 10**) and in agreement with the NFSA.

Cropping systems included in the risk assessment are grassland, cereals and vegetables.

Crop rotations were considered in this risk assessment because they may influence the removal of contaminants from soil through plant harvesting. This factor is only relevant when plant uptake occurs to a meaningful extent. For many organic contaminants, the plant uptake is low and removal via this pathway is negligible. However, for certain contaminants with higher uptake rates, plant harvesting may represent a relevant mechanism contributing to their removal from soil.

The present risk assessment also includes calculations of the potential uptake of organic contaminants into different plant species and plant parts, enabling the prediction of exposure levels for both **farm animals and human** (**Chapter 8**).

Exposure time of sewage sludge in soil, and consequently to plants, is defined as the period between the sludge application and the start of plant cultivation, or time until harvesting for the different cropping systems. The exposure times applied in this risk assessment are based on the Norwegian Fertiliser Use Regulations.

Methods and equipment for the spreading of sewage sludge and sewage sludge-based products are adapted to the consistency of the sludge and the sludge-based products and on the type of crops cultivated. For instance, to arable crops sludge and sludge products may be applied and incorporated into the topsoil layer. To established grassland, most products may be spread onto the soil surface without soil incorporation and liquid forms may even to various degree adhere to the foliage. (**Appendix I Chapter 2**

Table 2.3.2-1 Overview of ToRs, scenarios and information about sewage sludge fertilising products and parameters related to the regulation.

ToR	Description/Evaluation	Product	Limiting parameter1, 2	Amount & Frequency appl. (Given as P and N)	Amount & Frequency appl. (Given as dm)	Soil depth (m)
ToR 2	Today's practices – application of dewatered sewage sludge according to the P-limitation in Norwegian fertilising regulation					
ToR 2a	Average / worste case scenario[3]	Dewatered SS	P	250 kg P/ha/10 yr	11.2 t dm/ha/10 yr	0.15
ToR 2d-1	Reduced appl. if risk 2c	Dewatered SS	P		8 t dm/ha/10 yr	0.15
ToR 2d-2	Reduced appl. if risk 2c	Dewatered SS	P		1 t dm/ha/yr	0.15
ToR 3a	Evaluation of a shorter application to cultivation period for vegetables and potato (10 mo versus 3 yrs in ToR2) - for SS and SS-based products (pellets, liquid digestate, biochar, struvite)					
	Potato & carrot[4] 10 mo. appl - cultivation	Dewatered SS	P	250 kg P/ha/10 yr	11.2 t dm/ha/10 yr	0.15
		Liquid digestate	N	120 N/ha/yr	0.5 t dm/ha/yr	0.15
		Pellets	P	250 kg P/ha/10 yr	1.7 t dm/ha/yr	0.15
		Biochar	P	250 kg P/ha/10 yr	5 t dm/ha/10yrs	0.15
	Cereal	Pellets	P	250 kg P/ha/10 yr	1.7 t dm/ha/yr	0.15
		Biochar	P	250 kg P/10 yr	5 t dm/ha/10yrs	0.15
		Liquid digestate	N	120 N/ha/yr	0.5 t dm/ha/yr	0.15
		Struvite	P	25 kg P/ha/ yr	0.2 t dm/ha/yr	0.15
ToR3b	Evaluation of risks to farm animals and humans resulting from a reduced interval between application and cultivation of grass for grazing, harvesting, and grassland establishment (3 wks versus 10 mo in ToR2) – for SS and SS-based products (pellets, liquid digestate, biochar, struvite)					
	Grassland shorter than 10 mo after application	Dewatered SS	P	250 kg P/ha/10 yr	11.2 t dm/ha/10 yr	0.15
	Grazing or harvesting 3 wks after surface application & establishing grassland	Liquid digestate	N	200 - 300 kg N/yr, 170 kg N/yr in Oslofjord watershed	0.9-1.3 t dm/ha/yr, 0.7 t dm/ha/yr in Oslofjord watershed	0.05
	Establishing grassland shorter than approx. 2 mo	Liquid digestate	N	200 - 300 kg N/yr, 170 kg N/yr in Oslofjord watershed	0.9-1.3 t dm/ha/yr, 0.7 dm/ha/yr in Oslofjord watershed	0.15
	Establishing grassland shorter than 10 mo after application	Pellets	P	250 kg P/ha/10 yr	1.7 t dm/ha/yr	0.15

	Establishing grassland shorter than 10 mo after application	Biochar	P	250 kg P/ha/10 yr	5 t dm/ha/10yrs	0.15
	Grazing or harvesting 3 wks after surface application & establishing grassland	Struvite	P	25 kg P/ha/ yr	0.2 t dm/ha/yr	0.05
ToR3d	Evaluation of environmental risks to organisms after surface spreading of sewage sludge-based products evaluated inToR3b					
	Grazing or harvesting 3 wks after surface application & establishing grassland	Liquid digestate	N	200 - 300 kg N/yr, 170 kg N/yr in Oslofjord watershed	0.9-1.3 t dm/ha/yr, 0.7 t dm/ha/yr in Oslofjord watershed	0.05
	Grazing and harvesting 3 wks after surface application	Struvite	P	25 kg P/ha/ yr	0.2 t dm/ha/yr	0.05

[1]According to the Norwegian Fertiliser Use Regulations, the maximum amounts of P applied to agricultural soil vary between regions. In agreement with NFSA, it is used 250 kg P/ha/10yr or 25 kg P/ha/yr, for all locations.

[2]The application rate of the liquid fraction of digested sewage sludge was determined based on the N-recommendation for the crop but accounting for N-limitation, 170 kg N/ha/yr, from organic fertilisers in accordance with the Norwegian Fertiliser Use Regulations for the Oslofjord watershed.

[3]It was chosen to use a more conservative approach using median concentration of the 90-percentile from each WWTP using Upper Bound concentration. For compounds with no detection in sewage sludge after 2010, the older measured data were replaced with LOD.

[4]Potato and carrot were both included in the risk assessment. While carrot is a root vegetable and contaminants are taken up via the thin roots directly into the edible part (carrot), potato is a tuber and contaminants are not taken up directly into root but either transported via xylem or diffusion directly

3 Methodology

3.1 Assessment approach

This risk assessment is based on four steps:

Step 1: **Hazard identification** – prioritisation of organic contaminants, based on 1) occurrence data in sewage sludge and sewage sludge products, and 2) physicochemical characteristics, kinetic parameters, and 3) their toxic potentials. The prioritisation of relevant organic contaminants in sewage sludge is based on a similar approach to the one used in the recent JRC report (JRC, 2022). The prioritisation of contaminants (**Chapter 6**) is directly answering ToR1.

Step 2: **Hazard characterisation** – evaluation of measured or predicted tolerance levels for prioritised organic compounds with regard to the selected endpoints, such as the environment, farm animals and humans, based on data retrieved from databases and published studies, and predicted parameters including environmental no-effect concentrations (PNEC), no-observed (adverse) effect level (NO(A)EL), no-observed (adverse) effect level (LO(A)EL) in animals and humans, and established tolerable daily intake (TDI), accepted daily intake (ADI) or predicted ADIp in humans..

Step 3: **Exposure/Intake assessment** – modelling of exposure data for target organisms based on occurrence data with regard to exposure pathways (*here*: PEC_{soil}, PEC_{sw} and plants, PEC_{plant} ; PEC_{root}, PEC_{leaf}, PEC_{seed}) after the application of sewage sludge, as well as considerations of different application methods and frequencies, with focus on short-term (Year 1) and long-term (Year 100) increase in contaminant PEC. In this risk assessment, the predicted accumulation of contaminants, adding to the existing exposure levels in environmental organisms, farm animal and humans was basis for the risk assessment, since complete intake calculations following typical diet compositions were not accomplishable for all prioritised organic contaminants in the given framework of the NFSA request.

Step 4: **Risk characterisation** – comparison of predicted exposures/intakes to the established tolerance levels in target organisms, assessing potential health risks (*here*: considering the potential for the accumulation of organic contaminants after applications of sewage sludge in soil and plant parts with typical diets (e.g. grazing, grass silage, composite feed in farm animals; intake of vegetables, cereals, meat, dairy in humans), together with the measured frequencies and levels of the prioritised organic contaminants in the sewage sludge, and the respective tolerance levels in environmental organisms, farm animals and humans).

3.2 Compound-specific properties influencing target organism exposure

The fate of a chemical after release into the environment is dependent on its specific physicochemical and biological properties. Environmental degradation or accumulation are decisive for the chemical's potential to propagate in the food chain and risks of exposure of animals and humans. Important compound properties are the binding affinities to soil and organic matter, transfer to hydrophobic phase and the molecular structure, which determine the degradation rate under different environmental conditions, the compound mobility, period of time in the environment, likelihood for uptake into plants, transfer into fish and farm

animals including carry-over into milk and meat, leading to possible biomagnification in the feed web.

3.2.1 Chemical properties, Persistence, Bioaccumulation, Mobility and Toxicity

The environmental behaviour of organic contaminants in soil is determined by their potential for Persistence (P), Bioaccumulation (B), Mobility (M), and Toxicity (T). These properties are collectively responsible for the potential of contaminants to transfer from soil into groundwater, surface water and crops. Both Persistent, Bioaccumulative and Toxic (PBT) and Persistent, Mobile and Toxic (PMT) chemicals are important, and they represent conceptual differences.

While PBT chemicals are predisposed to long-term accumulation in organisms and food webs and can become persistent in ecosystems, leading to human exposure via the food chain, PMT chemicals cause continuous exposure via water resources (water cycle) and lead to widespread, long-term contamination of drinking water and aquatic systems.

Historically, mainly PBT chemicals have been considered in the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation for chemicals (REACH, and the Stockholm Convention) implemented by the European Chemicals Agency (ECHA). However, in the last decade also PMT and very Persistent and very Mobile chemicals are recognised in REACH, with strong links to the Drinking Water Directive, Water Framework Directive and restrictions for PFAS. EU agencies now explicitly state that PMT chemicals can pose health risks comparable to those of PBT chemicals, even without bioaccumulation.

Both, mobile and persistent chemicals can pass through processes in sludge treatment facilities so that they could be transferred into sludge-based fertilising products. Thus, PBT and PMT chemicals have been considered in the present risk assessment.

Contaminants of emerging concern, i.e. chemicals found through analysis of surface water and other environmental samples, belong typically in the PMT and very Persistent and very Mobile categories, being persistent, polar and mobile, but not bioaccumulating as strongly as PBT. There are therefore increasing efforts for more research on CEC with the aim of developing policies for these chemicals.

3.2.2 Sorption to soil (partitioning coefficient K_d)

The distribution of a chemical between the soil matrix and soil pore water, expressed as the partitioning coefficient K_d, is a crucial parameter for its environmental fate, e.g. after the application of sewage sludge to soil. K_d is also decisive for the half-life of a chemical in soil, because it is used to predict losses from leaching and run-off, and the uptake into plants. If the K_d is high, the chemical remains in the soil, whereas it is quickly leached out if the K_d is low.

Usually, K_d is calculated in accordance with the linear adsorption isotherm for the concentration ratio between dry soil and soil pore water, leading to

$$K_d = \frac{C_{dry\_soil}}{C_{water}} \qquad (3.1)$$

where K_d (L/kg) is the distribution coefficient between soil matrix (dry soil) and soil pore water; C_{dry_soil} is the concentration of the chemical in dry soil (mg/kg), and C_{water} is the concentration in the adjacent soil pore water (mg/L).

The properties of soils can affect the K_d. The adsorption of organic chemicals in most soils is linearly proportional to the organic carbon content (orgC ; g/g) (Karickhoff 1981):

$$K_d = K_{OC} \times orgC \quad (3.2)$$

where Koc is the partition coefficient of organic carbon to water. Other soil properties, such as pH and cation exchange capacity can also affect the K_d, particularly for charged organic electrolytes (anions, cations, zwitterions), but usually to a lower extent. The Koc is widely used to characterise molecular properties of chemicals, and measured values are available for a wide range of chemicals. Moreover, a couple of predictive methods for this parameter have been established.

3.2.3 Empirical K_{OC} values

If available, empirical K_{OC} values based on observed data rather than theory were used for the organic contaminants included in this risk assessment. Only high-quality data, measured according to The Organisation for Economic Co-operation and Development (OECD) test guidelines such as OECD 106 were considered (OECD, 2000). A large dataset with K_{OC} data was recently published by Liu et al. (2025). These authors listed quality-assured K_{OC} values for 785 chemicals, with up to 39 K_{OC} values per substance, in total 4080 empirical log K_{OC} values. The CAS number, a unique, numeric identifier assigned by the Chemical Abstracts Service (CAS), was used to cross-reference to the chemicals that are included in this risk assessment. If a specific chemical could be found in the published dataset, the average K_{OC} was calculated and used. Data for 83 of the prioritised chemicals could be retrieved.

3.2.4 Prediction methods for K_{OC}

Predictive methods for K_{OC} were retrieved from literature. Several approaches were applied:

I. Regressions for K_{OC} with K_{OW} (octanol-water partition coefficient) as predictive variable, as described in the EU Technical Guidance Document on Risk Assessment (TGD 2003, Part 3, page 26, Table 4).

II. K_{OC} estimations listed in Comptox (U.S. Environmental Protection Agency (EPA); generated by using the OPERA software package (https://comptox.epa.gov/dashboard/)).

III. Prediction of K_{OC} for weak acids and bases using log K_{OW}, pKa and the soil pH in regression equations (Franco and Trapp 2008).

IV. Prediction of K_{OC} for bases using log D, the pH-dependent distribution coefficient of ionisable compounds, and the soil pH in regression equations (ECETOC 2013).

V. Prediction of K_{OC} for cations based on the molar volume (Vx) and number of hydrogen ligands at the charged nitrogen (NAi) in regression equations (Droge and Goss 2013). Related work studied the influence of ionic strength on the adsorption to organic matter (Droge and Goss 2012) and provided additional regression equations for clay (Droge and Goss 2013b).

VI. Prediction of K_{OC} for neutrals, weak and strong bases and acids in regression equations (Li et al. 2020).

All relevant equations are shown in **Appendix I Chapter 7.**

3.2.5 Evaluation of existing prediction methods for K_{oc} with measured data

In order to decide which of the available prediction methods was the most suitable for the organic contaminants included in this risk assessment with respect to delivering realistic K_{OC} values, the available empirical K_{OC} were compared to results calculated with the prediction methods described above. For this comparison, the soil data of Målselv/Troms with pH 5.7 and orgC 3.3% were used. Chemical-specific characteristics such as log K_{OW}, molecular weight, Vd and pKa were calculated using ACD/Percepta software (ACD/Labs, Toronto, Canada). The following K_{OC} estimation methods were explored with this data set:

I), EU/TGD (3 regression equations); II), Comptox/Opera; III), regression equations for neutral electrolytes, acids and bases; IV), regression equation for bases; V), regression equations for the K_{OC} of cations; VI), regression equations for neutrals, weak bases, strong bases, and acids. The dataset contained 57 values for neutral priority chemicals; however, one measured K_{OC} (pentachlorobenzene, mean log K_{OC} 10.77) was considered as unlikely and excluded from the test. The pKa of the basic chemicals ranged from 6.98 to 11.9, so that they were in their cationic form at the given soil pH 5.7. Consequently, the equation 3 in Table 3 of the prediction method VI for “strong bases” was applied.

The detailed outcome of K_{OC} prediction testing is shown in **Appendix I Chapter 7.** Decision criteria for determining the quality of the results were the precision and accuracy of the estimation, the availability of the chemical and environmental input data, and the feasibility to adapt the estimation method to Norwegian soil conditions, particularly the soil pH.

In conclusion, the following preferences were applied to select suitable K_{OC} for the prioritised organic contaminants included in this risk assessment: If a high-quality measured K_{OC} was available for a chemical, this value would be used for the subsequent calculation of K_d. If K_{OC} had to be predicted, method I) (EU/TGD) for hydrophobic molecules would be applied to neutral lipophilic chemicals (log K_{OW} > 4). For the remaining chemicals (polar, acids and bases), method III) (Franco regressions) was chosen for the calculation of K_{OC}.

3.2.6 Degradation half-lives (DT_{50}) of organic contaminants in the environment

The specific degradation rate of an organic contaminant in environmental matrices (e.g. soil), determines for how long it will be present and cause a potential risk for different target organisms through direct or indirect exposure. Half-lives increase with adsorption to soil. The degradation half-life (DT_{50}) of a chemical is thus a key parameter for the assessment of risks.

3.2.6.1 Physicochemical properties and environmental factors/parameters

Organic chemicals released into the environment frequently undergo transformation processes such as hydrolysis, photolysis and biodegradation. The extent, to which these processes occur, is strongly influenced by the molecular structure of a specific chemical and its physicochemical properties.

The **inherent degradability** of a compound is directly dependent on its molecular architecture such as functional groups, aromatic rings, branching and heterogeneity. For instance, halogenated molecules (e.g., chlorinated, brominated and fluorinated organics compounds) show a higher resistance to microbial and chemical breakdown than homogeneous hydrocarbons.

Molecular characteristics are relevant for both, **biotic** and **abiotic** transformation processes, which ultimately determine persistence, mobility, and risk of exposure. With regard to the fate of organic contaminants in soil, biodegradation is usually the most important transformation process. The thermodynamic end products of hydrocarbons under aerobic conditions are CO_2 and H_2O. This final stage of biodegradation is also called mineralisation and characterised by the total breakdown of organic matter by soil-living microorganisms into inorganic minerals such as water, CO_2 and nutrients. In contrast, primary biodegradation describes changes in the molecular structure of a chemical that not necessarily leads to its deactivation, since persistent and toxic fragments might remain, which would also have to be considered in an evaluation of a chemical's immanent risks.

The extent of degradation of organic contaminants is additionally influenced by several other factors:

Soil properties: Soil properties and conditions such as soil organic carbon (SOC) or matter (SOM), humidity and pH influence the microbial community structure and activity, and therefore also the degradation rates (Terzaghi et al., 2018).

SOM content influences the composition of the soil microbiome, at best causing a diverse and active microbial population, but also determines the extent to which organic contaminants are absorbed – particularly hydrophobic molecules, thus reducing the environmental bioavailability and degradation rate. The presence of dissolved organic carbon (DOC, the labile fraction of SOC), represents a carrier for contaminants and a transport pathway from soil to surface water og groundwater.

pH likewise influences the composition of the microbial community and their enzyme activities. The application of sewage sludge and sewage sludge products might influence the soil pH in some scenarios. However, since agricultural soils are adjusted to an optimal pH, it can be assumed that pH will not have significant effects on chemical degradation rates after the application of sludge as fertiliser.

Soil moisture affects degradation rates of organic contaminants in agricultural soils, which experience fluctuations in moisture content through precipitation, because of the influence on the microbial composition and activity. Microbial activity is typical at an optimum at about 50 to 60% of the soil water holding capacity (WHC). Too much precipitation causes waterlogging, reduces the oxygen concentration and favours anaerobic microbes, while dry soil conditions (< 20-25% WHC) inhibit the microbial activity (Kaestner et al. 2014). Aerobic conditions favour oxygenase-mediated degradation processes (e.g. for hydrocarbons) whereas anaerobic conditions are required for reductive dehalogenation (e.g., for highly brominated and chlorinated PCBs). Fluctuation in moisture and redox conditions can shift the balance between aerobic and anaerobic microbial populations, thus altering the dominant degradation pathways. Abiotic degradation is part of degradation processes such as dehalogenation- and photodegradation. Farmers will attempt to stabilise the soil moisture by soil draining or water

irrigation in dry periods. However, after heavy rain events, agricultural fields can be waterlogged for periods.

Microbial composition and activity are central for the biotic degradation of organic contaminants. The great diversity, abundance and metabolic activity of soil microorganisms increase the likelihood that some organisms possess the metabolic pathways needed to degrade a wide variety of contaminants. Degradation often involves microbial succession: initial breakdown by one group produces metabolites (intermediate products) that serve as substrates for others. Microbial degradation depends on the production of specific enzymes, of which some are always present while others are only produced in the presence of contaminants. Over time, they may form bound residues that are effectively removed from active degradation pathways.

Certain plant species can stimulate microbial communities and enhance degradation through root exudates, secondary metabolites, and interactions with rhizosphere microorganisms. However, direct uptake of highly hydrophobic contaminants into the roots is limited (Terzaghi et al., 2018).

Non-Extractable Residue (NER) formation can originate from several processes: NER type I (Jespersen et al., 2024) is sorbed and later sequestered contaminants bound so strongly to SOM or clay minerals that they cannot be extracted with the usual chemical extraction methods. If NER I are released at later times, the unchanged parent compounds become again available. NER II are defined as chemicals covalently bound to the soil matrix. Later release in form of the parent compound is very unlikely. Finally, NER III are incorporated into the biomass and of no concern (ECHA 2023, R.11).

Temperature is of particularly high relevance, because biotic processes happen faster at elevated temperatures. When the temperature rises from 10 to 20 °C, rates more than double. Degradation rates measured at 20 °C can be corrected with an Arrhenius type of equation and a factor of 2.58 to a 10 °C change in temperature (EFSA 2008).

3.2.6.2 Categorisation of biodegradability in soil of organic contaminants

The biodegradability of organic compounds is typically determined using standardized biodegradability tests. These are primarily defined by OECD and ISO guidelines and cover freshwater, marine, and soil environments using a tiered approach. Screening tests for freshwater (e.g., OECD 301 and 310) assess “ready biodegradability” under stringent conditions, while OECD 302 evaluates “inherent biodegradability” under more permissive conditions, and higher-tier simulation tests (e.g., OECD 303) provide more realistic system behaviour. Marine biodegradation is typically assessed using OECD 306 and related ISO methods, which adapt similar principles to seawater conditions and indigenous microbial communities. For terrestrial and sediment compartments, OECD 307 (soil) and 308 (water–sediment systems) simulate environmental conditions to determine degradation rates, pathways, and transformation products. The use of standard biodegradability tests is associated with inherent uncertainties, as screening tests (e.g. OECD 301/310 and 306) are conducted under simplified and often optimal conditions that may not reflect environmental variability, microbial diversity, or adaptation processes, while simulation tests (e.g. OECD 303, 307, and 308) provide more realistic estimates but still rely on controlled laboratory systems. Consequently, results from these tests are best interpreted as indicative of degradation potential rather than precise environmental rates; among these, ready biodegradability tests

(OECD 301/310), inherent biodegradability tests (OECD 302), and simulation tests for soil and aquatic systems (OECD 307 and 308) are the most commonly used endpoints in environmental risk assessments.

However, for most of the compounds included in this risk assessment such experimentally determined biodegradability using standardized test were not available. Hence, the biodegradability of most of the compounds was predicted using the BIOWIN module implemented in **EPI Suite™ v4.11** (U.S. EPA / Syracuse Research Corporation). The BIOWIN module applies quantitative structure–activity relationship (QSAR) approaches to predict biodegradation potential based on molecular structure.

Predictions are derived from fragment contribution methods, in which predefined molecular substructures and molecular weight are used as descriptors in multiple linear and nonlinear regression models. The program incorporates seven individual models (BIOWIN1–7), addressing different aspects of biodegradation under aerobic and anaerobic conditions. Only BIOWIN3 (ultimate biodegradability), BIOWIN4 (primary biodegradability) and BIOWIN5 (MITI linear model) were used in the biodegradability predictions. Predictions were based on SMILES input structures using default settings, and ready biodegradability classifications were interpreted using the built-in BIOWIN decision criteria. Results are considered screening-level and were interpreted using a weight-of-evidence approach. Limitations inherent to fragment-based QSAR models – such as reduced accuracy for chemicals outside the model domain or containing uncommon functional groups – were considered when evaluating the reliability of predictions.

The following criteria were used to assign the four different categories for biodegradability in surface water:

- Readily biodegradable: BIOWIN3>2.75 (weeks) and BIOWIN5>0.5 (readily degradable)
- Readily biodegradable, but failing 10-day window: Failing “Readily biodegradable” but BIOWIN4>2.75 (weeks) and BIOWIN5>0.5 (readily degradable)
- Inherently biodegradable: Failing “Readily biodegradable, but failing 10-day window” but BIOWIN4>1.75 and BIOWIN5<0.5 (not readily degradable)
- Not biodegradable: Failing “Inherently biodegradable” and BIOWIN4<1.75

These categories were inferred to biodegradation half-lives (DT_{50}) in surface water ($DT_{50,sw}$) and soil ($DT_{50,soil}$) as suggested by the Forum for the co-ordination of pesticide fate models and their use (FOCUS), providing guidance for the prediction of environmental concentrations of plant protection products in soil, groundwater and surface water within the EU regulatory framework. The DT_{50} values in soil are strongly dependent on how strongly the compounds are associated with organic matter in soil, hence the $DT_{50,soil}$ value is increased by several orders of magnitude for compounds with high $K_{p,soil}$ values. See **Table 3.2.6.2-1** for $DT_{50,soil}$ values in soil and **Table 3.2.6.2-2** for $DT_{50,sw}$ values in surface water.

Many PFAS compounds came out as inherently biodegradable even if they are regarded as forever-lasting chemicals (Klingelhöfer et al. 2024), and since many of these have relatively low $K_{p,soil}$ values, they were relatively quickly decimated in the soil compartment. As a precautionary step, all PFAS compounds were assigned as not biodegradable.

Table 3.2.6.2-1**. DT50 in soil at 20 °C associated with biodegradability categories (FOCUS surface water guidance, European Soil Data Centre (ESDAC))**

Kp soil (L/kg)	Readily biodegradable (DT50, d)	Readily biodegradable, failing 10-day window (DT50, d)	Inherently biodegradable (DT50, d)	Not biodegradable (DT50, d)
≤100	15.8	47.5	158	527 292
>100, ≤1000	158	475	1 582	527 292
>1000, ≤10000	1 582	4 746	15 819	527 292
>10000, ≤100000	15 819	47 456	158 188	527 292

K_p soil = K_{OC} * fraction organic carbon in standard soil (0.02)

Table 3.2.6.2-2**. DT50 in surface water at 20 °C associated with biodegradability categories (FOCUS surface water guidance, European Soil Data Centre (ESDAC))**

Readily biodegradable (DT50, d)	Readily biodegradable, failing 10-day window (DT50, d)	Inherently biodegradable (DT50, d)	Not biodegradable (DT50, d)
7.91	26.36	79.09	263 6460

3.3 Methodology used for the characterisation of hazards to aquatic and terrestrial environmental organisms

Environmental risks of organic contaminants to organisms are assessed based on the comparison of measured or predicted environmental concentrations (PEC) to predicted no-effect concentrations (PNEC). The ratio of PEC/PNEC, called the risk characterisation ratio (RCR), is and used to evaluate potential environmental risks. If RCR is <<1, the risk is considered small, RCR > 1 indicates a higher risk for exposed organisms. Thus, RCR <1 is often considered as a threshold; however, this is not always appropriate since PNECs have been mostly established based on a chemical's toxicity to organisms under controlled experimental conditions, and not to organisms in nature. Therefore, there is an uncertainty with respect to the real-life effects of organic contaminants on different environmental organisms; e.g. certain life stages might be more susceptible to contaminants (e.g. juvenile or stages of metamorphosis) than others. Thus, the RCR <1 threshold could be too conservative or not conservative enough.

Methods to establish PNEC are described in the EU Technical Guidance Document (TGD, 2003). PNECs are mainly derived from laboratory studies on acute and/or chronic toxicity. Acute exposure concentrations of contaminants are used to derive PNECs that could be tolerated for a very short period of the life span of an organism. However, PNECs are mostly derived based on concentration data for chronic exposure studies, representing contaminant levels that an organism should be able to tolerate for more than a short period of their life span. Toxicity data for at least three organisms from different trophic levels are necessary for deriving a PNEC for a specific chemical. Usually, PNEC is derived based on the lowest no observed effect concentration (NOEC) among the species studied. The lowest NOEC is then divided by an assessment factor (AF), which can vary from 10 and up to 1,000. The better founded the toxicity data are and the more species were studied, the lower the applied AF is. This practice is meant as an incentive for chemical producers to provide substantial toxicity data, which they are obliged to provide according to the REACH regulation.

PNECs used in this risk assessment:

1. PNECs for organic contaminants from Norman Ecotox (1531 PNECs)

2. PNECs for pharmaceutical compounds, mainly collected from www.fass.se/www.felleskatalogen.no (316 PNECs)
3. Environmental Quality Standards (EQS) derived for the Water Framework Directive for single compounds or compound groups (57 EQS)
4. QSAR derived PNEC
5. PNEC derived from toxicity data
6. PNEC for soil-living organisms

3.3.1 Norman Ecotox-based PNECs

The Norman network (https://www.norman-network.com/nds/ecotox provides reliable PNEC data for organic contaminants based on experimental ecotoxicity testing. The data show the lowest PNEC for freshwater, marine water, sediment and biota, which can be used for compound prioritisation purposes. Several identifiers of chemicals such as the molecular formula, CASRN, INCHIKEY, SMILES and DTXSID/DTXCID (USEPA) are given if available. Often, the bibliographical source is reported along with the link to the dossier, country, region and institution providing the PNEC. For some of the PNECs, the assessment factor (AF) applied to derive the PNEC is also reported, together with a justification for the selection of the specific AF. A number of PNECs have been assigned a quality class (ranging from 1 to 5a; 1 being the highest). Quality class 1 is only assigned to data that have been strictly controlled in accordance with the chronic environmental quality standard (AA-EQS).

For this risk assessment, experimentally determined PNEC values for 221 compounds were downloaded from the Norman Ecotoxicology Database on October 31st, 2025.

3.3.2 PNECs for drugs

The European Medicines Agency (EMA) has determined that also the environmental risk of drugs should be assessed. Thus, EMA has published a “Guideline on the environmental risk assessment (ERA) of medicinal products for human use” in 2024 (EMA 2024), establishing that an ERA is required before new medicinal products obtain marketing authorisation. Furthermore, if an increase of environmental exposure, e.g. from increased use, is anticipated, the ERA has to be updated. Toxicity data are often owned by pharmaceutical companies and therefore not necessarily publicly available; however, toxicity data that are updated for an ERA revision, can be sometimes open accessible.

In 2018/2019, the Norwegian Institute for Water Research (NIVA) received the available PNECs for drugs from the Norwegian Pharmaceutical Product Compendium (felleskatalogen.no). These PNECs originated from the Swedish National Medical Information System (www.fass.se). The retrieved data were added upon in 2022 with new PNECs that had become available since 2019. Some of the PNECs are no longer available from felleskatalogen.no, probably because the respective drugs are not used anymore. Less than a third of the drugs in use in Norway have a PNEC assigned. For the drugs listed in felleskatalogen.no, there is limited information about i.e. the most sensitive organism and the AF used. More information is available at www.fass.se. Information about drugs and their environmental effects, independent of pharmaceutical companies, can be found at www.Janusinfo.se. For some drugs, information on applied AFs and the most sensitive organism is available; however, such data are lacking for the majority.

3.3.3 Environmental quality standards (EQS) from the Water Framework Directive

Environmental quality standards (EQS) are legally binding, science-based limits defining the maximum allowable concentration of contaminants in the environmental (air, water, soil) to protect human health and ecosystems (ECHA). They differ from PNECs since EQS are intended to achieve protection for several target organisms, including pelagic community, benthic community, predators from secondary poisoning, humans from consumption of drinking water or from the consumption of fishery products.

When deriving EQS for a specific contaminant, all available EQS for the different protection goals were derived according to a guidance document by the European Commission (EC, 2018), as shown for PFOS (EC, 2011). Among the different protection goals, the lowest derived EQS has been chosen to be the valid EQS. Most EQS are derived for concentrations in water, but also concentrations in biota and sediment have been determined for some contaminants. Each country in the EU can establish EQS for contaminants that are defined as important. Norway has chosen to derive EQS for the sediment compartment and also for some contaminants not considered by the EU (e.g. sum of PCB7), expressed as river basin specific pollutants.

3.3.4 QSAR-derived PNECs through Norman

Norman network also has QSAR-derived PNECs ($PNEC_{aqua/QSAR}$). These are not derived PNECs based on toxicity data, where both long term ($PNEC_{chronic}$) and short term ($PNEC_{acute}$) versions can be derived. QSAR-based PNECs are based on read across data from similar compounds. The method for obtaining the QSAR-based PNECs are described by Von der Ohe et al. (2011). It is stated in Norman documentation that the QSAR-based PNECs should only be used for prioritisation purposes and should therefore be used with caution.

The $PNEC_{aqua/QSAR}$ were compared to derived $PNEC_{auqa/exp}$ by matched-pairs statistic (Bland-Altman analysis) to compare concentrations in the different species. The method was developed to test whether two different methods can be used for measuring clinical data in medicine (e.g. oxygen saturation in blood) (Bland and Altman, 1986; Tim, 2016). However, the method can be used more widely, and the approach is used here to answer two questions: (i) are the $PNEC_{aqua/exp}$ in agreement with $PNEC_{aqua/QSAR}$, and (ii) can they be used interchangeably. Instead of just comparing the average values from the two methods, Bland-Altman visualises if one PNEC is consistently higher than the other, and if the PNECs are close enough to be used interchangeably.

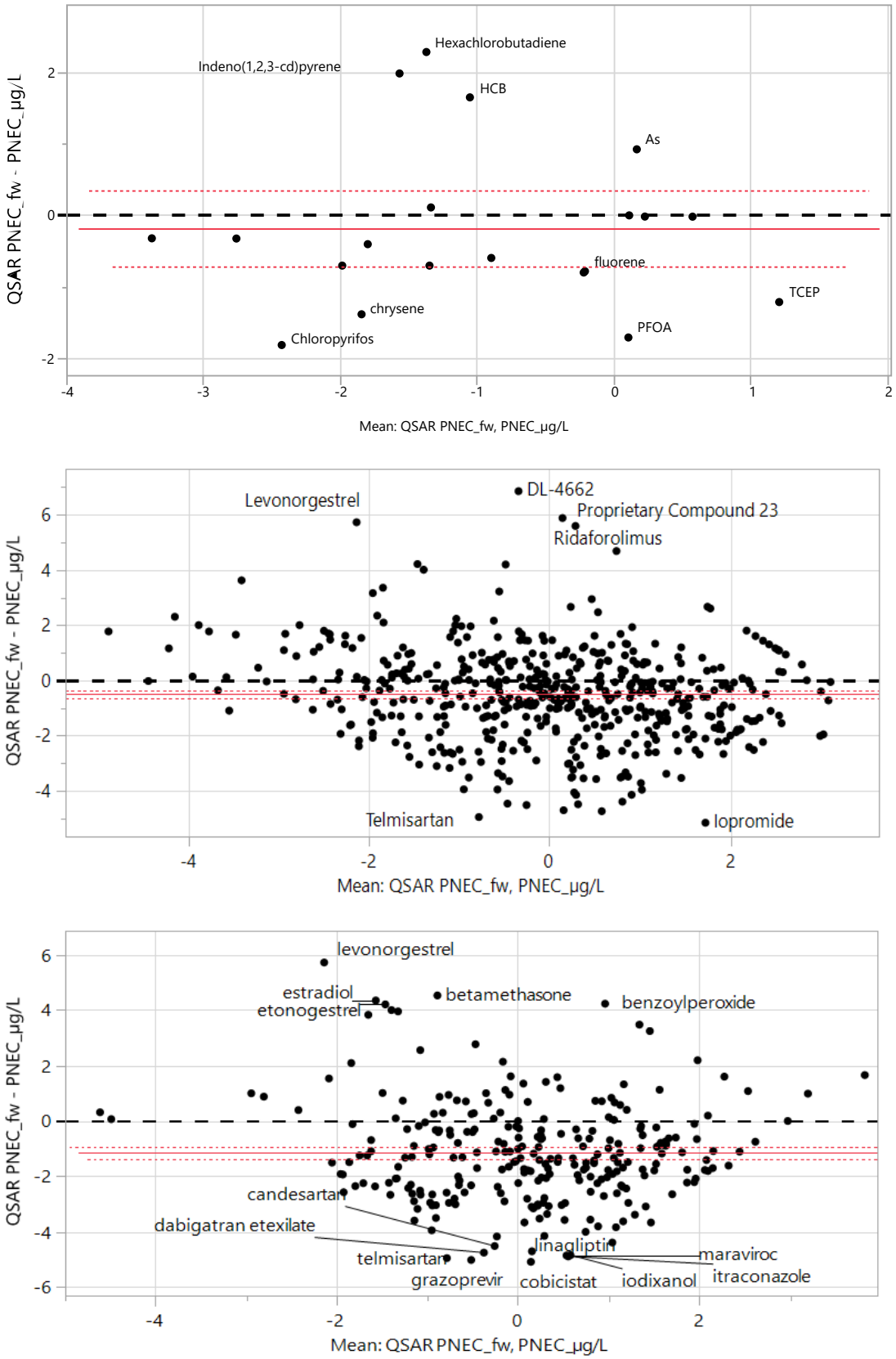


Figure 3.3.4-1. Matched pairs statistics for PNECaqua/QSAR versus PNECaqua/exp.
Note: Compounds with PNECaqua/QSAR equal to $PNEC_{aqua/exp}$ were excluded. Three different groups are shown: compounds with EQS from the Water Framework directive, compounds with $PNEC_{aqua/exp}$

from Norman network and drugs, from the top to bottom, respectively.The difference between $PNEC_{aqua/exp}$ and $PNEC_{aqua/QSAR}$ is shown along the vertical axes. The mean of the two PNECs is shown along the horizontal axes. Zero difference is indicated by the horizontal dashed black line. Above this line, $PNEC_{aqua/exp}$ are lower than $PNEC_{aqua/QSAR}$, below, $PNEC_{aqua/exp}$ are higher than $PNEC_{aqua/QSAR}$. The red line indicates the mean difference for the group of compounds, with the 95 % confidence intervals of the mean shown as dashed red lines. A few outliers are labelled. The correlations of the data were (from the top) 0.63, 0.48 and 0.29, respectively. All values are on a log10 scale

Figure 3.3.4-1 shows the matched pairs for three different PNEC groups: compounds with EQS from the Water Framework directive, compounds with $PNEC_{aqua/exp}$ from Norman network and drugs. All data were log10-transformed, and data are therefore on a log10 scale. For EQS vs $PNEC_{aqua/QSAR}$, the mean difference was -0.19 log10 units, and zero was inside of the confidence interval. This means that on average, there was no significant difference between the two datasets. However, there were outliers outside the confidence interval, and important outliers are labelled with a name. Compounds like HCB, hexaclorobutadiene and indeno(1,2,3-cd)pyrene had about 100 times lower (2 log10-units lower) $PNEC_{aqua/exp}$ than $PNEC_{aqua/QSAR}$. Conversely, for chloropyrifos, chrysene , PFOA and TCEP, the $PNEC_{aqua/QSAR}$ was lower than $PNEC_{aqua/exp}$ since the difference was negative, almost 2 log10 units below.

The resulting plot has a middle line indicating the *average difference* (called the bias). The top and bottom lines show the limits of agreement with a 95% confidence interval of the mean differences. This tells you how much the two PNECs differ in practice. If the difference is close to zero, the two PNECs are quite similar.

For the Norman network substances and the drugs, the differences between conventionally derived $PNEC_{aqua/exp}$ and $PNEC_{aqua/exp}$ were generally larger, with up to 6 log10 units differences for outliers. For Norman Exotox based ($PNEC_{aqua/exp}$) the mean difference was -0.51 log10 units, which means that the $PNEC_{aqua/exp}$ were on average higher than $PNEC_{aqua/QSAR}$. However, there are outliers on both sides. Similarly, the mean difference was below zero for drugs, with a mean difference of -1.1 log10. In both cases, zero is outside of the confidence interval, meaning that the difference is statistically significant in both cases.

Hence, when using the $PNEC_{aqua/QSAR}$, potentially large variability should be kept in mind.

3.3.5 PNECs derived from toxicity data

For contaminants that had predicted (QSAR) toxicity data (n=272), an attempt at deriving PNECs based on toxicity data available in literature was performed. Of these contaminants, 131 had toxicity data available in the US EPA ECOTOX knowledgebase[1]. The toxicity data were downloaded to an excel file (comma-separated list), which was imported to JMP statistical software for further data handling. PNEC were derived using the "Technical guidance for deriving environmental quality standards" (SHEER, 2017).

For mortality (i.e. $PNEC_{acute}$), toxicity data for 103 chemicals were found. The following criteria were set for estimating the $PNEC_{acute}$; only chemicals, for which toxicity data met the following criteria were used:

[1] https://cfpub.epa.gov/ecotox/

i) toxicity data only for the taxa fish, invertebrates and/or algae
and
ii) only chemicals with *data for all three taxa*

The dataset was thereby reduced to only 5 chemicals, for which $PNEC_{acute}$ were derived. The $PNEC_{acute}$ are listed in **Table 3.3.5-1**. The derived $PNEC_{acute}$ were lower than the QSAR PNECs.

For long-term toxicological effects, the effects presented in **Table 3.3.5-2** were included in the data, for which $PNEC_{chronic}$ had been derived. Adverse data for 102 chemicals (896 effects data) were found.

The following criteria were set for estimating the $PNEC_{chronic}$; only for chemicals where toxicity data met the following criteria were used:

i) only the taxa fish, invertebrates and/or algae were used,
and
ii) only effect studies with durations longer than 2 days for algae, 7 days for invertebrates and 28 days for fish were used

The dataset was thereby reduced to 59 chemicals with 138 effects data for which $PNEC_{chronic}$ was derived. Assessments factors (AF) were set to 100, 50 and 10, when the number of taxa, for which toxicity was found, were 1, 2 and 3, respectively. If only toxicity data for algae were found, the AF was set to 100, whereas if toxicity data for fish, algae and invertebrates were available, the AF was set to 10. The resulting PNEC was derived by dividing the lowest concentration for adverse effect stated in the database by the AF.

$PNEC_{chronic}$ was derived for 59 chemicals, listed in **Table 3.3.5-2** with the following data: lowest concentration (mg/L) for adverse effect, number of groups of species investigated, AF used, and the derived/calculated $PNEC_{chronic}$ (µg/L), and the QSAR PNEC and QSAR PNEC/ $PNEC_{chronic}$.

For chemicals, for which the ratio for QSAR PNEC and derived $PNEC_{chronic}$ were determined as >1, the QSAR PNEC used for prioritising chemicals are probably not sufficiently protective. A total of 17 (of the 59) chemicals had a PNEC, which was less protective than the $PNEC_{chronic}$ derived here. For chemicals with the PNECs at the lower end of **Table 3.3.5-2** (i.e. those that are below 0.1 in the column "QSAR PNEC $PNEC_{chronic}$)", the QSAR PNECs used may have been overly protective.

There are uncertainties linked to the derived PNECs, since time did not allow for quality assurance of the PNECs derived. Also, there was no time to scrutinise the toxicity data in detail. The derived PNECs should therefore only be used for the prioritisation of contaminants, and not for other purposes.

Table 3.3.5-1**. PNECacute derived from ECOTOX knowledge base. For each CAS nr, the lowest concentration, number of taxa for which toxicity was investigated, assessment factor (AF), derived PNECacute , the QSAR PNEC and the ratio of QSAR PNEC divided by the derived PNECacut are listed. The list is ordered by ratio of QSAR/PNEC in descending order.**

CAS_nr	Most sensitive organism	AF	Lowest concen-tration (mg/L)	$PNEC_{acute}$ µg/L	QSAR PNEC	QSAR PNEC/ $PNEC_{acute}$
151-21-3	Invertebrates	1000	0.30	0.3	91	300
65277-42-1	Fish	1000	0.090	0.090	6.9	77
57-09-0	Invertebrates	1000	0.16	0.16	11	67

121-54-0	Invertebrates	1000	0.4	0.4	24	59
2211-98-5	Fish	1000	3	3	8.6	2.9

Table 3.3.5-2. PNECchronic derived from data downloaded from ECOTOX knowledge base. For each CAS RN, the lowest concentration, number of taxa for which toxicity was found, AF, and derived PNECchronic is listed. The QSAR PNEC used for prioritizing the chemicals are also shown. The ratio (QSAR PNEC divided by the derived PNECchronic) is also listed. The list is ordered by PNEC ratios (column to the right) in descending order.

CAS RN	Lowest concentration (mg/L)	Number of taxa investigated	AF used to derive $PNEC_{chronic}$	Derived $PNEC_{chronic}$ (µg/L)	QSAR PNEC (µg/L)	QSAR PNEC/ $PNEC_{chronic}$
80-09-1	0.0010	2	50	0.020	13	640
26172-55-4	0.010	2	50	0.20	5.7	29
23593-75-1	0.00014	1	100	0.0014	0.030	21
131-57-7	0.0037	2	50	0.074	1.5	21
754-91-6	0.0012	1	100	0.012	0.17	14
43210-67-9	0.00063	1	100	0.0063	0.063	10
882-09-7	0.017	3	10	1.7	17	9.7
31430-15-6	0.0025	1	100	0.025	0.24	9.4
82419-36-1	0.021	1	100	0.21	1.4	6.6
556-67-2	0.0044	3	10	0.44	2.7	6.2
73606-19-6	0.0050	2	50	0.10	0.33	3.3
207122-16-5	0.00010	1	100	0.0010	0.0029	2.9
1806-26-4	0.020	1	100	0.20	0.47	2.3
108-46-3	1.1	2	50	22	49	2.2
151-21-3	0.020	3	10	2.0	4.1	2.1
93106-60-6	0.049	2	50	0.98	1.6	1.6
57-09-0	0.025	1	100	0.25	0.29	1.2
27854-31-5	0.010	2	50	0.20	0.19	0.94
134237-52-8	0.0020	3	10	0.20	0.18	0.90
793-24-8	0.0050	1	100	0.050	0.045	0.89
31508-00-6	0.0010	2	50	0.020	0.010	0.50
131-16-8	0.90	1	100	9.0	3.1	0.35
149-30-4	0.23	1	100	2.3	0.76	0.33
620-92-8	1.0	2	50	20	5.4	0.27
1119-94-4	0.19	1	100	1.9	0.38	0.20
121-54-0	0.050	1	100	0.50	0.097	0.19
73231-34-2	2.5	2	50	50	7.8	0.16
84-61-7	0.18	2	50	3.6	0.53	0.15
14938-35-3	0.98	1	100	9.8	1.4	0.14
443-48-1	13	2	50	250	33	0.13
3778-73-2	6.3	1	100	63	7.0	0.11
134237-51-7	0.0020	3	10	0.20	0.019	0.094
4376-20-9	0.10	2	50	2.0	0.19	0.094
1120-02-1	0.11	1	100	1.1	0.10	0.094
95-48-7	6.8	1	100	68	6.3	0.092
35065-29-3	0.0010	2	50	0.020	0.0014	0.072
35065-28-2	0.0025	2	50	0.050	0.0035	0.069
189084-64-8	0.013	1	100	0.13	0.0092	0.069
128-37-0	0.069	3	10	6.9	0.38	0.055
68631-49-2	0.015	1	100	0.15	0.0064	0.044
79-57-2	0.10	3	10	10	0.43	0.043
68105-02-2	0.021	1	100	0.21	0.0086	0.041
78-42-2	0.11	1	100	1.1	0.039	0.034
86386-73-4	3.1	1	100	31	1.0	0.034
139-07-1	0.20	1	100	2.0	0.062	0.031
139-08-2	0.17	1	100	1.7	0.050	0.029

CAS RN	Lowest concentration (mg/L)	Number of taxa investigated	AF used to derive $PNEC_{chronic}$	Derived $PNEC_{chronic}$ (µg/L)	QSAR PNEC (µg/L)	QSAR PNEC/ $PNEC_{chronic}$
50-18-0	13	2	50	250	7.0	0.028
5436-43-1	0.0066	3	10	0.66	0.016	0.024
122-18-9	0.16	1	100	1.6	0.030	0.019
72-14-0	11	1	100	110	1.9	0.017
21145-77-7	0.035	3	10	3.5	0.023	0.0066
87-83-2	0.50	1	100	5.0	0.029	0.0057
105-60-2	1300	1	100	13000	67	0.0054
914637-49-3	23	1	100	230	0.91	0.0040
127-54-8	16	1	100	160	0.24	0.0015
65277-42-1	1.0	1	100	10	0.0081	0.00081
100-97-0	1500	1	100	15000	11	0.00073
1844-01-5	220	1	100	2200	0.030	0.000014
35065-30-6	41000	1	100	410000	0.00097	0.0000000024

3.3.6 PNEC for soil-living organisms

As very few ecotoxicological data for soil-living organisms were available, the equilibrium partitioning method (EPM) was used to calculate $PNEC_{soil}$ from $PNEC_{aqua}$ for all compounds for which the $PNEC_{aqua}$ was available (European Commission 2003):

$$PNEC_{soil} = \frac{K_{soil-water}}{RHO_{soil}} \cdot PNEC_{aqua} \cdot 1000$$

$$K_{soil-water} = Fair_{soil} \cdot K_{air-water} + Fwater_{soil} + Fsolid_{soil} \cdot \frac{Foc_{soil} \cdot K_{oc}}{1000} \cdot RHO_{solid}$$

The description of the different parameters and default values are shown in **Table 3.3.6-1**.

Table 3.3.6-1. **Parameters used in the equilibrium partitioning method to calculate $PNEC_{soil}$ (data from the ChemSafePRO web page: *How to Calculate Predicted No-Effect Concentration (PNEC)*).**

Parameter	Description	Default value
$\boldsymbol{K_{soil-water}}$	Soil-water partition coefficient	Calculated
$\boldsymbol{RHO_{soil}}$	Bulk density of wet soil	1700 kg/m3
$\boldsymbol{Fair_{soil}}$	Volume fraction of air in soil	0.2
$\boldsymbol{K_{air-water}}$	Air-water partitioning coefficient1	0 for non-volatile substances
$\boldsymbol{Fwater_{soil}}$	Volume fraction water in soil	0.2
$\boldsymbol{Fsolid_{soil}}$	Volume fraction solid in soil	0.6
$\boldsymbol{Foc_{soil}}$	Weight fraction organic carbon in soil solids	0.02
$\boldsymbol{RHO_{solid}}$	Density of solid phase	2500 kg/m3

[1] Henry's law constant (in Pa·m^3/mol)/8.314·temperature in K

If default values are used, the above equation can be simplified to:

$$PNEC_{soil} = (0.1176 + 0.01764 \cdot K_{oc}) \cdot PNEC_{water}$$

The EPM derives a Hazardous Concentration 5% (HC5), equal to the 5th percentile of the distribution of the no-effect concentration (NOEC), is expected to protect at least 95 % of the terrestrial species (Van Straalen and Dennemann 1989). Van Beelen et al. (2001) have found

that for 5 % of the compounds they have considered, where both $PNEC_{water}$ and $PNEC_{soil}$ were available, the EPM-calculated HC5 value was by a factor 20 higher than the $PNEC_{soil}$. They concluded that when less than four terrestrial toxicity data are available and the quality of the $PNEC_{water}$ and K_{oc} values are considered high, the use of the EPM can be advocated because the uncertainty in the estimation of the HC5 is much larger than a factor 20. If the four available terrestrial toxicity data have a large standard deviation, EPM may also be advocated if the $PNEC_{water}$ and K_{oc} values are sufficiently strong. The EMP-derived HC5 values should in any way be considered as preliminary to be used in comparisons with environmental concentrations in order to decide whether more research is needed for the risk evaluation of a specific pollutant (Van Beelen et al. 2001).

- From equation 5, it is evident that $PNEC_{soil}$ only considers the fraction of the compound that is in the pore water, hence PEC in equation 3 should be the total soil concentration (or sludge concentration if no mixing is performed).
- RQ_{soil} values were calculated for each compound based on the median, 75-percentile and 90-percentile sludge concentrations and only if a PNEC value was available. PNEC values were found in the NORMAN Ecotoxicology Database (https://www.norman-network.com/nds/ecotox/). Experimentally derived PNEC values were ranked higher than PNEC values based on quantitative structure–activity relationship models (QSAR). PNEC values used by Huygens et al. (JRC Report 2022; Excel file received from Dries Huygens 2. February 2022) were also used to calculate $RQ_{aquatic}$ values when experimentally derived values were not available. These PNEC values were considered equal to the QSAR-derived PNEC values.

3.4 Modelling environmental concentrations

In the following paragraphs, the main model rationale and its implementation is elaborated. The premises of the model were given by a need for process explicitness. This allows for the optimal use of values of compound properties and environmental conditions from a variety of sources. Regional differences are therefore represented directly in the model through the values of the input parameters for climate and soil.

3.4.1 Model rationale – model output

A model was developed to simulate the temporal development of chemical concentrations in agricultural soil following repeated applications of sewage sludge. In order to capture both the long-term effect of compounds that accumulate, and acute peak concentrations upon sludge application, the model is resolved at a monthly time step. It is designed for the analysis of the effect of sludge application in different climatic conditions, for different crops and for different fertilisation regimes.

On the input side, the variables include the amount of sludge applied, the concentration of the chemical in the sludge, the timing of the application and the subsequent harvesting and the soil depth over which the applied sludge is assumed to be integrated. The climatic drivers for these processes are a function of the selected regions and associated representative municipalities.

On the output side, chemicals are mobilised through plant uptake and successive harvesting and through leaching towards the (tile) drainage system and deep infiltration towards the

groundwater. Plant uptake and leaching both vary throughout the year and growing season and are driven by growing stage and soil moisture content. A simple method for estimating the terms of the soil water balance was developed, based on readily available input data. Actual soil moisture content was not estimated, due to the added complexity of the model, and the relatively small gain in the assumed accuracy of the monthly concentrations.

The concentration of the chemical in the soil profile is adjusted for temperature-dependent biodegradation and is calculated at monthly time steps.

The long-term effect on the concentration of individual chemicals is assessed by simulating a 100-year period of sludge application at set intervals (that are given by the scenarios).

Model platform: R

While the simulation of concentrations of chemicals is a relatively straightforward exercise, the number of chemicals assessed in this study combined with the variables describing the different scenarios (crop, rotation, pathways, etcetera) required an approach with more automation than what a spreadsheet programme offers. The high-level scripting and programming language R was chosen for several reasons. R has become a standard tool for researchers due to its intuitive syntax. It is able to interact with data stored in many formats, including proprietary ones like MS Office Excel. It is user-developed and open-source and offers an almost unlimited range of libraries for data manipulation and analysis. These range from generic ones to packages developed within and for a certain scientific discipline.

Input data for the model were calculated, derived, gathered, and harmonised by the respective specialists in the project team. MS Excel was the most appropriate format for input data management by multiple users. The same applies for the raw model output, which, on its turn, was used by multiple members of the project team.

Model output

Raw model output consisted of separate Excel files with the following data:

- Peak concentrations (after application month)
- Concentrations in harvested plant matter (for scenario main crop)
- Concentrations in effluent water (combined overland flow and drainage)
- Concentrations in composite animal feed (weighed combinations of grazing grass, feed grass and soil)
- Monthly concentrations in soil (for selected compounds and scenarios)

Soil water balance terms

The purpose of estimating the monthly terms of the water balance is to provide realistic estimates of the water uptake by plants, the amount of water leaching out of the soil profile, and to estimate the dilution factor for the concentration in effluent water. The available input data consisted of monthly rainfall (*R*, mm) and average daily temperature (*T*, at 2m height, °C).

Monthly water uptake by plants was equated to the actual evapotranspiration ET_{act}. The difference between plant uptake and actual evapotranspiration was considered to be minimal during the growing season. Evapotranspiration (ET_{act}) for a given month *t* was given as:

$$ET_{act}(t) = PET(t) \cdot K_c(t)$$

Where *PET* is the potential evapotranspiration and K_c the crop coefficient as estimated by the method described in Allen *et al.* (1998). K_c is a function of crop and crop stage (expressed in cumulative degree days) and the values (*ibid.*) are given in Appendix 7.4. Monthly PET estimates (mm) are based on a simplified radiation–temperature approach. The daily potential evapotranspiration is calculated from incoming radiation *Q0* (W/m^2) and the mean air temperature *T*:

$$PET(t) = 0.0023 \cdot Q0 \cdot (T + 17.8)$$

This approach sometimes results in negative *PET* values; these are then set to zero. Daily averages for incoming radiation were calculated based on data from representative meteorological stations in the study areas. The method first prepares daily radiation and temperature data, groups them by day-of-year, and calculates average daily values. *PET* is then estimated for each climatological day and summed by month to obtain monthly *PET* totals for each location.

Monthly leaching $Q_{leaching}$ (mm) was defined as the difference between rainfall and the sum of the overland flow and actual evapotranspiration, so that:

$$Q_{leaching}(t) = R(t) - Q_{runoff}(t) - ET_{act}(t)$$

Where $Q_{runoff}(t)$ is the monthly estimated overland flow (i.e. rainfall that does not infiltrate). This value is taken from the Pan-European Soil Erosion Risk model (PESERA), for which results are available for all soil-mapped agricultural soils in Norway (Kværnø *et al.*, 2020). Average values were taken for the study areas (*i.e.* the municipalities).

3.4.2 Modelling predicted environmental concentrations in soil (PEC_{soil}) and effluent ($C_{effluent}$)

The main state variable is the soil concentration, denoted as $PEC_{soil}(t)$, representing the concentration at month *t (g/kg),* is given by:

$$PEC_{soil}(t) = PEC_{soil}(t-1) + A(t)\, e^{-\left(k_{plant}(t)+k_{plant}(t)\left(1-fraction\_frost(t)\right)\right)} e^{-k_{deg}(t)} - H(t)$$

where *A(t)* is the application input, k_{plant}(t) and k_{leach}(t) are rate constants for plant uptake and leaching, k_{deg}(t) is the biodegradation rate, *fraction_frost*(t) represents soil frost effects (expressed as the ratio of days with sub-zero temperatures over a month), and *H(t)* is the removal due to harvest.

The contaminant input *A* (µg 10^{-4}m^2) is defined as following in the months during which a sludge application was defined:

$$A(t) = \frac{rate\ 1000\ c_{sludge}}{n_{applications}\ (10^4\ z\ \rho_{soil})}$$

where *rate* is the application rate for the application year (tonne dry weight 10^{-4}m^2). In some scenarios, this amount is applied in multiple applications ($n_{applications}$), *z* is the soil depth (m) and ρ_{soil} the dry soil bulk density (10^3 kg m^{-3}), c_{sludge} is the concentration of the compound in applied sludge (dependent on sludge type, µg kg^{-1}).

The rate constants are a function of the changes in the water balance, so that for leaching:

$$k_{leach}(t) = \frac{Q_{leaching}(t)}{(K_d\ z\ \rho_{soil})}$$

And for plant uptake:

$$k_{plant}(t) = \frac{ET_{act}(t)}{(K_d\ z\ \rho_{soil})}$$

where *Kd* is the soil–water partition coefficient, $Q_{leaching}$ is the monthly amount of excess soil water (drainage water; m) and ET_{act} the monthly actual evapotranspiration (m).

$$k_{deg}(t) = \frac{\ln(2)}{DT50\ e^{0.08(20-T(t))}}$$

where DT50 is the half-life at 20°C and T(t) is the soil temperature. Finally, at harvest, contaminant removal is calculated as:

$$H(t) = Y\left(1 - \theta(m)\right)BCF\ PEC_{soil}(t)$$

where *Y* is crop yield (kg $10^{-4}m^2$), $\vartheta(t)$ is soil moisture ($m^3\ m^{-3}$), BCF is the bioconcentration factor, and PEC_{soil} (t) is the soil concentration at harvest.

Concentrations in harvested matter

While *H(t)* is calculated for every harvest month in the given crop rotation (see scenario descriptions), concentrations in harvested material for scenarios' main crops are taken out separately. The BCF values used for this estimate differentiate are specific for the harvestable plant part. BCF_{leaf} is used for grass, BCF_{potato} for potato, BCF_{carrot} for carrot and BCF_{cereal} for cereals.

Effluent Concentration

The concentration in leachate (μL^{-1}) is estimated as:

$$C_{effluent}(t) = \frac{\Delta PEC_{soil,\,leaching}(t)z}{Q_{leaching}(t)\ +\ Q_{runoff}(t)}$$

This represents the concentration of the effluent water leaving the soil profile ($\Delta PEC_{soil,leaching}$), diluted by the two distinct water fluxes towards the surface water recipient.

Important assumptions

The model assumes first-order kinetics for all loss processes, homogeneous mixing within the soil layer, constant soil depth and density, crop uptake proportional to soil concentration, and the use of monthly averaged climate data.

3.4.3 Modelling surface water environmental concentrations (PEC_{sw})

Predicted concentrations of chemicals in surface water (PEC_{sw}) were calculated in accordance with the recommendation for local exposure estimation in TGD (ECB, 2003). The calculation is based on the mass in leachate, the volume of leachate and runoff and some assumptions about the characteristics of surface water quality.

The calculation also included removal from aqueous medium by adsorption to suspended matter. PEC_{sw} (µg L^{-1}) is estimated by the following equation:

$$PEC_{sw} = PEC_{regional} + \frac{C_{effluent}}{\left(1 + Kp_{susp}SUSP_{water,mix}10^6\right) \cdot DILUTION}$$

Where $PEC_{regional}$ is the predicted region-specific environmental background concentration surface water (µg L^{-1}), $C_{effluent}$ is the contaminant concentration in effluent water (drainage and runoff, µg L^{-1}), Kp_{susp} is the partitioning coefficient of suspended solids after mixing (L kg-1), $SUSP_{water,\ mix}$ the concentration of suspended solids in surface water after mixing (mg kg^{-1}), and *DILUTION* is a dilution factor. A dilution factor of 10, which is the recommended default dilution for local PEC calculation inTGD (ECB, 2003; ECHA, 2016), is used for calculation of PEC_{sw}. On similar grounds, a value of 15 mg kg-1 was assumed for $SUSP_{water,\ mix}$. Since background concentrations of individual chemicals were not available, $PEC_{regional}$ was ignored in this study.

3.4.4 Modelling concentrations in plants (PEC_{plant})

Chemicals present in soil may be taken up into plants, accumulate in the food chain and affect the health of animals and humans. Hence, indirect human exposure to chemicals released to soil is an essential part of chemical risk assessment. The exposure to the large number of chemicals released to soil by sewage sludge application cannot be assessed by field tests or monitoring studies alone but relies mostly on predictive methods such as plant uptake models. Typically, one generic plant type is considered, consisting of one root and one leaf compartment. Here, we apply a set of plant-specific models that were developed for root vegetables, potatoes, leafy vegetables and cereals that were published earlier (Legind and Trapp 2009), substituted by a model specifically derived for potatoes, and a new model approach developed for polar and ionising compounds such as drugs and personal care products PPCP (Trapp et al. 2023). These crop-specific plant models predict the concentrations of chemicals in roots, potatoes, leafy vegetables or grass, and cereals following uptake from soil and air. For neutral chemicals, these models (or similar ones) were repeatedly validated (for example, Trapp 2015), while experience with the new PPCP model is still rare.

The basic equations for the crop-specific models are listed in **Table 3.4.4-1**, those of the PPCP model are found in Trapp et al. (2023). All input data are listed in the Appendix.

All plant models are based on the same physicochemical principles and describe the same basic processes such as advective uptake into plants, diffusive uptake, partitioning to plant tissue, fluxes inside the plants with xylem and phloem, dilution by growth, and particle deposition from soil and air. However, the actually occurring processes and the parameterization vary with the type of crop (**Figure 3.4.4-1**).

For cereals and for leaves (grass, lettuce and other leafy vegetables), the “standard model” in Trapp (2015) (same as the standard model in Trapp et al. 2023) was applied. The model is similar to the TGD model (EC 2003), except that it omits the TSCF-regression. For more polar chemicals, it predicts the uptake better than the latter. A soil resuspension to leaf surfaces of 1% attached soil (ww) was assumed for leaves, and of 0.1% for corn (Li et al., 1994). Concentrations in roots were calculated by a dynamic root model (Trapp, 2002) that considers growth dilution. Uptake of chemicals into potatoes was calculated with a model for diffusion into a growing sphere (Trapp et al., 2007) (**Figure 3.4.4-1**).

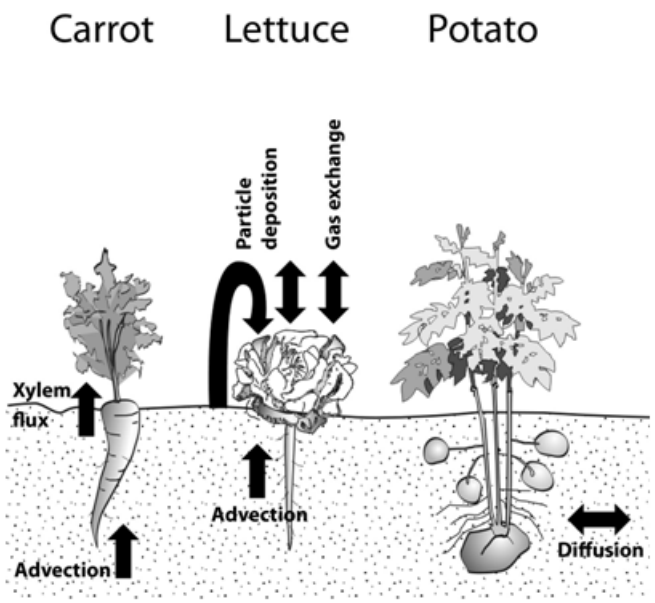


Figure 3.4.4-1**. Processes of the crop specific models. According to Legind and Trapp (2009), modified. The basic equations are listed in** Table 3.4.4-1**. Detailed equations are found in the appendix, and in Trapp et al. (2023). The reader is encouraged to consult the primary literature for more details, validation studies, application examples, and further explanations.**

The models were used to calculate uptake from soil, and, if measured concentrations in air were available, also the uptake from air was calculated. However, only for a small set of chemicals, such air concentrations could be found, including for Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6), Octamethylcyclotetrasiloxane (D4), Naphtalene, Acenaphthalene, Phenantrene, Anthracene, Fluoranthene, Fluorene, Pyrene, Indeno[1,2,3-cd]pyrene, Benzo[ghi]perylene, Benzo[b]fluoranthene, Chrysene, Benzo[a]anthracene, Benzo[k]fluoranthene, Benzo[a]pyrene, 1H,1H,2H,2H-Perfluorodecanol (8:2 FTOH), PBDE209, PBDE47, PBDE100, PBDE183, PBDE154, PCB52, PCB101, PCB118, PCB153, PCB138, PCB180. For all other chemicals, the concentration in air was set to zero.

For the calculation of BCF, the concentration in air was set to zero for all chemicals. Then, the calculated concentration in plants is solely due to uptake from air and represents the *additional* concentration, that can be expected due to uptake from soil.

Table 3.4.4-1. **Equations for the estimation of plant uptake from soil (standard model, root model and potato model). For detailed equations see the** Appendix I Chapter 7.8**.**

Pathway	Equation	Ref.
All leaf crops, grass and cereals	$C_L = \frac{b}{a}$ $\quad a = \frac{A \times g}{K_{LA} \times M_L} + k$ $\quad b = \frac{Q_L}{M_L} \times C_X + g \times A_L \times (1 - f_p) \times \frac{C_A}{M_L} + \frac{v_{dep} \times A_L}{2} \times f_P \times \frac{C_A}{M_L}$	(a),(b)
Root vegetables	$C_R = \frac{Q}{\frac{Q}{K_{RW}} + kM} \times K_{WS} \times C_S$	(c)

Pathway	Equation	Ref.
BCFpotato	$BCF = \frac{k_{uptake}}{k_{loss} + k_{growth}}$	(d)

(a) Trapp 2015; (b) Trapp et al. (2023); (c) Trapp (2002); (d) Trapp (2007). *C* is concentration, *Q* is water flow, *g* is conductance, *A* is surface area, v_{dep} is deposition velocity of particles (0 in TGD), *k* is loss rate, *K* is partition coefficient; *M* is mass; f_P is the fraction of particles in air; *BCF* is the bioconcentration factor (C_{potato}/C_{soil}). Indices: L leaf; W soil water, R root, S bulk soil; A air; X xylem.

The plant models can be adapted to specific crops and specific environmental conditions, but a whole set of data is required, and the data must be consistent. Hence, specific data are usually only collected as part of larger experimental field studies (e.g., Trapp (2015)). No specific Norwegian plant data were available nor were any collected, instead the default data set of the models determined earlier was used. Exceptions were the soils data: K_d was calculated from the soil properties of the five Norwegian regions, as described elsewhere. Chemical input data were calculated using ACD/Percepta. Degradation inside plants was set to zero (conservative assumption). The list of input data used to calculate BCF_{plant} is shown in **Appendix I Chapter 7.8**.

Equations and input data for the plant uptake models for root vegetables (BCF_{carrot}), leaves/grass (BCF_{leaf}), cereals (BCF_{cereal}) and potatoes (BCF_{potato}), of neutral chemicals and ionised chemicals (PPCP model paper Trapp et al. (2023) are shown in **Appendix I Chapter 7.8**. The models are implemented in Excel and fully parameterised. All models are published in scientific literature, for example, Legind and Trapp (2009), Trapp (2015).

Limitations. The plant uptake models have limitations, which are listed in the original references. The standard model is only applicable to neutral organic chemicals. The model was mainly tested and applied to medium to highly lipophilic chemicals. Contrary, the PPCP model was developed to consider additional effects which occur with ionizing chemicals, that is: dissociation; ion trap; phloem transport; adsorption to proteins. Trapp et al. (2023) compares the outcome of the PPCP model to that of the standard model. The difference is variable and depends on a number of factors, for example, pH of the soil and pKa of the chemicals. For neutral chemicals, the main difference between standard model and PPCP model is that with the latter, polar neutral chemicals show higher concentration in fruits or cereals, due to the phloem transport, but lower concentrations in leaves. The PPCP model was only used for chemicals that ionise at the given soil pH, else, the models for neutral chemicals were applied.

The usage of all model variants to very polar chemicals (log Kow < 1) is critical: the equations assume an uptake of the chemicals as fast or faster than water at the entry to the roots. This is given when the diffusion of the chemical across biomembranes is faster than the uptake of water. This is usually the case, unless the chemical is very polar (log Kow < -2) or charged. Hence, an application to very polar chemicals, or to 100% ionised chemicals will lead to an overestimation of uptake. For permanently charged PFAS, good uptake was observed, but an empirical “retardation factor” at the root entry had to be applied to consider the slower-than-water permeation of root biomembranes (Gredelj et al. 2019). Hence, uptake and BCF-values of very polar chemicals, or highly ionised chemicals, will be overestimated.

The potential biodegradation of chemicals in plants was neglected. However, the root zone is the biologically most active zone of the soils. Thus, biodegradation, if it occurs, will lead to

lower concentrations. This is also not considered here. Hence, uptake calculations are on the conservative side, so that the likelihood of overestimation is much higher than that of underestimation.

The models were solved for the steady-state, or for t = 60 days. In both cases, the model parameters were kept constant during simulations. This is a gross simplification, as the growth of plants and the fluxes in xylem (upwards) and phloem (downwards and to fruits) are highly dynamic, changing with the day and night cycle, the weather, and the plant growth stage. Dynamic simulations of the system is possible, see for example Rein et al. (2024), but requires high efforts and detailed daily data, which were not available in this risk assessment.

The detailed equations and all plant-model-specific input data are listed in the separate **Appendix I Chapter 7.8**

Plant uptake of PFAS. Another method was chosen to estimate K_d and BCFs of per- and polyfluoroalkyl substances, brief PFAS. PFAS are acidic surfactants that differ in perfluoroalkyl chain length and in the terminal polar group (carboxylic, sulfonic, sulfonic, phosphonic and other). PFAS are moderate to strong acids and ionise at environmental pH. They do not have the usual lipid partitioning mechanisms and have low affinity to lipids but high affinity for proteins (Droge, 2019). Their estimated or experimental partition coefficients K_{ow} are very uncertain (Droge, 2019) and fate models, such as the described plant uptake models, but also the K_d estimations, may fail to predict correctly for PFAS (Gredelj et al. 2020b). However, relations between PFAS chain length (length of the fluorinated alkyl chain) and properties such as adsorption to soil (K_d) and plant uptake (BCF_{plant}) have previously been established (Blaine et al. 2014, Gredelj et al. 2020a). Therefore, for the group of 22 PFAS, regressions based on chain length were used to estimate K_d and BCF. The following regressions were used:

$\log K_d = 0.26 \times -1.21$ (Gredelj et al. 2020b, for a soil with 2% orgC)

where x is the chain length of the alkyl rest.

Moreover, for 14 PFAS, measured K_{oc}-values were listed in Liu et al. (2025). Those were preferred over the estimated K_d. For uptake into plants, regressions from irrigation experiments were found in Gredelj et al. (2020a),

$\log BCF_{root} = -0.308 \times +3.253$ (Gredelj et al. 2020a; for radish roots, unit dw:dw)

$\log BCF_{leaf} = -0.275 \times +2.291$ (Gredelj et al. 2020a; for radish leaves, unit dw:dw)

and derived from experiments with biosolids (Blaine et al. 2013, 2014). BCFs derived from those data gave lower BCF for PFAS, but were selected because the experimental setting (addition of sewage sludge) was closer to the task of this risk assessment. The regressions fitted to uptake into celery were chosen, because they gave the highest BCF:

$\log BCF_{root} = -0.17 \times +1.49$ (Blaine et al. 2014; for celery roots, unit dw:dw)

$\log BCF_{leaf} = -0.36 \times +2.70$ (Blaine et al. 2014; for celery shoots, unit dw:dw)

$\log BCF_{fruit} = -0.54 \times +2.84$ (Blaine et al. 2014; for a tomato fruit, unit dw:dw).

Values were recalculated to fresh weight using a water content of 95% for leaves, roots and tomato, and of 15% for cereals, plus a soil dry density of 1.2 kg/L and wet density of 1.5 kg/L.

3.5 Methodology for the characterisation of hazards to wildlife from secondary poisoning

In the present risk assessment, hazards to wildlife from secondary poisoning were not explicitly calculated for the prioritised contaminants is sewage sludge, but conclusions were based on available reference data.

The potency for bioaccumulation and biomagnification of contaminants in the environment has to be considered when risks to wildlife by secondary poisoning are evaluated. In this context, persistent organic pollutants are of special importance. Biomagnification is defined as accumulation and transfer of contaminants via the food chain, resulting in an increase of the internal concentrations in organisms at higher levels of the trophic chain. Secondary poisoning of wild terrestrial mammals and birds occurs, when these animals are exposed to hazardous substances through the ingestion of contaminated prey, plants or soil.

For organic chemicals, PNEC values relevant to secondary poisoning are typically denoted as $PNEC_{oral}$ in prey (food), reflecting the oral exposure route for predators. $PNEC_{oral}$ values represent dietary predicted no-effect concentrations, below which feed concentrations are not expected to pose a risk to birds or mammals (ECHA 2008).

The potential risk for soil-living organisms (earthworm etc.) and organisms at higher trophic level may also be estimated by the calculation of bioaccumulation in soil and biomagnification from one trophic level to the next.

Biota-Soil Accumulation Factor (BSAF): This factor quantifies the ratio of a contaminant's concentration in animal tissue (usually lipid-normalised for hydrophobic substances) to its concentration in soil (organic carbon-normalised). A high BSAF indicates strong potential for bioaccumulation from soil to biota.

$$BSAF = \frac{C_{biota}/f_{lipid}}{C_{soil}/f_{OC}}$$

where C_{biota} is the concentration in biota (mg/kg lipid), C_{soil} is the concentration in soil (mg/kg organic carbon), f_{lipid} is the fraction of lipid in biota, and f_{OC} is the fraction of organic carbon in soil.

Biomagnification Factor (BMF): This factor describes the increase in contaminant concentration from one trophic level to the next (e.g., from prey to predator). The BMF can be used to estimate the contaminant concentration in a predator (e.g., mammal) from the concentration in its prey (e.g., earthworm or bird egg). BMF > 1 indicates biomagnification, which is particularly relevant for secondary poisoning risk.

$$BMF = \frac{C_{biota}/f_{lipid}}{C_{soil}/f_{OC}}$$

In the absence of established $PNEC_{oral}$ values, a risk assessment may proceed by:

- Estimating exposure of mammals (e.g., shrews, voles, foxes) based on measured or predicted concentrations in soil, prey, and plants.
- Applying BSAF and BMF values (from literature or laboratory studies) to estimate internal doses in mammals.
- Comparing these doses to available toxicity reference values (e.g., NOAELs, LOAELs) to characterise risk.

Organic contaminants of concern for secondary poisoning in wildlife often share the following properties:

- high lipophilicity (high $logK_{ow}$ or logD – $logK_{ow}$ > 4) - promoting bioaccumulation in animal tissues,
- environmental persistence (resistant to biodegradation)**,** leading to long-term presence in soil and food webs,
- potential for biomagnification (BMF > 1)
- Toxicity at low doses to mammals

In Norway, the Norwegian Environment Agency (NEA) has established an environmental monitoring program for pollutants in the terrestrial and urban environment (urban Oslo)), named MILBY-program (Environmental pollutants in urban wildlife). The MILBY program was initiated as part of Norway's efforts to strengthen environmental monitoring and risk assessment of organic contaminants in terrestrial ecosystems. A overall objective is to evaluate whether contaminants used in everyday consumer products are detectable in urban ecosystems, and whether they accumulate in food chains and represent a risk to wildlife and the environment. The data generated provide a basis for environmental risk assessment and support the identification of chemicals that may require regulatory action at national or international level.

The primary objectives of MILBY are:

- Evaluate the fate and effects of organic contaminants in soil and biota, focusing on terrestrial food chains.
- Investigate exposure and risk for higher trophic level organisms (e.g., birds and mammals) through contaminated prey such as earthworms.
- Provide measured concentrations of priority contaminants in soil, earthworms, and selected predators to support calculation of BSAF, BMF and PNEC for secondary poisoning.

The MILBY program has generated concentration data for over 150 organic contaminants in soil, relevant for bioaccumulation and biomagnification, and has performed risk evaluation for predators with a food chain approach (e.g., earthworm → fieldfare → sparrowhawk; using $MEC/PNEC_{oral}$ ratios to assess secondary poisoning potential for many organic contaminants. MILBY reports BSAF and BMF, the latter estimating exposure of contaminants to wildlife via the diet. Norwegian reports (e.g., Andersen et al., 2012) provide reference tables for $PNEC_{oral}$ for selected contaminants (**Table 3.5-1**). These values were adopted in the MILBY assessment. Values are first and foremost based on chronic NOECs for mammals/birds and adjusted with AF.

$PNEC_{soil}$ values for soil ecosystem are given in **Table 3.5-2**. Most data adopted from Andersen et al. (2012) are from EU risk assessment reports (EU RAR), Environment Agency risk evaluation reports (EA ERAR), and the European Chemicals Agency, http://echa.europe.eu. Entries with font coloured in grey are considered as of second priority due to assumed lower reliability.

Table 3.5-1. PNECoral values (mg/kg in food) for secondary poisoning, with references. Most data adopted from Andersen et al 2012, EU risk assessment reports (EU RAR), Environment Agency risk evaluation reports (EA ERAR), and European Chemicals Agency, http://echa.europe.eu. Entries with font coloured in grey have second priority.

Compound	$PNEC_{oral}$ mg/kg food	Reference	Safety factor	Comment
PCBs	0.001	INERIS: Annex VII PNEC values and hazard information for candidate substances, 2009. *Uncertainty to the value since not based on EU Risk Assessment report*		Based on TDI of 0.02 µg/kg bw/day for total PCBs via diet (WHO, 2003 & ATSDR, 2000) and TDI of 0.01 µg/kgbw/day for total PCBs, via diet (RIVM, 2001)
PCB-153	0.67	TemaNord 2011: 506. ISBN 978-92.893-2194-5 Using Sludge on Arable Land (Table 7)	20	Risk assessment of bioaccumulation in the food webs of two marine AMOE BE species: common tern and harbor seal. RIVM Report 719102040.Jongbloed et al 1995
BPA	2.67	EU RAR BPA add	30	Three generation feeding study of rats
TBBPA	667	(mammalian) EU RAR TBBPA	30	2-generation rat reproduction study
PentaBDE	1	EU Risk assessment-Diphenyl Ether, Pentabromo derivative Final Report, August 2000	10	30 day oral rat study-liver effects
OctaBDE	6.7	EU Risk assessment-Diphenyl Ether, Octabromo derivative Final Report, August 2003	10	Rabbit phetotoxicity
DecaBDE	833	DecaBDE, EA-ENvRA-2009	30	Rat, two years carcinogenicity study
PFOS	0.037	RIVM 2010 http://www.rivm.nl/dsresource?objectid=rivmp:15878&type=org&disposition=inline&ns_nc=1	90	NOAEL of 0.1 mg/kg bw/d for maternal weight gain from a teratogenicity study
PFOS	0.033	European Commission. 2011. Perfluorooctane sulfonate. PFOS Environmental Quality Standard (EQS) dossier. Brussels, Belgium.		QSbiota (secondary poisoning: predators)
PFOA	0.9E-03	Valsecchia et al 2016 doi:10.1016/j.jhazmat.2016.04.055	90	Developmental abnormalities in mice
HCB	0.0167	Science Dossier http://www.eurochlor.org/media/90477/sd16-hcbaquaticra-final.pdf	30	NOEC mink 0.5 mg/kg
DEHP	3.3	ECHA Chemical Information		
DnBP	1.33	ECHA Chemical Information		https://echa.europa.eu/brief-profile/-/briefprofile/100.001.416
Cyclic Siloxane (D4)	1.7	EA ERAR 2009 Octamethylcyclotetra-siloxane	300	Rat liver effects
Cyclic Siloxane (D5)	13	EA ERAR 2009 Decamethylcyclopenta-Siloxane,	30	Repeated exposure, liver effects
Cyclic Siloxane (D6)	66.7	Source: European Chemicals Agency, http://echa.europa.eu/	300	https://echa.europa.eu/brief-profile/-/briefprofile/100.007.967
Nonylphenols	10	EU RAR nonylphenol	10	Rat multi-generation study, reproduction effect
Octylphenols	10	Environmental Agency (UK) 2005	30	Rat, two-generation study, systemic and postnatal toxicity
4-tert-octylphenol	10	EA RER 2005 4-tert-octylphenol	30	

Compound	$PNEC_{oral}$ mg/kg food	Reference	Safety factor	Comment
LCCP	10	ECHA chemical Information		https://echa.europa.eu/brief-profile/-/briefprofile/100.058.300
MCCP	10	EU RAR addendum 2007	30	Rat, 90 days study, kidney effects
SCCP	5.5	EU RAR addendum 2008	30	Reproduction effects on wild duck
TDCPP 13674-87-8	3.3	EU RAR 2008	30	Two-years carcinogenicity rat study
TBEP 78-51-3	4.44	ECHA chemical Information		https://echa.europa.eu/brief-profile/-/briefprofile/100.001.021
EHDPP	1.1	Environmental Agency (UK) 2009	90	Rat 90 d oral exposure
EHDP	1.62	ECHA chemical Information		https://echa.europa.eu/brief-profile/-/briefprofile/100.013.625
TCP	1.7	EA RER 2009 (1330-78-5)	30	Two-years reproduction mouse study
TCP	0.65	ECHA chemical Information		https://echa.europa.eu/brief-profile/-/briefprofile/100.239.100
TCPP	11.6	EU RAR TCPP 2008	90	rat, 13 weeks study, liver effects
TPP/TPhP	16.7	ECHA chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.003.739
DEHP	3.3	ECHA chemical information (scientific information)		https://echa.europa.eu/brief-profile/-/briefprofile/100.003.829
DnBP	1.33	ECHA chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.001.416
DEP	33	ECHA chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.001.409
BBP	100	ECHA chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.001.475
DCHP	133 000	ECHA chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.001.405
DDPT	20.7	ECHA chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.079.428
HHCB	20.4	ECHA chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.013.588
UV-328	13.2	ECHA chemical information (scientific information)		

Table 3.5-2. $PNEC_{soil}$ values with references. Most data adopted from Andersen et al 2012, EU risk assessment reports (EU RAR), Environment Agency risk evaluation reports (EA ERAR), and European Chemicals Agency, http://echa.europe.eu. Entries with font coloured in grey have second priority.

Table 3.5-2. PNECsoil values with references. Most data adopted from Andersen et al 2012, EU risk assessment reports (EU RAR), Environment Agency risk evaluation reports (EA ERAR), and European Chemicals Agency, http://echa.europe.eu. Entries with font coloured in grey have second priority.

Compound	$PNEC_{Soil}$	Unit in soil	Reference	Safety factor	Comment
BPA (4,4 Bis-A)	3.2	mg/kg dw	EU RAR BPA	10	Calculated from PNECaquatic –D. magna
TBBPA	0.012	mg/kg dw	EU draft RAR TBBPA	10	Earthworm reproduction
PentaBDE	0.38	mg/kg dw	TA-2625	50	
OctaBDE	20.9	mg/kg ww	EU RAR 2003	50	Phytotoxicity
DecaBDE	98	mg/kg ww	EU RAR 2002	50	
HexBDE	1.2	mg/kg ww	EU RAR 2003	50	Phytotoxicity
TriBDE	20.9	mg/kg ww	Using Octa BDE value	50	Phytotoxicity

Compound	$PNEC_{Soil}$	Unit in soil	Reference	Safety factor	Comment
TetraBDE	20.9	mg/kg ww	Using Octa BDE value*	50	Phytotoxicity
HeptaBDE	20.9	mg/kg ww	Using Octa BDE value	50	Phytotoxicity
NonaBDE	20.9	mg/kg ww	Using Octa BDE value	50	Phytotoxicity
Cyclic siloxane (D4)	0.16	mg/kg ww	EA ERA 2009 Octamethylcyclotetra-siloxane		PNEC for water, equilibrium partitioning method
Cyclic siloxane (D4)	0.15	mg/kg dw	European Chemicals Agency,		partition coefficient
Cyclic siloxane (D5)	4.8	mg/kg ww	EA ERA 2009 Decamethylcyclo-pentasiloxane		PNEC for water, equilibrium partitioning method
Cyclic siloxane (D5)	3.77	mg/kg dw	European Chemicals Agency	100	
Nonylphenols	0.3	mg/kg dw	European Chemicals Bureau, 2002	10	Earthworm reproduction
Octylphenols	0.0067	mg/kg dw	Environmental Agency (UK) 2005	10	Calculated from PNECaquatic-mysid M. bahia
4-tert-octylphenol	0.0059	*mg/kg ww*	EA RER 2005 4-tert-octylphenol	Large uncertainty	PNEC surface water and equilibrium partitioning
4-tert-octylphenol	2.3	mg/kg dw	European Chemicals Agency,	10	
LCCP	4.64	g/kg dw	ECHA Chemical information (Scientific Properties)		https://echa.europa.eu/brief-profile/-/briefprofile/100.058.300
MCCP	11.9	mg/kg dw	European Chemicals Agency,	10	
SCCP	5.95	mg/kg dw	European Chemicals Agency,	20	
MCCP	10.6	mg/kg ww	EU RAR addendum 2007	10	Earthworm reproduction
SCCP	1.76	mg/kg ww	EU RAR addendum 2008	0	LogKow estimation- no safety factor
TFA	4.7	ng/g dw	ECHA Chemical information (Scientific Properties)		Secondary poisoning: No potential for bioaccumulation (1)
PFOA	0.16	mg/kg dw	TA-2444/2008	100	Worm reproductivity
PFOS	0.373	mg/kg dw	pfos.uk.risk.eval.report.2004	1000	Worm toxicity
$SumPCB_7$	0.01	mg/kg dw	Aquateam rapport nr 06-039	50	Calculated from aquatic data
TCEP	0.386	mg/kg dw	EURAS, 2009	50	Folsomia candida 28 d exposure
TCPP	1.7	mg/kg dw	EU RAR TCPP	10	Spiring Lactuca sativa
TCPP	1.33-1.7	mg/kg dw	Echa Chemical Information		
TDCP/TDCPP	0.33	mg/kg dw	EU RAR 2008	10	57d NOEC reproduction toxicity E.foetida
TBEP	0.81	mg/kg dw	TA-2784	EqP	Calculated
EHDPP	0.302	mg/kg ww	Environmental Agency (UK), 2009	10	Estimated from aquatic data
TCP	0.0027	mg/kg dw	EU-RER	10	Spiring Lactuca sativa

Compound	$PNEC_{Soil}$	Unit in soil	Reference	Safety factor	Comment
TCP	1.01	mg/kg dw	ECHA Chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.239.100
TBP/TnBP	5.3	mg/kg dw	TA-2784	EqP	Based on LogKow
TBP/TnBP	640-2830	µg/kg dw	ECHA Chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.004.365
TBP/TiBP	420	µg/kg dw	ECHA Chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.004.363
TEP	640	µg/kg dw	ECHA Chemical information		
TIBP	0.64	mg/kg dw	TA-2784	EqP	Based on LogKow
TPP/TPhP	28.2	µg/kg dw			https://echa.europa.eu/brief-profile/-/briefprofile/100.003.739
TXP	11.7	mg/kg dw			https://echa.europa.eu/brief-profile/-/briefprofile/100.042.419
TEHP	3.7	mg/kg dw			https://echa.europa.eu/brief-profile/-/briefprofile/100.001.015
DEHP	13	mg/kg dw	ECHA Chemical information (Scientific Properties)		https://echa.europa.eu/brief-profile/-/briefprofile/100.003.829
DiNP	30	mg/kg dw			No potential for bioaccumulation
DPHP	26.5	mg/kg dw			No potential for bioaccumulation
DnBP	50	ng/g dw			https://echa.europa.eu/brief-profile/-/briefprofile/100.001.416
DiBP	23.1	ng/g dw			No potential for bioaccumulation
DEP	137	µg/kg dw	ECHA Chemical information		https://echa.europa.eu/brief-profile/-/briefprofile/100.001.409
BBP	1.57	mg/kg dw			https://echa.europa.eu/brief-profile/-/briefprofile/100.001.475
DCHP	310	µg/kg dw			https://echa.europa.eu/brief-profile/-/briefprofile/100.001.405
DDPT	109	µg/kg dw			https://echa.europa.eu/brief-profile/-/briefprofile/100.079.428
HHCB	1.5	mg/kg dw			https://echa.europa.eu/brief-profile/-/briefprofile/100.013.588
MCKETON	4.87	mg/kg dw			https://echa.europa.eu/brief-profile/-/briefprofile/100.046.367
UV-328 (25973-55-1)	90	mg/kg dw	ECHA Chemical information (Scientific Properties		

Compound	$PNEC_{Soil}$	Unit in soil	Reference	Safety factor	Comment
UV-329 (3147-75-9)	10	mg/kg dw	ECHA Chemical information (Scientific Properties		No potential to cause toxic effects if accumulated (in higher organisms) via the food chain
OC (6197-30-4)	1.25	mg/kg dw	ECHA Chemical information (Scientific Properties		No potential to cause toxic effects if accumulated (in higher organisms) via the food chain
Homosalate	54.11	mg/kg dw	ECHA Chemical information (Scientific Properties		No potential to cause toxic effects if accumulated (in higher organisms) via the food chain
BP3 (131-57-7)	13	ng/g dw	ECHA Chemical information (Scientific Properties		Additional info: No potential for bioaccumulation

3.6 Methodology for the characterisation of hazards in farm animals

The risk for farm animals from the application of sewage sludge and derived products to agricultural soils are in this assessment characterised by modelling four exposure routes for organic contaminants (**Table 3.6-1**).

Table 3.6-1**. Overview of modelled routes of exposure to organic contaminants in sewage sludge in farm animals.**

Exposure route	Overview of exposure pathways for farm animals
1	Intake of organic contaminants from grazed pastures and compound feed grown on soils receiving dewatered sewage sludge. Additionally, the animals ingest sludge amended soil while grazing.
2	Intake of organic contaminants from preserved forage (silage or hay) and compound feed grown on soils receiving dewatered sewage sludge. Soil ingestion is not relevant in this case.
3	Intake of organic contaminants from grazed pastures and compound feed grown on soils receiving liquid fraction of digested sewage sludge (surface application). The animals accidentally ingest sewage sludge with soil while grazing and with grass to which sewage sludge adheres.
4	Intake of organic contaminants from preserved forage (silage or hay) and compound feed grown on soils receiving liquid fraction of digested sewage sludge. Soil ingestion is not relevant in this case.

Grazing animals naturally ingest variable amounts of soil in addition to the pasture plants. The intake can be inadvertent due to soil adhered to vegetation or as an active ingestion. The soil intake my vary between animal species, with the quality of the pasture, soil type, the animals´ need for minerals and their metabolic health state (Herlin and Andersson, 1996; Collas et al. 2023).

In this assessment, a level of soil intake considered as average for each species was used. For cattle and horse, 3 % soil of the total nutrient DM intake was used. For sheep and poultry, 6 % was used and for pigs, 10 % (see **Table 3.6-2**).

Harvested forage may also contain trace amounts of soil, but the level is considered as negligible, and thus, was omitted in this assessment. When applying liquid digestate of sewage sludge onto soil surface, however, (exposure route 3), it is assumed that grazing animals directly ingest sludge due to adhesion to grass. According to the EU regulations and TOR3, grazing is not allowed the first 3 weeks after sewage sludge application. For the calculations, it has been assumed that the one percent of the total ration is due to intake of digested sewage sludge (see **Table 3.6-2**).

Comparison of animal exposure to organic contaminants from compound feed, grazed pastures/preserved forage, soil and sewage sludge provides information about the relative importance of the different intake sources. Summarised, the total intake will give information about risks connected to sewage sludge application for those contaminants, for which data for dose-response effects exist.

Exposure route 1 models the intake of organic contaminants in animals grazing (forage feed, grassland) on soils that have received sewage sludge (11.2 tonnes/ha/10 years mixed with 0.15m of soil). These animals are also given various amounts of compound feed (cereals) grown on the sludge-amended soils (11.2 tonnes/ha/10years mixed with 0.15m of soil). The animals digest a fraction of the sludge-amended soil (11.2 tonnes/ha/10years mixed with 0.15m of soil).

Exposure route 2 models the intake of organic contaminants in animals receiving compound feed and preserved forage grown on soils that have received sewage sludge (11.2 tonnes/ha/10years mixed with 0.15 m of soil). Direct soil intake is not considered.

The calculations for exposure routes 1 and 2 (**Table 3.6-3**) were performed using median and Q90 concentrations of measured sewage sludge concentrations of the different contaminants, considering region 2 (Melhus), region 3 (Stange) and region 4 (Ås).

Exposure route 3 models the intake of organic contaminants from grazed pastures and compound feed grown on soils receiving digested sewage sludge products (surface application). On grassland, 0.40 tonnes (DM) digested sewage sludge are applied three times (spring, 1.cut, 2.cut) per season, amounting to 1.20 tonnes/ha/year. The assumption was made that the applied digested sewage sludge to grassland infiltrates into the upper 0.05 m of the topsoil. The compound feed (cereals) that these animals consume are produced on soils that receive 0.5 tonnes/ha/year (spring) mixed within 0.15m of soil. The animals digest a fraction of digested sewage sludge (DM) from the plants (1% of the total intake), as well as a fraction of soil.

Exposure route 4 models the intake of organic contaminants in animals receiving compound feed and preserved forage grown on soils that have received digested sewage sludge products (surface application). On grassland, 0.40 tonnes (DM) digested sewage sludge are applied three times (spring, 1.cut, 2.cut) per season, amounting to 1.20 tonnes/ha/year. The assumption was made that the applied liquid fraction of digested sewage sludgeto grassland infiltrates into the upper 0.05 m of the topsoil. The compound feed (cereals) that these animals consume are produced on soils that receive 0.5 tonnes/ha/year (spring) mixed within 0.15m of soil. The animals digest a fraction of digested sewage sludge (DM) from the plants (1% of the total intake). Direct soil intake is not considered.

The fractions of compound feed, forage feed, soil and sewage sludge ingested by the farm animals are shown in **Table 3.6-2.**

Table 3.6-2. Ratios of compound feed, forage, soil, and digestated sewage sludge in the total rations on DM basis for five groups of farm animals. The animals are exposed on pasture via grazing, or indoors by compound feed and forage.

	Appl. of dewat. sewage sludge					**Appl. of liquid digestate of sewage sludge (Liq dig)**						
	(11.2 tonnes (dw)/ha/10years)					(1.3 tonnes (dw)/ha/year)						
	Pasture based			Housed system		Pasture based				Housed system		
	Ratio			Ratio		Ratio				Ratio		
Species	Comp Feed	Forage	Soil	Comp. feed	Forage	Comp. feed	Forage	Soil	Liq. dig.	Comp. feed	Forage	Liq. dig.
High-lact. cows	0.5	0.47	0.03	0.5	0.5	0.5	0.46	0.03	0.01	0.5	0.49	0.01
Adult sheep w/twins	0	0.94	0.06	0.25	0.75	0	0.93	0.06	0.01	0.25	0.74	0.01
Grow. pigs	0.8	0.1	0.1	1	0	0.79	0.1	0.1	0.01	1	0	0
Laying hens	0.8	0.14	0.06	1	0	0.79	0.14	0.06	0.01	1	0	0
Adult lact. goats	0.5	0.45	0.05	0.5	0.5	0.5	0.44	0.05	0.01	0.5	0.49	0.01

Note: All intake numbers are specified in terms of dry weight. Shares of different substances consumed, compound feed, forage, and soil (exposure routes 1 and 3), and sewage sludge (exposure route 3 and 4) are in relation to total daily consumption.

Total ration = Σ(Ratio Comp Feed*[Comp Feed]+Ratio Forage*[Forage]+Ratio Soil*[Soil]+Ratio liq.dig SS*[Liq dig SS]) (3.6-1)

Total ration	**Amount (µg) of organic contaminants per kg of animal ration**
Ratio Comp Feed	Ratio of total intake (DM) coming from compound feed
Ratio Forage	Ratio of total intake (DM) coming from forage
Ratio Soil	Ratio of total intake (DM) coming from soil
Ratio Liq dig SS	Ratio of total intake (DM) coming from liquid digested sewage sludge
[Comp Feed]	Concentration of organic contaminant (DM) in cereals grown on soils that have received sewage sludge: exposure route 1 and 2: – 11.2 tonnes/ha/10 years mixed with 0.15 m of soil; exposure route 3 and 4: 0,5 tonnes liquid digested sewage sludge (dw)/ha, applied in spring and mixed with 0.15 m of soil
[Forage]	Concentration of organic contaminant (DM) in grass grown on soils that have received sewage sludge: exposure route 1 and 2 :11.2 tonnes/ha/10 years mixed with 0.15 m of soil; exposure route 3: 0.40 tonnes liquid digested sewage sludge (dw)/ha/yr, three times (spring, 1.cut, 2.cut) mixed with 0.05 m of soil

[Liq dig SS]	Calculated concentration of organic contaminant in digested sewage sludge (DM) (Chapter 6.3)

In "Exposure routes 3 and 4" (Table 3.6-3), the amount of digested sewage sludge applied to the soil (surface) is based upon the plant needs for nitrogen. It is assumed that the dry matter of the digested sewage sludge product is 1.1%, the concentration of nitrogen is 2.55 kg N/tonnes (ww). To produce 5000 kg of cereal/ha (normal) the needs for nitrogen will be about 120 kg N and thus, 500 kg (dw) digested sewage sludge are applied (NIBIO fertiliser recommendations).

The production of 8250 kg dry matter/ha (standard yield for grassland cut three times per season in Central Norway NIBIO fertiliser recommendation) requires 240 kg N/ha, and 1300 kg (dw) (400 kg x3) digested sewage sludge are applied assuming a 70-80% N replacement value of the sludge.

See **Appendix I Chapter 2.7** for calculations regarding phosphorous and nitrogen application rates.

Table 3.6-3**: Data used for the calculation of farm animal exposure with organic contaminants in sewage sludge products used as fertiliser. For description of exposure routes, see Table 3.6-1.**

Exp. route	MEC_{sludg}	MEC_{sludg}	MEC_{sludg}	Site	Appl. meth	Soil ingest	Sludg ingest	Soil depth (m)	PEC plant
1	Dewat. sewage sludge	Measur. conc.	Median, Q90	Melhus Stange Ås	Mixed with soil	Yes	No	0.15/0.15	Cereal/ grass
2	Dewat. sewage sludge	Measur. conc.	Median, Q90	Melhus Stange Ås	Mixed with soil	No	No	0.15/0.15	Cereal/ grass
3	Liquid dig. sewage sludge	Predict conc.	Median, Q90	Melhus	Surf. applic.	Yes	Yes	0.15/0.05*	Cereal/ grass
4	Liquid dig. sewage sludge	Predict conc.	Median, Q90	Melhus	Surf. applic.	No	Yes	0.15/0.05*	Cereal/ grass

*In scenario 3 and 4, the concentration of organic contaminant in grass is calculated by assuming that the sludge is mixed with 0.05 m of soil.

3.7 Methodology for the identification and characterisation of hazards in humans

A complete intake estimation in humans from food for all contaminants in sewage sludge based on food consumption data, dietary habits and occurrence in all food categories was not feasible within the framework of the present risk assessment nor possible due to lack of both toxicity data and occurrence data in most types of food for a large number of the assessed contaminants. Moreover, the calculation of intake only from sewage sludge without taking other sources into consideration is incomplete and may be misleading. A total intake estimation in humans was also not required in the Terms of Reference provided by the Norwegian Food Safety Authority.

Thus, a simplified and pragmatic approach has been used: The predicted increases in concentrations of the contaminants in plant derived foods were assessed for contaminants

with predicted addition in plant concentrations from sewage sludge exceeding 0.00001 µg/kg dry weight. Available information on toxic potencies for humans, such as Acceptable Daily Intake (ADI), Tolerable Daily Intake (TDI), or Benchmark Dose (BMDL) combined with an appropriate Margin of Exposure, were collected for these compounds. If no such value was identified, a No Observed Adverse Effect Level (NOAEL) was used as a Health Based Guidance Value (HBGV) if identified. If a dietary intake estimate was available, the increase in contaminant concentrations coming from the consumption of relevant food items, produced on sludge-treated agricultural soils, to the total intake was estimated:

a) If the estimated current dietary intake indicated no significant risk from exposure to a specific contaminant, and the additional intake coming from food grown after the application of sewage sludge was limited, the overall risk was considered as low; b) If the estimated current dietary intake level of a contaminant was close to its HBGV, and the additional intake coming from food grown after the application of sewage sludge contributed significantly to the total intake, the overall risk was considered as moderate or high, and monitoring of the contaminant was recommended; c) If the high daily consumption of the vegetables or cereals (for cereals about 500 g, which is above the 95-percentile, and about 250 g for potatoes and carrots, which is above the 95-percentile for both carrots and potatoes, but below the 95-percentile of the dietary intake of all vegetables, was estimated to be below 10% of the HBGV, the risk was considered as low.

The approach is comparable to what was used in previous risk assessments (VKM 2009; VKM 2022).

4 Background concentrations of organic contaminants in Norway

4.1 Background concentrations of priority contaminants in soil

Environmental contaminants in air, precipitation, waters and biota are monitored in various surveyance programmes in Norway and reveal the significance of local and long-range transport for the ubiquitous nature of many groups of contaminants.

Atmospheric deposition due to emissions from local and distant sources, as well as former use of sewage sludge, other organic fertilisers and pesticides, contribute to a certain background level of contaminants in soil and water. For some contaminants (e.g. PFAS) also windblown sea sprays may be of significance for the ubiquity of these compounds, at least in coastal areas.

4.1.1 Atmospheric contribution

Organic pollutants such as PCBs, DDT and other chlorinated pesticides, HCB (Hexachlorobenzene), dioxins and furans, PAHs, flame retardants (e.g., PBDEs – Polybrominated Diphenyl Ethers), and PFAS can be transported from urban or industrial regions to remote agricultural and natural environments. Some organic pollutants have natural analogues or can be produced naturally through biological or geochemical processes. Two examples are PAHs, which can be formed during wildfires, volcanic activity and natural combustion of organic matter, and PCDD/Fs which also can be formed during forest fires, volcanic eruptions, and some microbial processes.

These substances share several key characteristics. They are chemically stable, meaning they degrade very slowly in the environment, they are often lipophilic, allowing them to accumulate in the fatty tissues of living organisms, and they are highly toxic to both humans and wildlife, even at very low concentrations. A chemical group like PFAS contain a lot of compounds that bind strongly to proteins, resulting in high concentrations in blood, liver and kidneys. Many are also classified as persistent organic pollutants (POPs) due to their long-range environmental transport potential and harmful effects.

The primary mechanism for this atmospheric long-range transport is known as “global distillation”, also referred to as the “grasshopper effect.” In this process, pollutants evaporate in warmer regions, travel through the atmosphere, and then condense and deposit in cooler climates. This phenomenon enables pollutants to “hop” across the globe in stages, accumulating over time in regions far from their original source, including pristine environments like remote agricultural lands, forests, mountain areas, and the Arctic.

As a result, even ecosystems with no direct pollution sources can experience contamination, posing significant ecological and health risks through bioaccumulation and biomagnification in food chains.

4.1.2 Previous sewage sludge application in agricultural soil

In some areas in Norway, especially in areas around the Oslofjord (counties Oslo, Akershus, Vestfold, Østfold, i.e. region 4), sludge has been used quite extensively during the last 4-5 decades. Statistics (SSB 2025; https://www.ssb.no/statbank/table/05279) show that about 1

million tonnes of sewage sludge were applied on agricultural areas in this region in the period 2001-2023. For organic contaminants (mostly POPs), this may contribute to the background level in agricultural soils.

In the present risk assessment, an indication of the background concentrations in soil due to previous sewage sludge applications (since the 1970ies) is modelled (Chapter 7). The estimated concentration in soil the last months before the 6th application in scenarios involving application dewatered sewage sludge every 10th year is assumed to represent an estimated background concentration reflecting previous use of sewage sludge.

4.2 Existing data on organic contaminants in Norwegian soil and air

In the previous risk assessment on contaminants in sewage sludge by VKM involving organic compounds (VKM, 2009), only sewage sludge as source was considered, i.e. the significance of soil background level of organic contaminants was assumed to be minimal. In the present risk assessment, the background concentration will not be included in the initial step(s). If RCR>1 in the calculation of $PEC_{soil,peak}/PNEC_{soil}$ the importance of background concentrations in soils should be discussed. Also, for other endpoints (water organisms, humans and domestic animals) the knowledge about the background levels in soil and water will to some degree be used to evaluate the relative importance of sewage sludge for endpoint exposure. Data on organic contaminant concentrations in Norwegian agricultural soils are limited. Therefore, existing soil concentrations from remote (preferred) and urban areas could be used as an indicator of background concentrations in agricultural soil and in some cases, its importance relative to sewage sludge. Organic contaminants in urban soils. Of the 922 organic compounds detected in sewage sludge (Tier 2, **Chapter 5.1.1**), 166 compounds have been determined in soil samples in the MILBY-project (NILU,2026).

In the MILBY monitoring program, surface soil has been collected (0 to 5cm) from several localities around the city of Oslo as part of an investigation of bioaccumulation and biomagnification of organic contaminants in the urban ecosystem. Organic contaminants in urban soils. In the present risk assessment, soil concentrations have been calculated (PEC_{soil}) for 151 of the 166 organic contaminants, which had been quantified in soils in the MILBY-project. 94 contaminants have higher measured soil concentrations (MILBY-data) than the predicted initial soil concentrations after sludge mixing with 0 to 5 cm of soil ($PEC_{soil,peak}$). 43 contaminants had measured soil concentrations in the MILJY-project that were ten times or more higher than the calculated for the soil-sewage sludge mix (0 to 5 cm), and for 12 organic contaminants in MILBY-soils, the concentrations were more than 100 times higher than the predicted ones in the soil-sewage sludge mix (0 to 5 cm) (**Figure 4.2.1-1**). Among the compounds that were determined with much higher concentrations in urban soils as predicted for the soil-sewage sludge mix were various bisphenols, PCBs, Phthalic esters, PFOS and HCB (as examples). Compounds like UV-329, PBDEs and several PFASs (other than PFOS) appear potentially more in sewage sludge than in soils.

More than 50 % of the 166 organic contaminants that had been analysed in soils in the MILBY-project have a DT50 of 1000 days (used in this risk assessment) with high K_{oc}-values, showing a high potential for accumulation in soils. Data from the MILBY-project show that there is an ongoing dispersion of organic contaminants to soils in densely populated areas like Oslo, most probably both by air and water (surface runoff). To what extent agricultural areas in the

regions are influenced by this dispersion can only be estimated by complex modelling including source emission, atmospheric dispersion and degradation data.

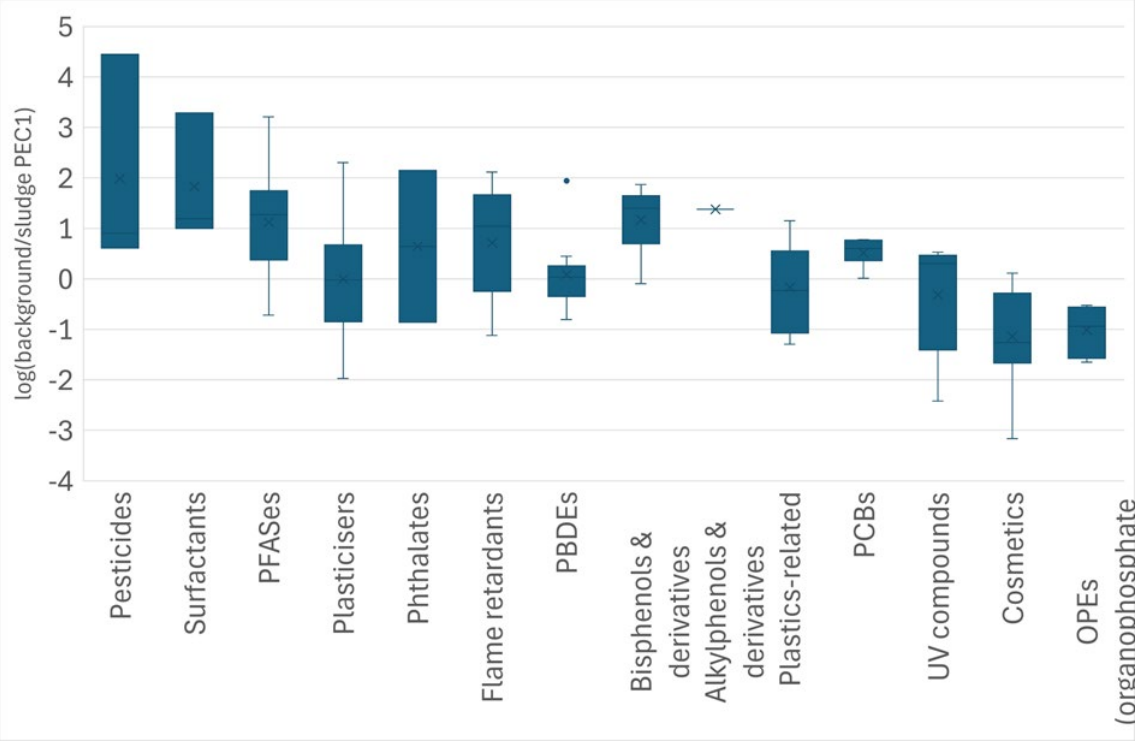


Figure **4.2.1-1**. Ratio between soil contaminants concentrations in urban soil (0 to 5 cm) from the MILBY-project and predicted soil concentrations after sludge application (11.2 tonnes/ha/10 yrs). The organic contaminants have been grouped according to industrial use and chemistry.

Persistent organic contaminants in Norwegian soils

Hoel (2019) sampled surface soil (0 to 5 cm) from urban (Oslo, n=10) and remote areas (n=45) in Norway, and the concentrations of various persistent organic contaminants were determined (**Table 4.2.2-1**). The results show that concentrations in urban areas for most compound groups are higher than in remote areas except for Σ3HCH and Σsyn+antiDP, which were found to be higher in remote areas of Norway. Using the data from (**Table 4.2.2-1**), it seems that sewage sludge may contribute by 30 % or more compared to the background level in remote soils for the chemical groups PCBs, PBDE and chlorinated paraffins. For the groups HCB, DDT, HCH and syn/ant DP the contribution from sewage sludge is much less.

Table 4.2.2-1. Concentrations (mean and std, µg/kg dm) of persistent organic contaminants in surface soil (0 to 5 cm) from urban (Oslo, n=10) and remote areas (n=45) in Norway (from Hoel 2019). PECsoil,peak: initial soil concentration (application year 1) after mixing 11.2 tonnes of dewatered sewage sludge/ha in 5 cm of soil. PEC50: soil concentration (application year 50 i.e. fifth dose of sewage sludge) after mixing 11.2 tonnes of dewatered sewage sludge/ha in 5 cm of soil.

Contaminant	Area	Mean	Std dev	PEC 1	PEC50
Σ32PCB	Remote area	2.8	4	1.2	5.4
	Oslo	6.7	4.7		
Σ7PCB	Remote area	1.5	2.3	0.66	3.6
	Oslo	3.8	2.5		
PeCB	Remote area	0.2	0.1	0.03	0.15

	Oslo	0.4	0.4		
HCB	Remote area	1.3	2	0.03	0.06
	Oslo	2.8	5.5		
Σ6DDx	Remote area	3.6	7.5	0.21	0.63
	Oslo	4.4	7		
Σ3HCH	Remote area	1.5	2.5	0.03	0.09
	Oslo	0.05	0.03		
Σ25PBDE	Remote area	1.2	2.6	25	72
	Oslo	150	460		
Σ5PBDE	Remote area	0.4	0.7	0.69	3.9
	Oslo	0.5	0.4		
Σ15NBFRs	Remote area	0.9	1.5		
	Oslo	0.8	0.6		
Σsyn+antiDP	Remote area	2.4	6	0.30	0.84
	Oslo	1.1	1.2		
Σ10,5-13,9SCCP	Remote area	15	16	57*	
	Oslo	510	1500		
Σ14,5-17,7MCCP	Remote area	67	47	260*	
	Oslo	87	95		
PFAS4				0**.72**	1**.2**
PFAS24				2**.4**	5**.4**

4.2.1 Organic contaminants in air from urban and remote areas

Air monitoring data from Birkenes and Oslo city centre (Sofienbergparken) for in total 324 different organic contaminants exist for the years 2022-24 (NILU,2026). For contaminants that have been determined at both places (SCCP, TFA, volatile PFAS, sum C4-C14 PFCAs, sum 26 BDEs, sum Siloxanes), the air concentrations in Oslo city centre are on average 7 times higher than at Birkenes. The highest "ratio" between Oslo and Birkenes are found for Siloxanes, Trifluoroacetic acid (TFA) and volatile PFAS (**Table 4.2.3-1**). Rather low differences (ratio < 3) between Oslo and Birkenes were observed for SCCP, Tribromoanisol (TBA), PBD-183 and Sum PFCAs. SCCP/MCCPs, volatile PFAS and Siloxanes were found with the highest concentrations in air samples at both sites (**Table 4.2.3-1**).

At Birkenes, compounds such as PAHs, PCBs, HCB, sum DDT/D/Es, α,ɣ-HCH were also determined in the air filters, indicating the potential for deposition of these contaminant groups at this background station" (**Table 4.2.3-1**).

Table 4.2.3-1**. Average of median (pg/m3) of organic contaminant concentrations in air filters in Birkenes, Agder, and Sofienberg park, Oslo**

Group	Compound	CAS	Birkenes	Sofienberg park (Oslo)	Ratio
Chlorinated paraffins	SCCP	85535-84-8	171	284	1.7
	MCCP	85535-85-9	*<113*	281	*2.4*
PFAS	TFA	76-05-1	2.24	24.3	11
	6:2 FTOH	647-42-7	12.7	65.2	5.1
	8:2 FTOH	678-39-7	4.81	35.9	7.5
	10:2 FTOH	865-86-1	1.8	8.2	4.6
	12:2 FTOH	39239-77-5	0.91	1.6	1.8

	PFHpA	375-85-9	0.097	0.66	6.7
	PFOA	335-67-1	0.096	0.25	2.6
	PFNA	375-95-1	0.046	0.09	1.9
	Sum PFCAs		0.396	1.06	2.7
	Sum Vol PFAS		14.8	144.53	9.8
POPs	BDE-17	147217-75-2	0.004	0.03	6.9
	BDE-28	41318-75-6	0.006	0.03	5.6
	BDE-47	5436-43-1	0.044	0.707	16
	BDE-49	60348-55-0	0.008	0.03	3.8
	BDE-66	189084-61-5	0.005	0.021	4.2
	BDE-99	60348-60-9	0.019	0.167	8.8
	BDE-100	189084-64-8	0.004	0.056	14
	BDE-154	207122-15-4	0.005	0.012	2.4
	BDE-183	207122-16-5	0.015	0.011	0.73
	BDE-209	1163-19-5	0.277	1.32	4.8
	sum 26 BDE		0.47	2.58	5.4
	sum HBCD		0.02	0.09	4.0
	TBA	607-99-8	4.54	7.14	1.6
Siloxanes	D4	556-67-2	2.14	13.2	6.2
	D5	541-02-6	4.88	118	24
	D6	540-97-6	0.38	8.80	23
	sum Siloxanes		6.88	141	21
POPs	PAH16		1.6	n.a.	
POPs	PCB7		1.6	n.a.	
POPs	PCB32		4.3	n.a.	
POPs	HCB		37	n.a.	
POPs	SUM DDT/DDD/DDE		0.8	n.a.	
POPs	α/ɣ-HCH		4.6	n.a.	
POPs	OPFR (27 compounds)			120	

Note: The screening was performed in 2022-24. Birkenes is located in Agder County in Southern Norway. The ratio of Oslo and Birkenes concentrations is given, when there are data from both locations. The unit of measurement in columns 4 and 5 is pg/m3.

Significance of soil background concentrations for the present risk assessment

Contaminant contents in agricultural soils in southern Norway are not only determined by sewage sludge applications but also by other sources. For persistent and semi-volatile organic contaminants, atmospheric transport is likely to be an important, and in some cases dominant, dispersal route (e.g. DDT, HCH, syn+anti DP). In contrast, for less volatile, current-use substances with strong sorption to solids (e.g. some plastic additives), application of sewage sludge may represent the more important source (PCBs, PBDEs and chlorinated paraffins). As Hoel (2019) has shown by using fugacity calculations, Norwegian soils are far from equilibrium with the atmosphere, i.e. Norwegian soils will be a future sink for POPs given the emissions (primary, secondary) and atmospheric transport of today. The relative importance of atmospheric transport versus sludge application depends not only on physicochemical properties of the chemicals, but also on emission patterns, including whether emissions are primary or secondary and whether they are predominantly linked to air or wastewater pathways.

For most persistent organic pollutants (POPs), the contribution from sewage sludge is probably of minor importance (<10%) for the contamination of the food and feed production system. Compounds like UV-329, PBDEs and several PFASs (other than PFOS) occur in higher levels in sewage sludge than in agricultural soils so that the application of sewage sludge will have a significant impact on soil levels and subsequently on the contaminant levels in food and feed.

The Norwegian Environment Agency (NEA) has prepared norm-values and a quality classification system for contaminated soils in 2009 (Norwegian Pollution Control Authority, SFT, 2009, TA 2553/2009). Revised values were suggested in 2022 (NGI-report M-2169, 2021). However, the revised norm-values and quality-classes for 59 contaminants (mostly organic), which are intended to protect the terrestrial and aquatic environment as well as human health, have still not been adopted.

For 28 out of 50 organic contaminants on the new (2021) norm-value list, the norm-values are determined based on toxic effects in soil and water (lowest soil value), while effect on human health decide the norm-value for 11 contaminants. The chemical and physical data used in the calculations of norm-values for the various contaminants, BCF-data for plants (stem and leaves) and fish, as well as PNEC-data for terrestrial and aquatic organisms, can be compared to the respective data in this risk assessment.

The norm-value for a contaminant in soil is considered as a safe level of contamination, also in case when 30% of the vegetables for human consumption are grown in the soil. The comparison of norm-values with predicted soil concentration in present risk assessment $PEC_{soil,peak}$ with soil background levels presented in this chapter may therefore be of some interest.

4.3 Background concentration of priority contaminants in surface water

There are some Norwegian projects that are measuring metals and organic contaminants in water, e.g. the River Monitoring Programme (Elveovervåkingsprogrammet) (Allan et al., 2021 and 2022). In River Monitoring, environmental pollutants have been measured in river water, but many samples have results below LOQ, with a few exceptions. River Monitoring focuses on the large rivers that are believed to contribute to environmental pollutants along the coast. There are quite a lot of data for metals, but also some for environmental pollutants. However, the concentrations in these rivers do probably not reflect background concentrations. One example is the Alna River in Oslo, which was among the investigated rivers. Some of the contaminant levels in the Alna are substantial and exceed EQS (Ruus et al. 2025).

In contrast, Norwegian Reference Rivers, which are small-to-medium-sized watercourses with watersheds under 10 km^2, considered as representing mostly pristine conditions, have been measured for many environmental pollutants in biota (salmon and trout) in all parts of the country. The Reference Rivers assumed to be largely unaffected by pollution and therefore to contain only low concentrations of environmental pollutants.

The monitoring of Reference Rivers is part of the Norwegian authorities' applicability testing of the classification system for watercourses in accordance with the Water Regulations (**Table 4.3-1)**. The project is carried out as basic monitoring and started in 2017. Contaminants have been analysed in biota until 2025. After 2025, analyses of contaminants in biota are only optional, and future data will therefore not necessarily be available.

For the monitoring programme, samples were collected at one station in the lower part of each water body. Water chemistry was measured monthly, and biology and environmental pollutants in biota were studied once a year. The water chemistry studies include nutrients, acidification parameters, metals and several supporting parameters, while the biological studies include algae, benthic fauna and fish (fish were sampled at up to 3 stations in each water body). The fish were analysed for 223 analytes. Some of these analytes represented summary concentrations of contaminant groups (e.g. sumBDE6, sum NonaBDEs, sumOctaBDEs etc). Excluding the groups, at the maximum 166 individual contaminants were analysed. Not all samples were being analysed for the full repertoire due to incidentally small sample sizes. A total of 183 fish samples were analysed between 2017 and 2023.

Table 4.3-1**. Reference rivers and ecoregions with fish contaminant screening.**

Ecoregion	River	First year	Last year	# Samples	Number of analyses
F	Komagelva (F)	2018	2022	9	1460
	Láhpojohka (F)	2018	2018	1	137
	Sametielva (F)	2018	2022	9	1501
	Stabburselva (F)	2018	2022	7	1099
N	Flakstadvåg (N)	2017	2023	13	2153
	Gjeddåga (N)	2021	2023	6	1159
	Kobbvåg (N)	2017	2019	6	718
	Kongsvikosen	2021	2023	5	947
	Mammakjosen	2019	2019	3	408
	Rotsund (N)	2017	2017	2	285
M	Eiteråga (M)	2017	2023	12	1999
	Sandøla (M)	2017	2023	8	1256
	Simskardelva	2019	2019	2	249
	Størdalselva (M)	2017	2023	12	1876
Ø	Døråe (Ø)	2017	2017	1	86
	Kjaglielva (Ø)	2018	2022	9	1644
	Lomma (Ø)	2018	2022	8	1403
	Mistra (Ø)	2018	2022	8	1369
	Smådøla (Ø)	2018	2018	2	294
S	Aslestadåi (S)	2019	2023	3	1575
	Berdalsbekken	2019	2019	6	122
	Farsjø (S)	2017	2017	3	423
	Lislefjøddåi (S)	2017	2023	8	1781
	Rørholtfjorden	2017	2023	5	1712
V	Bjoreio (V)	2020	2022	9	590
	Femangerelva	2020	2022	1	1152
	Raundalselva (V)	2018	2018	3	306
	Smedalselvi (V)	2018	2022	11	1347
	Utla (V)	2018	2020	5	580

Note: The first and last year, for which analyses have been performed, are indicated in columns 3 and 4, and the numbers of samples for each river are in column 5. The numbers of "datapoints" performed during the years are in column 6. Datapoints express the number of analytes summed over all samples in the river (i.e. the number of stations). The maximum number of analytes per sample was 223.

During the years, small trout and salmons were analysed for a range of contaminants, mainly those, for which Environmental Quality Standards (EQS) are defined in the Water Framework directive (**Table 4.3-2)**. Data for the period 2017 to 2023 were summarised in the study report (Eriksen et al., 2024). A total of 29 rivers across Norwegian ecoregions (F (Finnmark/Troms), N

(Nordland), M (Midt-Norge), Ø (Østlandet), S (Sørnorge) and V (Vestlandet) were included in the data.

Table 4.3-2**. Compound groups analysed for in biota.**

Group of compounds	Number of analytes
Alkylphenols	5
Dicofol	1
Dioxins	20
Dioxin furans and planar PCBs	35
Fat content	1
Phosphoric flame retardants	11
Phthalate (DEHP)	1
HBCD (a, b, g, and sum)	4
Chlorinated pesticides	26
Mercury	1
PAH metabolites in fish bile	9
PAH	18
PBDE	40
PCBs	25
Pentachlorphenols	1
PFAS	36
Chlorinated paraffins (SCCP/MCCP)	2
Tinorganic compounds	17
Trichlorobenzenes	3

Note: For a full record of contaminants analysed, please refer to the database hosted by the Norwegian Ministry of Environment “Vannmiljø” (NEA, 2025).

As an example for the figures presented in the report (Eriksen et al., 2024), sumPCB7 is shown below. The data represent sumPCB7 concentrations in fish in the ecoregions and rivers, for which data are available (**Figure 4.3-1**).

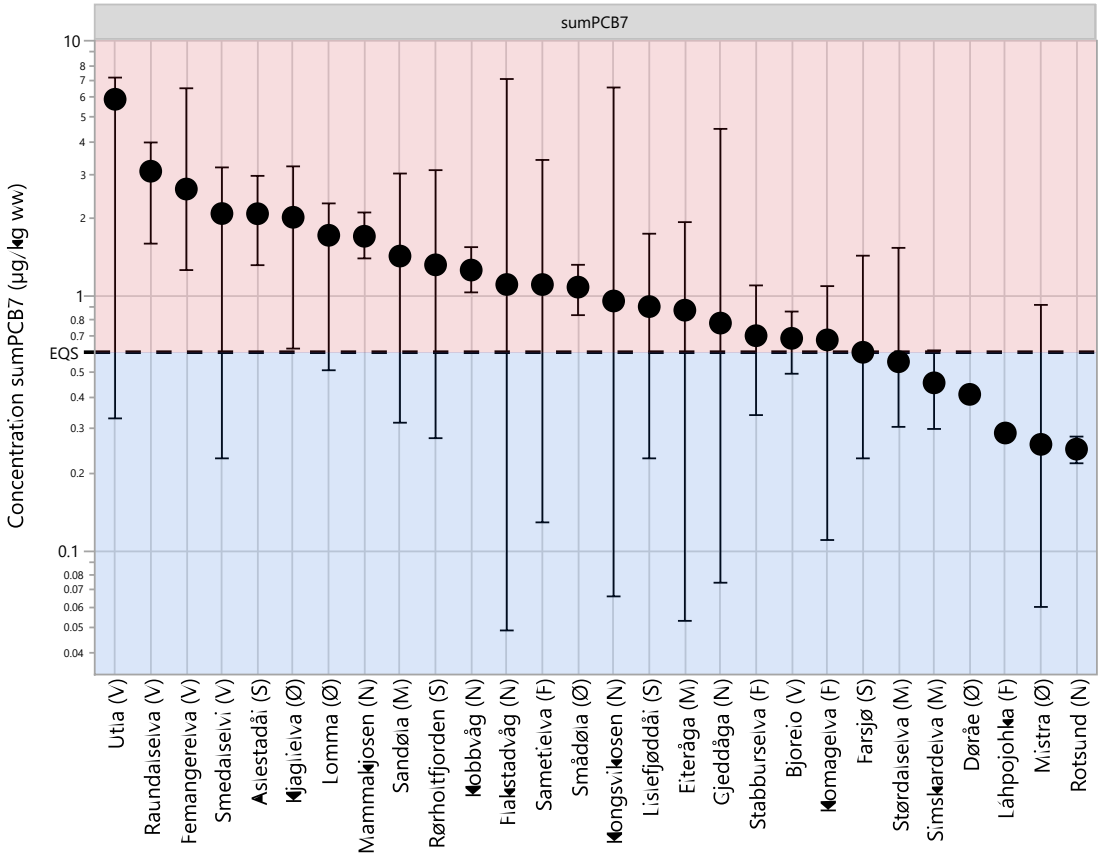


Figure 4.3-1**. Concentrations of PCB7 sums in fish.**
Note: **Each range corresponds to different rivers and ecoregions in Norway. Concentrations are reported in µg/kg ww. The vertical axis is in log_{10} units. The concentration ranges are taken across all considered scenarios, and their medians are indicated with a point. The environmental quality standard (EQS, Norwegian River Basin Specific Pollutant) for sumPCB7 (0.6 µg/kg ww) is indicated by a dashed black line, with values above EQS highlighted in pink and below—in blue. Source: Eriksen et al. (2024).**

Comparing the data from the rivers in the ecoregions revealed a pattern of statistical differences in the contaminant concentrations of some ecoregions. For statistical analysis with ANOVA and Tukey-Kramer post-hoc testing, the upper bound concentrations were first log10-transformed. In the data set, some compound sums are considered as representatives for the other contaminants in the group. For example, instead of running 7, or more, different statistical analyses, the sum of 7 PCBs (which have a designated EQS) was investigated. PCBs are thus represented by the sumPCB7.

An example of the statistic for sumPCB7 in biota in the ecoregions is shown in **Figure 4.3-2**. Ecoregion V had fish containing the highest concentrations of sumPCB7, but the concentrations were not significantly higher than in fish from S and Ø ecoregions. The concentrations of sumPCB7 in fish from ecoregion V were significantly higher than in fish from ecoregions F, N and M (see more details for the significant differences found in **Table 4.3-3**).

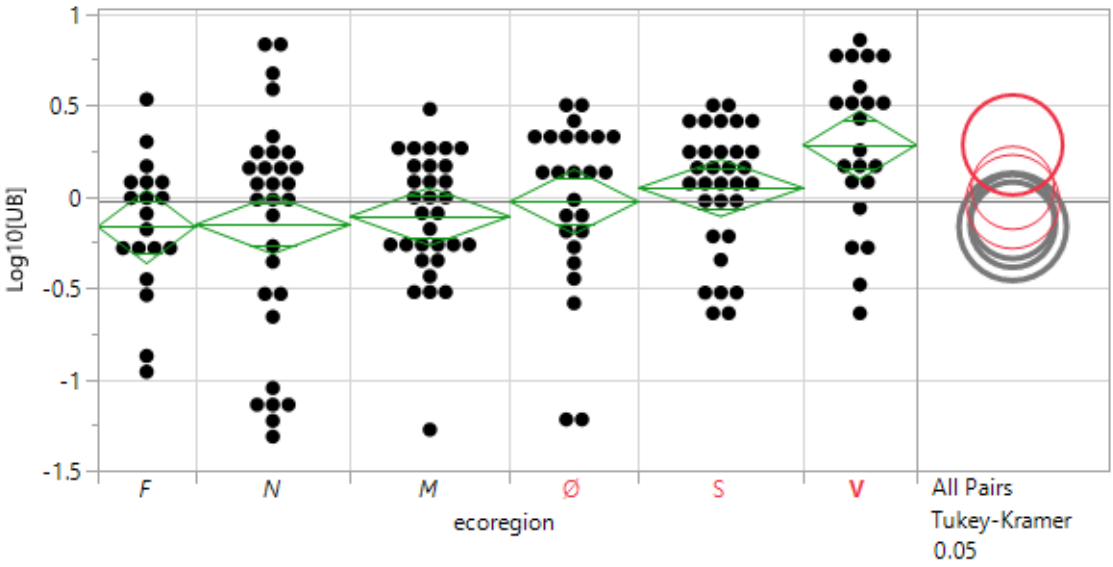


Figure 4.3-2. **PCB7 sum concentrations in biota in different ecoregions.**
Note: **Data for each fish (log10-transformed concentrations) are represented with a dot. The means for each ecoregion are represented by the green horizontal lines across the middle of the green diamonds. The top and bottom of the green diamond indicate the 95% confidence intervals for the mean of each ecoregion. The green horizonal lines near the top and bottom of the diamonds indicate overlap marks to other ecoregions. The widths of the horizontal axis for each ecoregion are proportional to the number of datapoints. In the right-most section of the figure, the circles provide a visual representation of the of the regional mean comparisons. Circles for means that are significantly different either do not intersect or intersect slightly, so that the outside angle of the intersection is less than 90 degrees. The circles that are grey are significantly different to the bold red circle (V).**

The statistical analysis was only performed for compound sums, if they were available, not for the individual components (e.g. sumPCB7 and not all individual PCBs). For some contaminants, the majority of data were below LOQ, making statistical analysis not feasible. These included pesticides (g-HBCD , dieldrin, heptachlor, heptachlor epoxide, pentachloro benzene, trans-heptachlor epoxide), organo-tins (dibutyltin, dioctyl tin, monobutyl tin, monooctyl tin, tetrabutyltin, tributyltin, triphenyl tin, tricyclohexyl tin), alkylphenols (4-n-nonylphenol, 4-tert-octylphenol, pentachlorophenol), organophosphates (2-etylhexyldiphenylphosphate (EHDPP), tri(1,3-dichloro-2-propyl)phosphate (TDCP),tri(1-chloro-2-propyl)phosphate (TCPP), triphenyl phosphate (TPhP), tris(2-ethylhexyl) phosphate (TEHP)) and diethylhexyl phthalate (DEHP).

Table 4.3-3. **Contaminants with statistically significantly different mean concentrations in fish in the ecoregions, as defined by Tukey connecting letters.**

Contaminant	F	N	M	Ø	S	V
1-OH-pyrene	B	B	AB	AB	A	B
a-HBCDD	C	C	BC	BC	AB	AB
Hg	B	B	A	B	A	B
Lipid %	AB	A	AB	B	A	AB

Contaminant	F	N	M	Ø	S	V
MCCP	C	BC	A	C	B	C
SCCP	AB	AB	A	AB	AB	B
sumBDE6	C	BC	B	BC	A	A
sumDDTs	C	C	C	AB	BC	A
sumPCB7	B	B	B	AB	AB	A
sumPFOS	B	B	B	A	B	B
Dioxins	BC	A	A	C	A	AB

Note: The highest concentrations are assigned the letter A. Ecoregions that do not share a common letter are statistically significantly different. For example, for 1-OH-pyrene, ecoregion S has the highest concentration (A), which is different from ecoregions F, N and V (B). Concentrations in ecoregions M and Ø (AB) share common letters with both S (A) and F, N, and V (B), and therefore not significantly different. sumPFOS is the sum of linear and branched PFOS (PFOS + brPFOS). Significant differences were also observed for other PFAS.

Statistical differences in regional contaminant concentrations were found for 10 contaminants/contaminant groups (**Table 4.3-4)**. In addition, statistical differences were also found for % lipid content in the analysed fish. In most samples, the contaminants were determined in whole fish after removal of the liver. PFAS was always analysed in liver, while the other contaminants were analysed in muscle in 2017 and 2018. In 2019, both muscle and whole fish were analysed. Analyses of whole fish were performed according to the Guidance document 32 on biota monitoring according to the Water Framework Directive (European Commission 2014).

Table 4.3-4. Concentrations (µg/kg ww) for the contaminants with significant differences between regional means.

Contaminant	Statistics	F	N	M	Ø	S	V
1-OH-pyren	Mean	0.39	0.69	0.85	0.86	1.7	0.66
	Q.025	0.24	0.48	0.61	0.55	1.2	0.4
	Q.975	0.64	0.99	1.2	1.3	2.4	1.1
a-HBCDD	Mean	0.0097	0.011	0.015	0.014	0.022	0.028
	Q.025	0.0073	0.0084	0.012	0.011	0.017	0.021
	Q.975	0.013	0.013	0.019	0.018	0.027	0.038
Hg	Mean	31	33	52	35	72	35
	Q.025	26	28	44	29	61	29
	Q.975	37	39	61	42	84	42
Lipid%	Mean	3.3	3.6	3.3	2.3	3.6	3.2
	Q.025	2.6	2.9	2.7	1.9	3	2.5
	Q.975	4.2	4.4	4	2.9	4.4	4.1
MCCP	Mean	3.5	11	140	4	15	3.5
	Q.025	1.7	6.5	66	2.3	9.2	1.9
	Q.975	7.3	19	280	7.1	26	6.4
SCCP	Mean	4.6	3.4	10	3.8	3.7	2
	Q.025	2.1	2	5.5	2.2	2.2	1.1
	Q.975	10	5.7	18	6.7	6.1	3.8
sumBDE6	Mean	0.052	0.057	0.087	0.086	0.15	0.17
	Q.025	0.039	0.045	0.07	0.067	0.12	0.13
	Q.975	0.068	0.071	0.11	0.11	0.18	0.22
sumDDTs	Mean	0.34	0.35	0.41	0.84	0.57	1.4

Contaminant	Statistics	F	N	M	Ø	S	V
	Q.025	0.24	0.21	0.3	0.62	0.43	1.1
	Q.975	0.48	0.56	0.57	1.1	0.77	1.9
sumPCB7	Mean	0.68	0.7	0.78	0.94	1.1	1.9
	Q.025	0.43	0.49	0.54	0.63	0.78	1.2
	Q.975	1.1	1	1.1	1.4	1.6	3
sumPFOS	Mean	1.2	2.1	2.1	7.7	1.4	1.2
	Q.025	0.85	1.6	1.6	5.7	1.1	0.84
	Q.975	1.6	2.7	2.7	10	1.8	1.6
Dioxins	Mean	0.00002	0.0000057	0.000023	0.000059	0.0000041	0.00018
	Q.025	0.0000021	0.00000072	0.0000029	0.0000087	0.00000076	0.000019
	Q.975	0.00019	0.000045	0.00018	0.0004	0.000022	0.0017

Note: All means and 95% confidence intervals are reported in µg/kg ww. 'Dioxins' is the sum of lower bounds (LB), in terms of WHO2005 TEQ. For sum compounds (including SCCP and MCCP), LB data were used, otherwise, UB data were used. sumPFOS is the sum of linear and branched PFOS (PFOS + brPFOS).

Conversion of fish concentrations into water concentrations

$C_{water} = C_{biota}/BCF_{fish}$,

where C_{water} is water concentration (µg/L), C_{biota} is concentration in fish (µg/kg ww), and BCF_{fish} is bioconcentration factor (for whole fish, measured in L/kg ww).

However, the calculated concentrations have to be considered with caution, especially with regard to the following points:

PFAS were analysed in liver samples (with a high fat/protein content, which was not determined), so that the results represent higher concentrations as compared to many of the other contaminants, which were measured in whole fish or muscle tissues.

Since fish can metabolise PAHs, PAH-metabolites were included in the analyses. PAH metabolites were measured in fish bile and thus are considered to represent the exposure to PAHs only during the last week before the fish was caught. The metabolite concentrations in bile can probably not be used for the calculation of PAHs in water.

Significant differences in calculated water concentrations were found for some or all contaminants that are included in congener sums– e.g. sumBDE6, sum PCB7, sum PFOS and sum DDTs. It is therefore suggested that back calculations from biota to water concentrations are only done on a group basis using validated BCF data of a typical congener within each group.

Conversion of water concentrations to sediment concentrations

$K_d = K_{oc} \times f_{oc}$

$C_{sediment} = C_{water} \times K_d$,

where K_{oc} is L/kg OC, f_{oc} is the fraction of organic content.

The fraction of organic carbon (f_{oc}) in these calculations must be obtained from the monthly analysis of water chemistry at the individual sampling stations.

This method of predicting concentrations in sediments from water concentrations has a high uncertainty. Comparison with modelled sediment quality as result of leaching from sewage sludge amended soils should therefore be used with care and considered only as indicative.

Water catchment areas can have very different characteristics (forest, peat, agriculture, bedrock etc), and soil erosion from the different areas influences the sediment composition. The K_{oc} model for sediment concentration works good for hydrophobic organic contaminants, for which sorption occurs mainly by adhesion to organic carbon. However, the model works not as good for polar compounds or compounds with specific binding mechanisms.

5 Scenarios for the application of sewage sludge and derived products used in this risk assessment

5.1 Application scenarios

An overview of scenarios, with focus on agronomic aspects, is presented and explained in **Chapter 2**, and their relation to fertilisation regulation is described in **Chapter 1.3.2** and in **Table 1.2.5-1**. In short, application rates for the different crops and regions were based on fertiliser recommendations provided by NIBIO (https://www.nibio.no/tema/jord/gjodslingshandbok/gjodslingsnormer?locationfilter=true).

Under current regulations, phosphorus application is limited to 25 kg P/ha/yr, while nitrogen application from animal manure is restricted to 170 kg N/ha/yr in the Oslofjord watershed. The limitation of the N fertilisation rate is only relevant for grasslands and the use of liquid fraction of digested sewage sludge. In addition to compliance with fertilising regulations, the application rate of liquid digestate was determined here based on the N recommendation of the crops. It was assumed that the liquid digestates had a dry matter content of 1.1 % and a total nitrogen concentration of 2.55 kg N/tonne (wet weight). For grassland in Central Norway cut three times annually and yielding 8,250 kg dry matter/ha/yr, the fertiliser recommendation is 240 kg N/ha. Based on this, the annual application rate of liquid digestate was set to 1300 kg (430 dw applied 3 times), assuming a nitrogen replacement value of 70-80 % for the sludge. For a similar grassland in Eastern Norway within the Oslofjord watershed, the annual application rate of liquid digestate was set to 700 kg DW/ha/yr.

An overview of all scenarios is provided in **Table 5.1-1**. This table includes information on practical application methods, application rates, application time, sawing time (where relevant), harvest time, applied limitations, soil depths, sources of contaminant concentration data, and whether sewage sludge or sewage-sludge-based products were mixed in or injected into the soil. In total 104 different scenarios were defined although not all were modelled. An overview of the phosphorous (P) content and corresponding application amounts (tonnes DW/ha/yr or per 10 yr period) is also included. The most relevant information for the modelled scenarios is presented in **Table 5.1-1** for ToR2 and **in Supplementary materials 2** for ToR3. Details on the input parameters used for calculating the fate of contaminants and the predicted exposure concentrations in soil, surface water and plants are given in **Supplementary materials 2.**

Table 5.1-1. Overview of scenarios included in ToR2 regarding applications of dewatered sewage sludge (SS) based on today's practices, the current Norwegian fertiliser use regulations and given P-limitations (calculated into tonnes dm). The application method in all scenarios in ToR2 is by solid manure spreader, and the sludge is incorporated by harrowing after ploughing. *Column appl-harvest displays the number of months between application and first harvest of the main crop.

Munici.	Scen.	Sludge type	Regulated by	Main crop	Soil depth	Appl-harvest*	Applicat. rate		Source of concentration
					m	months	tonne dm / ha / 1y	tonne dm / ha / 10y	
Based on P-limitation (Norwegian Regulation), 250 kg P/ha/10 yr, 11.2 tonnes dw/ha/10 yr (ToR2a)									
Ås	**1**	**Dewatered**	**P-limited**	**Cereals**	**0.15**	**4**		**11.2**	**MEDIAN 90Q**
Ås	2	Dewatered	P-limited	Grassland	0.15	10		11.2	MEDIAN 90Q
Stange	3	Dewatered	P-limited	Cereals	0.15	4		11.2	MEDIAN 90Q
Stange	4	Dewatered	P-limited	Potato	0.15	41		11.2	MEDIAN 90Q
Stange	5	Dewatered	P-limited	Vegetable	0.15	40		11.2	MEDIAN 90Q
Stange	6	Dewatered	P-limited	Grassland	0.15	10		11.2	MEDIAN 90Q
Melhus	7	Dewatered	P-limited	Cereals	0.15	4		11.2	MEDIAN 90Q
Melhus	8	Dewatered	P-limited	Grassland	0.15	10		11.2	MEDIAN 90Q
Reduced application 8 tonnes dw/ha/10 yr (ToR2d1)									
Ås	201	Dewatered	P-limited	Cereals	0.15	4		8	MEDIAN 90Q
Ås	202	Dewatered	P-limited	Grassland	0.15	10		8	MEDIAN 90Q
Stange	203	Dewatered	P-limited	Cereals	0.15	4		8	MEDIAN 90Q
Stange	204	Dewatered	P-limited	Potato	0.15	41		8	MEDIAN 90Q
Stange	205	Dewatered	P-limited	Vegetable	0.15	40		8	MEDIAN 90Q
Stange	206	Dewatered	P-limited	Grassland	0.15	10		8	MEDIAN 90Q
Melhus	207	Dewatered	P-limited	Cereals	0.15	4		8	MEDIAN 90Q
Melhus	208	Dewatered	P-limited	Grassland	0.15	10		8	MEDIAN 90Q
Reduced application 1 tonnen dw/ha/ yr (ToR2d2)									
Ås	301	Dewatered	P-limited	Cereals	0.15	4	1		MEDIAN 90Q
Ås	302	Dewatered	P-limited	Grassland	0.15	10	1		MEDIAN 90Q
Stange	303	Dewatered	P-limited	Cereals	0.15	4	1		MEDIAN 90Q
Stange	304	Dewatered	P-limited	Potato	0.15	41	1		MEDIAN 90Q
Stange	305	Dewatered	P-limited	Vegetable	0.15	40	1		MEDIAN 90Q
Stange	306	Dewatered	P-limited	Grassland	0.15	10	1		MEDIAN 90Q
Melhus	307	Dewatered	P-limited	Cereals	0.15	4	1		MEDIAN 90Q
Melhus	308	Dewatered	P-limited	Grassland	0.15	10	1		MEDIAN 90Q

6 Prioritisation of organic contaminants for risk assessment (Hazard identification)

6.1 Organic contaminants occurring in treated sewage sludge

6.1.1 Criteria for the selection of organic contaminants (in treated sewage sludge)

The range of organic contaminants found in sewage sludge from domestic WWTPs reflects their use and presence in society, the treatment processes applied at the local WWTPs, and the chemical and biological stability and physical-chemical properties of each contaminant. Current estimates of the global inventory of commercially produced and used chemicals and mixture of chemicals amount to more than 350 000, of which 157 000 are individually listed chemicals identified with CAS numbers (Wang et al. 2020). However, the CAS REGISTRY includes in total more than 290 million chemical substances. The majority of these have not been analysed in treated sewage sludge, both in Norway and internationally, so that possible hazards from their potential presence have to be estimated based on *in silico* data.

In contrast to the risk assessment conducted by VKM in 2009, there is now a considerable database available summarising analytical results from multiple sampling campaigns of both treated and untreated sewage sludge from 19 different Norwegian sludge treatment facilities during the 28-year period from 1996 to 2023. In total, 947 individual organic contaminants have been analysed, of which the majority were selected based on a perceived potential risk to the environment. About 500 of these organic contaminants were detected in at least one or more samples. For the present risk assessment, most data were extracted from the national "Vannmiljø" database(https://vannmiljo.miljodirektoratet.no/) on January 12th, 2024, containing primarily data from the screening programmes summarised in **Table 6.1.1-1**. Furthermore, the list of drugs was supplemented with 83 often prescribed drugs (>25 000 prescriptions in Norway in 2021), for which we had only drug consumption data. However, this is still just a minor fraction of the organic compounds potentially present in treated sewage sludge. For practical reasons, it was decided to limit the risk assessment to this list of 1030 important compounds.

Table 6.1.1-1. Data sources for measured concentrations in treated sewage sludge.

Screening program	Reference
Data extracted from the Vannmiljø database* on January 12 2024	
Screening programmes 2004, 2007, 2008	SFT (2005; 2008; 2009)
Screening programmes 2009, 2010	KLIF (2010; 2011)
Screening programmes 2013, 2014, 2015, 2016, 2017, 2019, 2021, 2022	NEA (2014; 2015; 2016; 2017; 2018, 2020; 2022; 2023)
Environmental contaminants in an Urban Fjord 2018, 2019, 2020	NEA (2019; 2020; 2021)
MILFERSK 2021	NEA (2022)
Organic pollutants in Norwegian wastewater sludge 1996/97, 2005/06, 2012/13, 2017/18	Norsk Vann (1998; 2007; 2014; 2019;
Data collected manually from the individual reports	

Screening program	Reference
Organic pollutants in Norwegian wastewater sludge 2022/23	Henninge and Blytt (2023)
Data for treated sewage sludge from Nedre Romerike avløpsanlegg (NRA) from 2019-2023	NRVA (2024)

* https://vannmiljo.miljodirektoratet.no/

In addition, group sums of known hazardous chemicals were included in the assessment. These are listed in **Table 6.1.1-2**. As a quality check that we had covered relevant organic contaminants of main environmental concern, the list of 1029 individual compounds and group sums (**Table 6.1.1-2**) were compared with the compounds on the Norwegian priority list, the EU priority substances in the field of water policy (i.e. associated with the EU Water Framework Directive; 2000/60/EC) and the associated EU Watch list, as well as with the Norwegian Water Region-specific list. The results of the comparison are summarised in **Table 6.1.1-3**.

The comparison showed that a relatively large number of compounds described in the mentioned priority lists was not included in the present risk assessment. Among others, these were heavy metals, which were intentionally omitted. Itraconazole (CAS 84625-61-6), the only pharmaceutical not included, is seldom prescribed in Norway (< 550 prescriptions in 2021), and data from sewage sludge analysis were not available. Some veterinary medicines, agricultural fungicides, herbicides and insecticides will likely not end up in sewage sludge at relevant levels.

Table 6.1.1-2. Individual compounds in the contaminant groups selected due to their acknowledged hazardous characteristics.

Contaminant group	Individual compounds
Sum PCB6	PCB28 (7012-37-5), PCB52 (35693-99-3), PCB101 (37680-73-2), PCB138 (35065-28-2), PCB153 (35065-27-1), PCB180 (35065-29-3)
Sum PCB7	PCB28 (7012-37-5), PCB52 (35693-99-3), PCB101 (37680-73-2), PCB118 (31508-00-6), PCB138 (35065-28-2), PCB153 (35065-27-1), PCB180 (35065-29-3)
Sum PAH4	Benz(a)anthracene (56-55-3), chrysene (218-01-9), benzo(b)fluoranthene (205-99-2), benzo(a)pyrene (50-32-8)
Sum PAH8	Benz(a)anthracene (56-55-3), chrysene (218-01-9), benzo(b)fluoranthene (205-99-2), benzo(k)fluoranthene (207-08-9), benzo(a)pyrene (50-32-8), dibenzo(a,h)anthracene (53-70-3), indeno(1,2,3,cd)pyrene (193-39-5), benzo(ghi)perylene (191-24-2)
Sum PAH16	Naphthalene (91-20-3), acenaphthylene (208-96-8), acenaphthene (83-32-9), fluorene (86-73-7), anthracene (120-12-7), phenanthrene (85-01-8), fluoranthene (206-44-0), pyrene (129-00-0), benz(a)anthracene (56-55-3), chrysene (218-01-9), benzo(b)fluoranthene (205-99-2), benzo(k)fluoranthene (207-08-9), benzo(a)pyrene (50-32-8), dibenzo(a,h)anthracene (53-70-3), indeno(1,2,3,cd)pyrene (193-39-5), benzo(ghi)perylene (191-24-2)
Sum BDE6	BDE28 (41318-75-6), BDE47 (5436-43-1), BDE99 (60348-60-9), BDE100 (189084-64-8), BDE153 (68631-49-2), BDE154 (207122-15-4)
Sum EFSA 4 PFAS	PFOA (335-67-1), PFNA (375-95-1), PFHxS (355-46-4), PFOS (1763-23-1), brPFOS (branched PFOS)
PFAS drinking water	PFBA (375-22-4), PFPeA (2706-90-3), PFHxA (307-24-4), PFHpA (375-85-9), PFOA (335-67-1), PFNA (375-95-1), PFDA (335-76-2), PFUnDA (2058-94-8), PFDoDA (307-55-1), PFTrDA (72629-94-8), PFBS (375-73-5), PFPeS (2706-91-4), PFHxS (355-46-4), PFHpS (375-92-8), PFOS (1763-

	23-1), brPFOS (branched PFOS), PFNS (68259-12-1), PFDS (335-77-3), PFUnDS (441296-91-9), PFDoDS (79780-39-5), PFTrDS (1260224-54-1)
PFOA equivalents EQS directive	TFA (76-05-1; 0.002), PFBA (375-22-4; 0.05), PFPeA (2706-90-3; 0.03), PFHxA (307-24-4; 0.01), PFHpA (375-85-9; 0.505), PFOA (335-67-1; 1), PFNA (375-95-1; 10), PFDA (335-76-2; 7), PFUnDA (2058-94-8; 4), PFDoDA (307-55-1; 3), PFTrDA (72629-94-8; 1.65), PFTeDA (376-06-7; 0.3), PFHxDA (67905-19-5; 0.02), PFODA (16517-11-6; 0.02), PFBS (375-73-5; 0.001), PFPeS (2706-91-4; 0.3005), PFHxS (355-46-4; 0.6), PFHpS (375-92-8; 1.3), PFOS (1763-23-1; 2), brPFOS (branched PFOS; 2), PFDS (335-77-3; 2), 6:2 FTOH (647-42-7; 0.02), 8:2 FTOH (678-39-7; 0.04), HFPO-DA (62037-80-3; 0.06), ADONA (958445-44-8; 0.03), C6O4 (1190931-41-9; 0.06)
Norwegian priority list PFAS	PFOS (1763-23-1), PFOA (335-67-1), PFHxA (307-24-4), PFHxS (355-46-4), PFBS (375-73-5), PFNA (C9 PFCA) (375-95-1), PFDA (C10 PFCA; 335-76-2), PFUnDA (C11 PFCA; 2058-94-8), PFDoDA (C12 PFCA; 307-55-1), PFTrDA (C13 PFCA; 72629-94-8), PFTeDA (C14 PFCA; 376-06-7), HFPO-DA (13252-13-6)
Sum dioxins and furans	Dioxin TCDD (1746-01-6 etc.), Furan TCDF (51207-31-9 etc.)

Table 6.1.1-3. Compounds in priority lists relevant for the environmental assessment of sewage sludge application on farmland excluded from the present risk assessment as they have not been included as single compounds in any of the screening studies, from which the data were derived.

Priority list*	Compounds not included in the current assessment
The Norwegian priority list (106+ compounds)	Methylstyrenated phenol (68512-30-1), dimethylmercury (593-74-8), phenylmercury compounds (62-38-4; 103-27-5; 13302-00-6), UV-326 (3896-11-5), UV-350 (36437-37-3), PCP (87-86-5), TCB (108-70-3; 87-61-6; 12002-48-1; 120-82-1; 79-01-6), DHTDMAC (61789-80-8), DTDMAC (68783-78-8), DSDMAC/DODMAC (107-64-2), DBTC (683-18-1), DBTDL (77-58-7), DOTC (3542-36-7), DOTE (15571-58-1)
The EU priority substances in the field of water policy (WFD list, 92+ compounds)	Alachlor (15972-60-8), Atrazine (1912-24-9), Cadmium og cadmium compounds (7440-43-9), Clofenvinfos (470-90-6), Dichloromethane (75-09-2), Endosulfan (115-29-7), Hexachlorocyclohexane (608-73-1), Isoproturon (34123-59-6), lead and lead compounds (7439-92-1), mercury and mercury compounds (7439-97-6), nickel and nickel compounds (7440-02-0), Pentachloro phenol (87-86-5), Simazine (122-34-9), Trichloro benzenes (12002-48-1), Trifluralin (1582-09-8), Dicofol (115-32-2), Quinoxyfen (124495-18-7), 3,3’,4,4’-T4CB/PCB 77 (32598-13-3), 3,3’,4’,5-T4CB/PCB 81 (70362-50-4), 3,3’,4,4’,5-P5CB/PCB 126 (57465-28-8), 3,3’,4,4’,5,5’-H6CB/PCB 169 (32774-16-6), Aclonifen (74070-46-5), Bifenox (42576-02-3), zeta-cypermethrin (52315-07-8), beta-cypermethrin (65731-84-2), theta-cypermethrin (71697-59-1), Dichlorvos (62-73-7), 1,3,5,7,9,11-Hexabromocyclododecane (25637-99-4), Heptachlor (76-44-8), heptachlor epoxide (1024-57-3), Terbutryn (886-50-0)
Hazardous compounds on the WFD list (58 compounds)	Cadmium and cadmium compounds (7440-43-9), Endosulfan (115-29-7), Hexachlorocyclohexane (608-73-1), mercury and mercury compounds (7439-97-6), Trifluralin (1582-09-8), Dicofol (115-32-2), Quinoxyfen (124495-18-7)), 3,3’,4,4’-T4CB/PCB 77 (32598-13-3), 3,3’,4’,5-T4CB/PCB 81 (70362-50-4), 3,3’,4,4’,5-P5CB/PCB 126 (57465-28-8), 3,3’,4,4’,5,5’-H6CB/PCB 169 (32774-16-6), Hexabromocyclododecane (25637-99-4), 1,2,5,6,9,10-Hexabromocyclododecane (3194-55-6), heptachlor epoxide (1024-57-3)
The EU Watch list of substances in the field of water policy (29 compounds)	Octisalate (2-ethylhexyl salicylate) (118-60-5), Abamectin (71751-41-2), Avermectin B1a (65195-55-3), Avermectin B1b (65195-56-4), Bromuconazole (116255-48-2), Climbazole (38083-17-9), Cyazofamid (120116-88-3), Difenoconazole (119446-68-3), Epoxiconazole (133855-98-8), Itraconazole (84625-61-6), Mefentrifluconazole (1417782-03-6), Triticonazole (131983-72-7), Etoxazole (153233-91-1)

The Norwegian Water Region-specific list (25 organic compounds)	Dodecyl phenol with isomers (121158-58-5), Diflubenzuron (35367-38-5), Teflubenzuron (83121-18-0)

* The numbers in parentheses are the numbers of individual compounds identified by CAS for each list. The "+" sign indicates that the respective list includes additional compounds, not identified by CAS.

6.1.2 Concentrations of organic contaminants in treated sewage sludge used in the risk assessment

6.1.2.1 Observed frequencies of organic contaminants in Norwegian treated sewage sludge

Data were available from 19 facilities for treating household sewage sludge in Norway from 1996 to 2024. A brief description of each of these facilities and the associated wastewater treatment, if applicable, is provided in **Appendix X**. The total number of samples and compounds that were analyzed at each facility varied a lot, though in general, the larger facilities have collected analytical data for a wider variety of compounds than the smaller facilities. An overview of the total number of compounds that were analysed at each facility and the frequency, with which they were found at concentrations exceeding the LOQ, is shown in **Table 6.1.2.1-1**.

Of the total of 947 organic contaminants that had been included in the analyses, 526 were reported to be above the limit of detection (LOD) or the limit of quantification (LOQ). 152 compounds were found in all collected samples at all treatment facilities, while 421 compounds were not found in any sample.

In the risk assessment, the median value of the 90-percentile dry-weight-based concentrations measured at all treatment facilities with data for the respective organic contaminant was used as the initial concentration in treated sewage sludge. The detected value, LOD[2] or LOQ, were used in the determination of the 90th percentiles and of the median value. If all measurements were below LOD or LOQ, the lowest LOD or LOQ after 2010 was used in the risk assessment.

Some of the data available from screening campaigns dates as far back as the mid-1990ies. Due to changes in chemical use patterns, implemented regulations on harmful compounds as well as improvements of analytical methods, the validity and/or appropriateness of these old data could be questioned. Thus, a simple trend analysis[3] was conducted for all compounds that were determined at concentrations above LOQ in at least 50% of the samples at the minimum of four different treatment facilities with the aim of assessing whether any clear trend, either increasing or decreasing, could be identified within the period, for which data we had. This threshold was passed by 81 compounds in the trend analysis, and for 23 of these compounds, a clear trend was identified. Additional four compounds showed a potential trend. The results for these 27 compounds are summarised in **Table 6.1.2.1-2**, while more details of the trend analysis are provided in **Supplementary 1**

[2] The LOD value was not multiplied with a factor 3 to derive the expected LOQ, which is often done.

[3] A more sophisticated trend analysis was also conducted using and comparing linear, quadratic and power models but was found to be sensitive to threshold choices for which subjective assessments were needed.

Table 6.1.2.1-1. **The total number of compounds analysed at the different sewage sludge treatment facilities and respective detection frequencies.**

Treatment facility	Number of compounds per WWTP					
	N	>LOQ, LOD	Ratio >LOQ, LOD = 1.00	Ratio >LOQ, LOD = 0.50-0.99	Ratio >LOQ, LOD = 0.01-0.49	Ratio >LOQ, LOD =0.00
Bekkelaget WWTP	580	319	139	103	77	261
Bergen biogas facility	287	180	133	26	21	107
Frevar (ØRA)	339	220	109	61	50	119
Fuglevik WWTP	314	182	108	38	36	132
Gardermoen WWTP	283	184	119	37	28	99
HIAS	628	377	207	98	72	251
Lindum biogas facility	204	138	112	13	13	66
SNJ*	315	214	122	48	44	101
RA2 (NRA)	527	291	150	81	60	236
Tønsberg WWTP	334	203	112	56	35	131
Veas WWTP	699	345	203	71	71	354
Grødaland WWTP	191	85	69	11	5	106
Høvringen WWTP	280	190	104	47	39	90
Ladehammeren WWTP	236	144	84	29	31	92
Rambekk biogas facility	309	190	119	51	20	119
Sandefjord WWTP	292	195	117	47	31	97
Saulekilen WWTP	79	54	42	12	0	25
Lillehammer WWTP	64	64	47	13	4	0
Lillevik WWTP	44	22	11	8	3	22
ALL treatment plants	947	526	152	196	178	421

* Sentral-renseanlegget Nord-Jæren

Table 6.1.2.1-2. Compounds with a significant concentration trend over time.

Cas no	Compound name	Cutoff date	Number of samples		# plants	Trend
			Before	After		
117-81-7	Bis(2-ethylhexyl)phthalate	2011	259	223	17	Dec*
120-12-7	Anthracene	2016	300	161	16	Dec
1241-94-7	2-Ethylhexyldiphenylphosphate (EHDPP)	2016	124	91	13	Dec
129-00-0	Pyrene	2006	301	265	17	Dec
13674-87-8	Tris(1,3-dichloro-2-propyl)phosphate (TDCPP)	2016	133	100	13	Dec
140-66-9	4-tert-Octylphenol	2016	126	86	15	Dec
15307-86-5	Diclofenac	2022	141	52	15	Inc*
189084-64-8	PBDE100	2010	342	295	18	Dec
206-44-0	Fluorantene	2006	301	265	17	Dec
207-08-9	Benzo[k]fluoranthene	2011	256	221	17	Dec
207122-15-4	PBDE154	2010	277	230	17	Dec
33704-61-9	Cashmeran	2022	170	75	15	Inc
3380-34-5	Triclosan	2021	151	46	15	Dec
34598-33-9	2H,2H,3H,3H-Perfluoroundecan acid (H4PFUnA)	2022	110	45	15	Inc
35065-28-2	PCB138	2005	252	216	17	Dec
3930-20-9	Sotalol	2019	129	57	15	Dec

Cas no	Compound name	Cutoff date	Number of samples		# plants	Trend
			Before	After		
437701-79-6	PBDE207	2017	190	147	16	Dec
50-32-8	Benzo[a]pyrene	2006	300	264	17	Dec
5436-43-1	PBDE47	2010	282	235	17	Dec
5466-77-3	Octylmethoxycinnamate (EHMC)	2019	157	80	15	Dec
6197-30-4	Octocrylene	2016	112	102	13	Dec
68631-49-2	PBDE153	2010	318	230	17	Dec
78-51-3	Tris(2-butoxyethyl)phosphate (TBEP)	2016	124	91	13	Dec
83799-24-0	Fexofenadine	2022	140	56	15	Dec
83905-01-5	Azithromycin	2022	136	52	15	Inc
85-01-8	Phenantrene	2006	301	265	17	Dec

Note: the trend does not consider the dynamics for each treatment plant separately. In column 'Trend', 'Dec' stands for decreasing trend, while 'Inc' stands for increasing trend.

6.1.3 Categorisation of compounds into groups

Chemicals were categorised either by common application or chemical group. Chemicals that did not fit in any defined group are classified as "Other chemicals." The "Pesticides" group includes insecticides, fungicides, herbicides, rodenticides, and plant-growth regulators. Many chemicals have multiple applications. In such cases, they are assigned to the group considered to represent their most common use. Organophosphate esters (OPEs) are treated as a separate group because they form an established environmental agent class, with fate properties that are more uniform within the group and distinct from those of other groups. Where applicable, antimicrobials used as drugs were classified as "Drugs," whereas chemicals with antimicrobial activity not used as drugs are classified as "Antimicrobial biocides." For most groups, intermediates and derivatives of the main group are also included. For the hazard identification and characterisation, the drugs are subdivided in accordance with the Anatomical Therapeutic Chemical (ATC) Classification system of the World Health Organisation (https://www.who.int/tools/atc-ddd-toolkit/atc-classification). ATC codes are assigned to active substances according to the organ or system, on which they act and their therapeutic, pharmacological and chemical properties. The drugs identified as relevant for the present risk assessment belonged to 14 main ATC groups.

6.2 Impact of thermal hydrolysis on the fate of organic contaminants during anaerobic digestion

6.2.1 Principles and mechanistic impact of thermal hydrolysis pretreatment

Thermal hydrolysis process (THP) is a high-temperature (125–170°C) and high-pressure (6–9 bar) pretreatment technology designed to intensify anaerobic digestion (AD) of sewage sludge (Alukkal et al. 2024; Azizi et al. 2024; Ngo et al. 2021). By disintegrating the network of extracellular polymeric substances (EPS) and rupturing microbial cell walls, THP converts particulate organic matter into more accessible soluble forms (Azizi et al. 2024; Yan et al.

2022). While this increases biogas yields and reduces residual biosolids, it also alters the chemical environment, impacting the fate of organic contaminants and producing refractory inhibitory compounds that affect downstream processes (Alukkal et al. 2024; Azizi et al. 2024; Ngo et al. 2021).

6.2.2 Impact on organic contaminants

The fate of organic micropollutants during THP and subsequent mesophilic anaerobic digestion (MAD) is highly compound-specific, driven by mechanisms such as abiotic transformation, volatilization, and altered biotransformation kinetics (Alukkal et al. 2024; McNamara et al. 2012).

- **PFAS:** AD generally reduces total PFAS molar concentrations through biotransformation, a phenomenon observed both before and after THP installation (Alukkal et al. 2024). Prior to THP, AD significantly reduces precursors and intermediates (e.g., diPAPs and FTCAs) while increasing terminal perfluoroalkyl carboxylic acids (PFCAs) (Alukkal et al. 2024). However, the integration of THP reduces the percent conversion of precursor PFAS during AD. In the THP stage itself, microbial transformation is nonexistent due to high temperatures, limiting changes to abiotic processes. Bench-scale studies at 165°C showed no statistically significant decrease in terminal perfluoroalkyl acid (PFAA) concentrations (Alukkal et al. 2024).
- **Pharmaceuticals and personal care products (PPCPs):** THP effectiveness on PPCPs varies widely. It significantly reduces triclocarban (TCC) (e.g., from >6000 to <90 ng/g dry weight), likely via reactive oxygen species generated during biomass degradation (Azizi et al. 2024). Conversely, triclosan (TCS) and bisphenol-A (BPA) are highly resistant to THP (Azizi et al. 2024). In combined THP-MAD schemes, overall removal efficiencies for ten studied pharmaceuticals (including ibuprofen, naproxen, and clofibric acid) reached approximately 80%, compared to only 54% in conventional AD (Azizi et al. 2024). Significantly improved removal ratios were also reported by Balasundaram et al. (2024) for trimethoprim, estrone, 17ß-estradiol, ciprofloxacin and bezafibrate when THP (the Cambi process at 160°C for 30 min) and MAD were combined as compared to only MAD. However, progesterone, 17α-ethinyl estradiol and carbamazepine showed no significant improved removal by introducing THP (Balasundaram et al. (2024).
- **Nonylphenols (NPE):** THP does not directly destroy nonylphenol diethoxylate (NP2EO), nonylphenol monoethoxylate (NP1EO), or nonylphenol (NP) in sludge or water (McNamara et al. 2012; Azizi et al. 2024). Observed mass losses in THP influent are attributed to volatilization into the headspace or condensate rather than chemical destruction (McNamara et al. 2012). Furthermore, THP-MAD may actually reduce the conversion of NPEOs to the more estrogenic NP compared to conventional MAD, possibly due to substrate competition or ammonia inhibition in the pretreated environment (McNamara et al. 2012).
- **Phthalate plasticizers:** THP-MAD increases the concentration of mono-(2-ethylhexyl) phthalate (MEHP) and benzyl butyl phthalate (BBP) faster than conventional AD, while the degradation of bis(2-ethylhexyl) phthalate (DEHP) remains largely unaffected by the pretreatment (Azizi et al. 2024).

6.2.3 Development of refractory and inhibitory compounds

High-temperature conditions in THP trigger undesirable side reactions that produce recalcitrant and antimicrobial substances (Ngo et al. 2021; Yan et al. 2022).

- **Melanoidins and the Maillard reaction:** The most significant drawback of THP is the **Maillard reaction**, a non-enzymatic browning process between reducing sugars and amino groups (Ngo et al. 2021; Yan et al. 2022). Starting at approximately 140°C, this reaction forms melanoidins–dark-coloured, high-molecular-weight polymers (>10 kDa) that are highly refractory to biological conversion (Yan et al. 2022). These compounds inhibit methanogenesis by binding metals, inactivating enzymes, and cross-linking proteins (Ngo et al. 2021; Azizi et al. 2024).
- **Ammonia Inhibition:** THP causes rapid ammonification of proteins, increasing total ammonia nitrogen by up to 100% (Azizi et al. 2024; Devos et al. 2023). In MAD reactors following THP, the typical operating pH (7.5-8.0) shifts the equilibrium toward free ammonia (NH_3), which can inhibit methanogenic activity at concentrations exceeding 150-200 mg NH_3-N/L (Yan et al. 2022; Azizi et al. 2024).
- **Other refractory compounds:** THP can also form complex antimicrobial compounds like humic acids and Maillard-derived intermediates such as furfural (Alukkal et al. 2024; Azizi et al. 2024).

6.2.4 Consequences for downstream quality and application

The accumulation of refractory products may degrade the quality of both the residual biosolids and the reject water (centrate) (Azizi et al. 2024; Devos et al. 2023).

- **Reject Water (Centrate) Quality:** The centrate from THP-AD systems contains higher concentrations of refractory soluble COD (sCOD) and dissolved organic nitrogen compared to conventional AD (Devos et al. 2023; Azizi et al. 2024). These substances cause UV quenching (absorbing UV light effectively), which leads to the failure of UV disinfection systems in tertiary treatment (Ngo et al. 2021; Devos et al. 2023). Furthermore, high organic carbon and residual inhibitors in the centrate can suppress side-stream nitrogen removal processes like anammox and nitrification by inhibiting ammonium-oxidizing bacteria.
- **Biosolids quality and dewaterability:** While THP provides the benefit of Class A biosolids through complete pathogen sterilization, the subsequent AD process can actually deteriorate the dewaterability of the hydrolysed sludge compared to its state immediately after THP (Yang et al. 2019; Azizi et al. 2024). However, the overall solid content of the final cake remains higher (30-35%) than in conventional processes (20-25%) (Gahlot et al. 2022).

6.2.5 Concluding remarks on thermal hydrolysis

Thermal hydrolysis improves sludge management by enhancing biogas production and ensuring pathogen-free residuals, but it does not uniformly degrade organic micropollutants (Alukkal et al. 2024; Azizi et al. 2024). A critical threshold exists around 140-160°C; exceeding this range sharply increases the production of melanoidins and refractory dissolved organic nitrogen (Devos et al. 2023). These by-products decrease AD efficiency and pose significant challenges for centrate treatment, including UV interference and biological nitrogen removal

inhibition (Devos et al. 2023; Azizi et al. 2024). Optimisation strategies currently focus on moderate temperatures (150°C) to balance solubilisation benefits against inhibitor formation (Devos et al. 2023; Wen et al. 2025).

6.3 Organic contaminants in the liquid fraction of digested sewage sludge

There are very limited data on the concentrations of organic contaminants in the liquid fraction of digested sewage sludge. However, since the dry-weight concentrations of numerous organic contaminants in dewatered treated sewage sludge were available, the concentrations in the liquid fraction after dewatering anaerobically-digested sewage sludge can be predicted. The following assumptions were made.

First, the median value of the 90th percentile of dry-weight-based concentration (C_{solid}) is representative for dewatered anaerobically-digested sludge.

Second, the solids fraction is typically 3-8 % during mesophilic anaerobic digestion (f_{s0}). 5 % was used (Metcalf and Eddy, 2003). The water fraction is therefore $1 - f_{s0}$.

Dewatering agents were applied to improve the dewaterability of the digested sludge and to retain 90% of the solids (r) during centrifugation or filtering through a belt-filter press (Metcalf and Eddy, 2003). The fraction of the solids retained in the cake (S_{cake}) and the fraction that escapes with the reject water (S_{rej}) are given by:

$$S_{cake} = rf_{s0} \quad (1)$$

$$S_{rej} = (1 - r)f_{s0} \quad (2)$$

Third, the contaminant concentration per kilogram of dry solids in the particles in the liquid fraction is the same as in the cake solids after dewatering.

Fourth, the solids fraction in the cake after dewatering (f_c) was assumed to be 35 %. The cake wet mass is then determined from the retained solids in the cake (S_{cake}) by:

$$Cake\ wet\ mass = \frac{S_{cake}}{f_c} \quad (3)$$

Water kept in the cake (W_{cake}) is:

$$W_{cake} = \frac{S_{cake}}{f_c} - S_{cake} = S_{cake}\left(\frac{1}{f_c} - 1\right) = \mathrm{r}f_{s0}\left(\frac{1}{f_c} - 1\right) \quad (4)$$

Hence, the reject water volume is:

$$V_{rej} = (1 - f_{s0}) - W_{cake} = 0.95 - rf_{s0}\left(\frac{1}{f_c} - 1\right) \quad (5)$$

The dry solids concentration in the reject stream (DS_{rej}; kg/L) is consequently:

$$DS_{rej} = \frac{S_{rej}}{V_{rej}} = \frac{(1-r)f_{s0}}{1 - f_{s0} - rf_{s0}\left(\frac{1}{f_c} - 1\right)} \quad (6)$$

Fifth, during the dewatering process, equilibrium is assumed between the solids and the water phase. Hence, the partitioning between solids and water is given by K_d, and the concentration in the water phase could be derived from the K_d value as:

$$K_d = \frac{C_{solid}}{C_{water}} \Rightarrow C_{water} = \frac{C_{solid}}{K_d} \quad (7)$$

Sixth, the pH during dewatering is close to neutral. This has, however, not been the case for Veas WWTP, which until 2024 had added slaked lime prior to the dewatering process, resulting in a liquid fraction with a pH close to 12. This has affected the K_d value of ionisable compounds.

To get the total concentration of the compound in the reject water ($C_{rej,total}$), we need to combine the dissolved part (C_{water}; µg/L) and the particle-associated part ($C_{solid} \cdot DS_{rej}$; µg/kg dw * kg dw/L):

$$C_{rej,total} = \frac{C_{solid}}{K_d} + C_{solid} \cdot DS_{rej} = \frac{C_{solid}}{K_d} + C_{solid} \cdot \frac{(1-r)f_{s0}}{0.95-rf_{s0}(\frac{1}{f_c}-1)} \quad (8)$$

Since K_d values and measured or predicted concentrations in sewage sludge ($C_{solid} = MEC_{sludge}$ or PEC_{sludge}) were available for 842 different compounds, the concentrations in reject water were calculated using equation (8). In **Figure 6.3-1**, the predicted values are shown as a function of the fraction of the compound that was predicted to be present in the water phase.

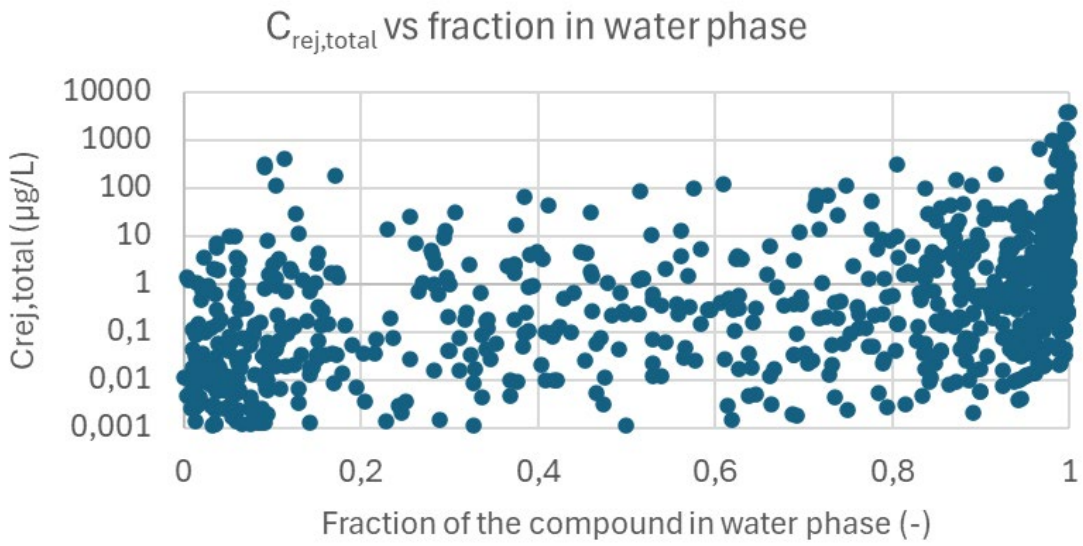


Figure 6.3-1**. Predicted concentrations in reject water for 842 prioritised contaminants in sewage sludge.**

6.4 Organic contaminants in bottom ash from incinerated sewage sludge

Ash is the inorganic solid residue that remains after the thermal treatment (e.g., combustion, incineration or gasification) of organic materials. During thermal processing, organic matter is oxidised or decomposed into gaseous products (CO_2, H_2O, CO, and other volatiles), while non-combustible inorganic constituents are transformed into a mineral-rich solid phase referred to as ash. In contrast to char, which is a carbon-rich solid formed during pyrolysis or incomplete combustion and contains significant organic carbon, ash is largely carbon-free, inorganic residue formed after complete oxidation or mineral transformation. The inorganic elements that form ash originate from minerals naturally present in the raw material (e.g., silicates, phosphates, carbonates in biomass or sludge), adsorbed or precipitated inorganic compounds

accumulated during use or treatment (e.g., metals captured in sewage sludge during wastewater treatment), or additives or contaminants introduced prior to or during thermal processing (e.g., coagulants, catalysts, lime, or sand in fluidised beds).

Ash is dominated by inorganic oxides and salts (i.e. SiO_2, Al_2O_3, CaO, Fe_2O_3, MgO, P_2O_5) and metals (i.e. Zn, Cu, Pb, Ni, Cd and Cr). The composition of ash varies, depending on the feedstock type (biomass, sewage sludge, coal, waste), as well as combustion temperature, atmosphere, and the use of additives and bed materials during the process (Zhai et al., 2022). Ash is commonly classified based on where and how it is collected in the thermal system; bottom ash or fly ash. Fly ash is a fine particulate matter entrained in flue gases and captured by air-pollution-control devices that can be enriched in volatile and semi-volatile elements and compounds, whereas bottom ash from incineration contains lower residual organic carbon and relatively low concentrations of volatile contaminants (Zhai et al. 2022).

Literature data indicated that PAH concentrations in bottom ash from sewage-sludge incineration are low, with concentrations for the sum 16 PAHs in the range of <0.002–0.345 mg/kg (Park et al., 2009; Zhai et al. 2022; Estoppey et al., 2024) (See **Appendix I, chapter 5, A-Table 5.1.-1**). The composition of PAHs in bottom ash was mainly dominated by low-molecular-weight (2–3 ring) compounds, while high-molecular-weight PAHs (e.g. benzo[a]pyrene) were present in low levels, or not detected (Park et al., 2009).

PCDD/F are found in low concentrations, or below the LOQs, in bottom ash from sewage-sludge incineration (Reijnders, 2005; Estoppey et al., 2024). This was explained by the fact that PCDD/Fs preferentially partition to fine particles during flue-gas cooling, resulting in higher levels present in fly ash rather than bottom ash (Reijnders, 2005).

For PFAS, relatively low concentrations have been reported in bottom ash produced from incineration of biosolids, ranging from < 0.2 to 15 µg/kg (see **Appendix I, A-Table 5.1-1**) (Saliu et al., 2024; Strandberg et al., 2021; Estoppey et al., 2024). In a Canadian study on PFAS profiles in biosolids, the average concentration of $\sum_{79}$ PFAS was 152 µg/kg in biosolids (n =33) and 216 µg/kg in sewage sludge (n = 48), whereas samples of ash was at an average of 15 µg/kg (n = 6), indicating PFAS degradation at higher temperatures (Saliu et al., 2024). In a recent study in Sweden (Strandberg et al., 2021), 9 out of 31 samples of bottom ash from different incineration plants had detectable levels of $\sum_{27}$ PFAS. The concentrations ranged from 0.22 to 12.79 µg/kg for $\sum_{27}$ PFAS, and it was concluded that high incineration temperatures do not guarantee low concentrations of PFAS. In several of the samples, the 6:2 diPAP (PFCA precursor) was dominant PFAS in the bottom ash (Strandberg et al., 2021). While laboratory and field studies indicate that high temperatures (typically ≥850–1100 °C) can achieve high PFAS destruction efficiency, complete mineralization is not always guaranteed. Some PFAS, particularly more stable or polymeric species, may require even higher temperatures for full degradation. In addition, transformation pathways during combustion can generate intermediate or secondary PFAS rather than fully breaking down the fluorinated carbon backbone. As a result, residues containing PFAS precursors may persist in bottom ash (Estoppey et al., 2024).

Data on PCBs, drugs, PFAS, and other emerging organic contaminants in sewage-sludge bottom ash are limited. Microplastics are largely destroyed during incineration, although some residues or transformation products may persist in ash; however, no quantitative bottom-ash concentrations have been reported (Cydzik-Kwiatkowska et al., 2022). The importance of using high temperatures to remove the target persistent organic substances was confirmed by

incineration at temperatures >850 °C (Estoppey et al., 2024), where concentrations of were close to or below LOQ. Ash have also been shown to be free of pesticides and pharmaceuticals in another study (Dong et al., 2023).

The low concentrations of organic contaminants in sewage-sludge bottom ash are primarily a result of operating conditions during thermal treatment, including combustion temperature (>850 –900 °C) and sufficient residence time.

6.5 Organic contaminants in biochar derived from sewage sludge

6.5.1 Factors determining the fate of organic micropollutants during pyrolysis

Pyrolysis is recognized as a promising thermal treatment method for managing sewage sludge, resulting in biochar as the main product to be used in agriculture as a soil conditioner due to its strong ability to retain water. The pyrolysis process also offers benefits such as hygienisation, phosphorus recirculation, and contaminant destruction. However, biochar derived from sewage sludge may still contain residual contaminants due to incomplete destruction, formation during processing, and concentration effects associated with mass reduction (Gkogkou et al. 2026; Buss et al. 2022). Reported contaminants include PAHs, PCDD/Fs, PCBs, PFAS, volatile organic compounds (VOCs) and pharmaceuticals.

Pyrolysis is conducted under an oxygen-limited atmosphere at temperatures typically ranging from 350 to 1000 °C, generating three final products: char, gas and liquid (bio-oil) (Weidemann et al. 2017). The fate of the organic contaminants during pyrolysis is primarily dependent on their physical-chemical properties (e.g. volatility, chemical bond strength and molecular structure) as well as the heating rate, peak temperature, residence time and gas atmosphere (Mukherjee et al. 2022; Kalina et al. 2022). Temperature is the key parameter controlling volatilisation and thermal decomposition, with higher temperatures generally enhancing the breakdown of organic pollutants and promoting the formation of a more stable carbon matrix. The use of an inert carrier gas (e.g. N_2 or CO_2) can further reduce contaminant retention in biochar by facilitating removal of volatilised compounds and limiting re-condensation.

PAHs

PAHs are among the most frequently detected organic contaminants in biochar. They may originate from the feedstock or form during pyrolysis through secondary reactions involving volatile intermediates (Wang et al., 2017; Buss et al. 2022; Alharbi et al. 2023). Their concentrations in sludge-derived biochar vary widely (<1 to >70 mg kg^{-1}) depending on operating conditions (Buss et al. 2022; Alharbi et al. 2023; Sørmo et al. 2024). Elevated temperatures promote both degradation and formation processes: while higher temperatures typically reduce total PAH content, they can also enhance the formation of high-molecular-weight PAHs through pyrosynthesis (Buss et al. 2022; Alharbi et al. 2023). Process parameters such as heating rate and carrier gas composition influence PAH formation, with lower heating rates and CO_2 atmospheres reported to reduce PAH yields (Buss et al. 2022; Ko et al., 2018; Kwon et al., 2012; Lee et al., 2017).

PCDD/Fs

PCDD/Fs can form during thermochemical treatment in the presence of chlorine and catalytic metals such as copper and iron (Xu et al. 2025; Potter et al. 2018; Lin et al. 2022). Their

formation is typically associated with incomplete combustion and surface-mediated reactions, while high sulphur concentrations and low oxygen concentrations typically supress their formation (Themba et al. 2023, Zhao et al. 2022). Pyrolysis temperature strongly affects their distribution: formation may occur at intermediate temperatures (approximately 200–400 °C), while higher temperatures (>500 °C) generally promote volatilisation and destruction, resulting in substantial reductions (Tang et al. 2024; Xu et al. 2025; Dai et al., 2018). A large fraction of PCDD/Fs is transferred to the gas phase under such conditions (Tang et al. 2024).

PCBs

PCBs can be present in sewage sludge and may also form during pyrolysis via mechanisms similar to PCDD/F formation, requiring chlorine and catalytic surfaces (Xu et al. 2025; Potter et al. 2018). Formation is typically favoured at intermediate temperatures (~300–400 °C) from benzene compounds (Xu et al. 2025), whereas higher temperatures (>600 °C) lead to significant reductions due to volatilisation and thermal decomposition (Mukherjee et al. 2022; Souza et al. 2021). Moško et al. (2021) reported at above 600 °C, the concentrations drop by over 97%, and at ≥700 °C, by up to 99.9 %. Reported concentrations in sludge-derived biochar are generally low (≤26.6 ng/g) or below detection limits when sufficient temperatures are applied (Alipour et al., 2022; Bleuler et al., 2020).

6.5.2 Concentrations observed in biochar derived from Norwegian sewage sludge

There is limited data available on concentrations of organic micropollutants in biochar produced from Norwegian sewage sludge. Most of the data are from pilot scale studies as part of research projects. The most relevant projects are the VOW project (Valorization of Organic Waste into Sustainable Products for Clean-up of Contaminated Water, Soil, and Air; 2019-2023) and the SLUDGEEFFECT project (2020-2024), in which a medium scale Biogreen® pyrolysis unit (2-10 kg biochar per hour) was used at temperatures of 500-800°C, and the RenCARBio project (2021-2025), in which a screw-type continuous pyrolysis pilot unit (20 kg per hour) was used at 400°C.

PFAS

Reported concentrations of PFAS congeners in biochars at different temperatures compared to the concentrations in the feedstock are summarised in **Table 6.5.2-1**. PFOS was consistently identified as the most recalcitrant congener, likely to remain in the biochar or be newly formed from precursors during thermal treatment.

Table 6.5.2-1**. PFAS concentrations in Norwegian sewage sludge feedstocks and the final biochar.**

PFAS Congener	Feedstock Concentration µg/kg dw	Sludge type	Pyrolysis temperature °C	Biochar concentration µg/kg dw
PFBA	1.55	Raw SS (avg)	550 / 750	<LOD
	84.5	DWSS	600 / 700 / 800	<LOD
PFPeA	2.18	Raw SS (avg)	550 / 750	<LOD
	336.5	DSS-2	500 / 600 / 700	0.82 / <LOQ / <LOQ
	216.9	LSS	600 / 750	<LOQ
PFHxA	17.92	Raw SS (avg)	550 / 750	<LOD
	22.9	DSS-2	500 / 600	0.33 / <LOQ

	26.5	LSS	600 / 750	<LOQ
PFOA	166.91	Raw SS (avg)	550 / 750	<LOD
	1.32	DSS-2	500 / 600	0.39 / <LOQ
	0.84	DSS-3	400	0.084
PFNA	<LOD	Raw SS (avg)	550 / 750	<LOD
	<LOQ	DSS-1	500 / 600 / 700	0.13 / 0.13 / <LOQ
PFOS	6.86	Raw SS (avg)	550 / 750	<0.215
	14.1	DSS-1	500 / 600 / 700 / 750	0.83 / 0.81 / 0.28 / 0.08
	37.9	DSS-2	500 / 600 / 700 / 800	0.91 / <LOQ / <LOQ / <LOQ
	8.0	DSS-3	400	<0.030
PFHpS	35.26	Raw SS (avg)	550 / 750	<LOD
	4.2	DSS-1	500 / 600 / 700 / 750	0.15 / 0.25 / 0.15 / 0.09
4:2 FTS	5.61	Raw SS (avg)	550 / 750	<LOD
	24.3	DSS-1	500 / 600 / 700 / 750	<LOQ
6:2 FTS	0.3	Raw SS (avg)	550 / 750	<LOD
	0.8	DSS-1	500 / 600	0.05 / <LOQ
10:2 FTS	0.54	Raw SS (avg)	550 / 750	<LOD
	1.94	DSS-1	500 / 600 / 700 / 750	<LOQ

Note: The sewage sludge feedstocks include raw sewage sludge (raw SS), digested sludge (DSS-1, DSS-2, DSS-3), limed digested sludge (LSS) and dewatered sludge (DWSS). Data are from Estoppey et al. (2024), Sørmo et al. (2023), Morales et al. (2024), and the RenCARBio project (data received by email from Maria Magdalena Rego Estevez on 13.08.2025).

Drugs

Table 6.5.2-2 summarises results from a pyrolysis test conducted on pilot scale at 400 °C within the RenCARBio project and shows the concentrations of drugs found above the LOQ in feedstock (14 of 158 compounds; one sample) or in biochar (3 of 153 compounds; one sample). The median 90-percentile concentration in Norwegian sewage sludge is shown as a reference for the feedstock concentrations.

The results shows that most drugs were lost from the feedstock during pyrolysis (biochar yield not provided) except for acetylsalicylic acid, caffeine and N-Acetylaminobenzene, which were the only drugs found >LOQ in the biochar sample.

Table 6.5.2-2**. Concentrations of drugs in feedstock and in biochar after pyrolysis at 400°C.**

Compound		**Feedstock**	**Biochar**	**Norwegian sewage sludge**
CAS	Name	µg/kg sludge	µg/kg biochar	µg/kg sludge
50-78-2	Acetylsalicylic acid	200	1,800	1,500
58-08-2	Caffeine	47	45	81.2
60-54-8	Tetracycline	12	<1	4,540
114798-26-4	Losartan	240	<2	450
137862-53-4	Valsartan	550	<1	1,500
22916-47-8	Miconazole	69	<1	390
50-48-6	Amitriptyline	35	<1	240
59729-33-8	Citalopram	32	<1	205
23593-75-1	Clotrimazole	65	<1	250

85721-33-1	Ciprofloxacin	340	<10	998
71675-85-9	Amisulpride	36	<1	210
93413-69-5	Venlafaxine	53	<1	73
298-46-4	Carbamazepine	34	<1	4,100
138402-11-6	Irbesartan	38	<1	73.5
103-84-4	N-Acetylaminobenzene	<10	64	5

Note: The data come from one experiment (one sample of each) from the RenCARBio project (data received by email from Maria Magdalena Rego Estevez on 13.08.2025). Only drugs found above LOQ in feedstock or in biochar are shown. The median 90-percentile concentration in Norwegian sewage sludge is shown as a reference for the feedstock

PAHs

Reported concentrations of sum ΣPAH16 in biochars at different temperatures compared to the concentrations in the feedstock are summarised in **Table 6.5.2-3**. The produced biochars contained between 100 % and 650 % more PAHs than their respective feedstocks, typically with peaks at temperatures around 600 °C. The ΣPAH16 generally decreased at higher temperatures (700–800 °C). While 3- and 4-ring PAHs (phenanthrene, fluoranthene and pyrene) dominated the feedstock, 2- and 3-ring PAHs and particularly naphthalene dominated in the biochars (72-97 %).

Table 6.5.2-3**. Concentrations of Σ16 PAH in the different Norwegian sewage sludge feedstocks and in the final biochars.**

Sludge Substrate	Feedstock Σ16 PAH	Pyrolysis temperature	Biochar Σ16 PAH
	µg/kg dw	°C	µg/kg dw
DSS-1	1 480 ± 30	500 / 600 / 700 / 770	18 000 ± 1000 / 22 000± 1 000 / 7 000 ± 300 / 3 700 ± 100
DSS-2	500 ± 20	500 / 600 / 700 / 800	37 000 ± 2 000 / 22 900 ± 500 / 5 900 ± 500 / 23 000 ± 1 000
DSS-3	550	400	14 800
LSS	980 ± 30	600 / 760	3 380 ± 40 / 2 700 ± 100

Note: The sewage sludge feedstocks include digested sludge (DSS-1, DSS-2, DSS-3) and limed digested sludge (LSS). Data are from Estoppey et al. (2024), Sørmo et al. (2024) and the RenCARBio project (data received by email from Maria Magdalena Rego Estevez on 13.08.2025).

PCBs

Reported concentrations of the sum of seven PCBs (PCB7 congeners 28, 52, 101, 118, 138, 153 and 180) in biochars at different temperatures compared to the concentrations in the feedstock are summarised in **Table 6.5.2-4**. Pyrolysis reduced the concentrations of PCB7 by one to two orders of magnitude compared to the feedstock. PCB 153 was the most persistent congener, detected in 90 % of the biochar samples, while PCB 180 was not found in any samples.

Table 6.5.2-4. Concentrations of PCB7 in different Norwegian sewage sludge feedstocks and in the final biochars.

Sludge Substrate	Feedstock PCB7	Chloride	Pyrolysis temperature	Biochar PCB7
	ng/kg dw	mg Cl/kg dw	°C	ng/kg dw
DSS-1	20.7 ± 0.6	240 ± 10	500 / 600 / 700 / 770	1.7 / LOQ / 1.3 / 0.3
DSS-2	7.6 ± 0.3	330 ± 80	500 / 600 / 700 / 800	0.6 / 0.4 / 0.4 / 0.5

LSS	17 ± 1	20 ± 30	600 / 760	0.3 / 0.2

Note: PCB7 covers the following PCB congeners: 28, 52, 101, 118, 138, 153, and 180. The sewage sludge feedstocks include digested sludge (DSS-1, DSS-2) and limed digested sludge (LSS). Data are from Sørmo et al. (2024).

PCDD/Fs

Reported concentrations of sum ΣPCDD/Fs in biochars at different temperatures compared to the concentrations in the feedstock are summarised in **Table 6.5.2-5**. Concentrations in biochar are typically two to three orders of magnitude lower than the initial concentrations. The most persistent congeners in the biochars were OCDD (found in 90% of biochar samples) and 1,2,3,4,6,7,8-HpCDD, which is explained by their high boiling points (Sørmo et al. 2024). Between 96% and 100% of the PCDD/Fs that were not destroyed ended up in the pyrolysis condensate, resulting in very high concentrations here (up to 1241 ng/kg).

Table 6.5.2-5. Concentrations of ΣPCDD/F17 in different Norwegian sewage sludge feedstocks and in the final biochars.

Sludge Substrate	Feedstock ΣPCDD/F17 ng TEQ/kg dw sludge	Pyrolysis temperature °C	Biochar ΣPCDD/F17 ng TEQ/kg dw biochar
DSS-1	8.3 ± 0.4	500 / 600 / 700 / 770	<LOD
DSS-2	1.78 ± 0.04	500 / 600 / 700 / 800	0.03 / 0.02 / 0.03 / 0.03
LSS	3.0 ± 0.1	600 / 760	<LOD

Note: The sewage sludge feedstocks include digested sludge (DSS-1, DSS-2) and limed digested sludge (LSS). Data are from Sørmo et al. (2024).

VOCs

Volatile organic compounds (VOCs) result from thermochemical transformation of biomass components like cellulose, lignin and hemicellulose, with formation occurring mainly between 250–350 °C (Buss and Mašek, 2014; Buss and Mašek, 2016). Due to their low boiling points, most VOCs remain in the vapor or bio-oil phases, which is why the detected VOCs in the biochar are mainly a result of re-condensation of VOCs during or after the pyrolysis process (Buss and Mašek, 2016; Han et al., 2022) The ten most frequently observed VOCs in biochar are benzene, toluene, propanol, acetone, methyl ethyl ketone, methyl acetate, octanal, 2,3-butadiene, pentanal and 3-methyl butanal (Schlederer et al. 2024). Their total concentration can exceed 100 mg/kg, when pyrolysis conditions are suboptimal (Han et al., 2022). Cellulose, hemicellulose and lignin are present in huge quantities in sewage sludge, originating from toilet paper, food/plant residues and/or industrial inputs, but the fraction varies widely, depending on sludge type and pre-treatment (Racek et al. 2020, Egle et al. 2023). Available data on VOCs in biochar remain limited, and no data were found for these compounds in biochar produced from sewage sludge. According to the predictive model, VOCs will mainly be produced at temperatures below 350 °C.

6.5.3 Predicted residual contaminants in the biochar

As indicated above, there are very limited data on organic contaminants in biochar derived from Norwegian sewage sludge, and for the vast majority of the contaminants included in the sewage sludge part of the risk assessment, there are no data. However, since their fate during pyrolysis is strongly dependent on their physicochemical properties and the operating conditions applied during pyrolysis (Mohan et al. 2006; Devi et al. 2021), it should be possible to roughly predict their concentrations in biochar when taking into account their initial concentrations in the sewage sludge feedstock. Hence, a semi-mechanistic, mass-balanced

model was developed using Microsoft Copilot 365 to simulate the fate and transformation of organic contaminants during sewage sludge pyrolysis. The model is described in detail in **Appendix I, Chapter 4**.

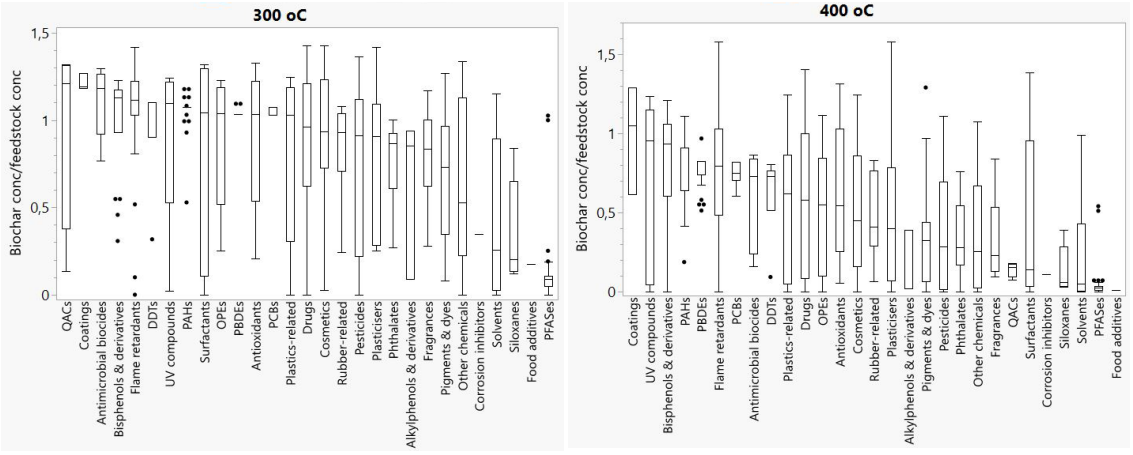
The predicted concentrations in the final biochar compared to the concentration in the sewage sludge feedstock (ratio between concentration in biochar and in feedstock) at the different pyrolysis temperatures are summarised for the different contaminant groups in **Figure 6.5.3-1**. At the lowest temperature (300 °C), the median ratio value was above 1.0 for 22 of the 29 groups, reflecting the predicted biochar yield of 0.65 at this temperature, while few of the compounds were expected to be degraded. Already at 400 °C, only one group (coatings) had its median ratio above 1.0. As the pyrolysis temperature increased, the general picture shows that most compounds are drastically reduced in the final biochar. However, some compounds are persistent, and their concentrations continue to increase as the biochar yield is reduced.

At 600 °C, four compounds were still predicted to be found at higher concentrations in the biochar than in the feedstock (**Table 6.5.3-1)**. The two Dechlorane Plus compounds (isomers) have an extremely stable cage structure (**Figure 6.5.3-2**), hence the relatively low degradation factors (both 0.24) seem reasonable. Bisoctrizole is a highly aromatic, large molecule. The predicted moderate degradation factor is probably caused by its phenolic nature, but it sorbs strongly to the biochar (log Koc = 4.93). Tris(2,4-di-tert-butylphenyl) phosphite is a very bulky and aromatic compound, but its phosphite structure is expected to be rather reactive, hence its strong persistence could be an artifact of the model.

Table 6.5.3-1. **Compounds found at equal or higher concentrations in biochar than in the feedstock based on model simulated fate during pyrolysis at 600 °C.**

CASRN	Compound name	Group	$D_i(T)$	f_{biochar}	Biochar (µg/kg)	Biochar/ feedstock
103597-45-1	Bisoctrizole	UV compounds	0.608	0.978	137	1.09
135821-74-8	Anti-Dechlorane Plus	Plasticisers	0.238	0.572	8.2	1.25
13560-89-9	Dechlorane Plus	Flame retardants	0.238	0.570	1.24	1.24
31570-04-4	Irgafos 168[1]	Antioxidants	0.498	0.777	111	1.11

Note: [1] Irgafos 168 is also known as Tris(2,4-di-tert-butylphenyl) phosphite. $D_i(T)$ is the fraction of the compound that has been degraded. f_{biochar} is the fraction of the compound found in the biochar. The last column shows the ratio between the concentration in the (dry) biochar and the concentration in the dry sewage sludge feedstock.



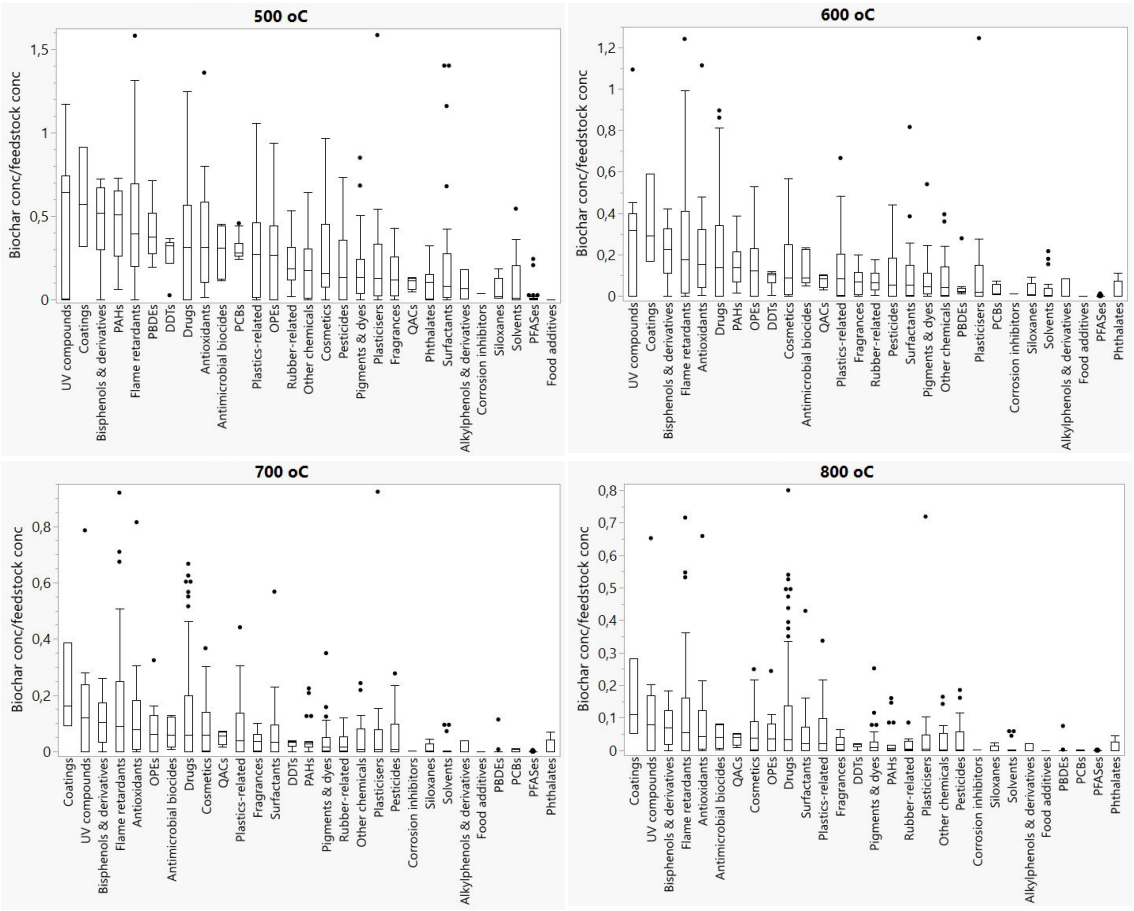
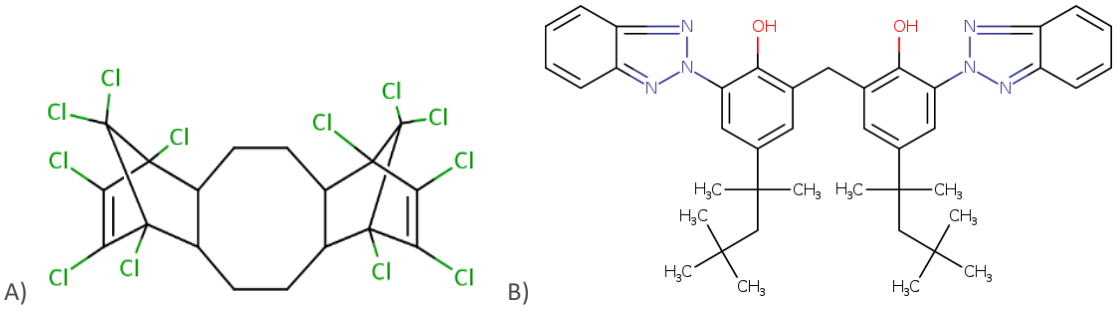
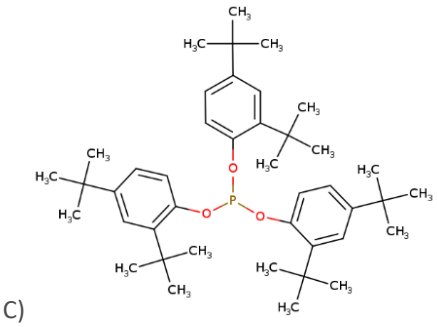


Figure 6.5.3-1. Model-predicted organic contaminant concentration ratios of sewage sludge feedstock and final biochar after pyrolysis at different temperatures.

Note: Concentrations are predicted by the pyrolysis simulation model. The ratio between the concentrations in the final biochar and in the feedstock are shown for all compounds with available data within the main groups of compounds. The boxes show the 25th, 50th and 75th percentiles, while dots show outliers. The results are sorted from left to right according to descending median values for each compound group.





C)

Figure 6.5.3-2. Cage-structures for (A) Dechlorane Plus and Anti-Dechlorane Plus, (B) Bisoctrizole, and (C) Tris(2,4-di-tert-butylphenyl) phosphite (Irgafos 168).
Note: Structures from CompTox Chemicals Dashboard v2.8.0.

The observed fate during pyrolysis at 400 °C as reported from an experiment in the RenCARBio project (**Table 6.5.3-2**) strongly contradicts the results from the model predictions. Most of the compounds were predicted to be largely retained within the biochar at 400 °C, while the only three compounds that were not reduced to <LOQ were predicted to be strongly reduced during pyrolysis at this temperature. It should be noted that this is only one feedstock-biochar sample.

Table 6.5.3-2. Comparison of drug concentrations in feedstock and biochar after pyrolysis at 400 °C.

Compound		**RenCARBio (400°C)**		**Model-predicted (400°C)**		
		Feedstock	Biochar	Feedstock	Biochar	BP
CAS	Name	µg/kg sludge	µg/kg biochar	µg/kg sludge	µg/kg biochar	°C
50-78-2	Acetylsalicylic acid	200	1,800	1,500	13.3	140
58-08-2	Caffeine	47	45	81.2	1.0	178
60-54-8	Tetracycline	12	<1	4540	3,058	580
114798-26-4	Losartan	240	<2	450	494	525
137862-53-4	Valsartan	550	<1	1,500	400	337
22916-47-8	Miconazole	69	<1	390	387	438
50-48-6	Amitriptyline	35	<1	240	241	362
59729-33-8	Citalopram	32	<1	205	219	380
23593-75-1	Clotrimazole	65	<1	250	218	433
85721-33-1	Ciprofloxacin	340	<10	998	132	440
71675-85-9	Amisulpride	36	<1	210	108	447
93413-69-5	Venlafaxine	53	<1	73	65	325
298-46-4	Carbamazepine	34	<1	4,100	53	371
138402-11-6	Irbesartan	38	<1	73.5	31	498
103-84-4	N-Acetylaminobenzene	<10	64	5	0.8	304

Note: Data are from the experiment in the RenCARBio project (data received by email from Maria Magdalena Rego Estevez on 13.08.2025) and the predicted concentrations of the same drugs when using the median 90th-percentile concentrations in Norwegian sewage sludge as feedstock. 'BP' is the boiling point used in the model.

6.5.4 Predicted formation of PAHs during pyrolysis

The model-predicted formation of PAHs in biochar at temperatures between 300 °C and 800 °C are shown in **Figure 6.5.4-1**. The formation peaked at ca. 12 mg PAH/kg biochar at 500 – 600 °C. This is in the same range as the reported PAH formations during pyrolysis of Norwegian sewage sludge (see **Table 6.5.2-3**); however, it is more than 3-times lower than the highest reported PAH formation at 500 °C (37±2 mg/kg biochar).

The apparent underestimation of PAHs in the present model can be attributed to the limited representation of precursor pools, as PAH formation during pyrolysis is dominated by the transformation of bulk organic matter rather than trace organic contaminants (Mendoza-Geney et al. 2022). Sewage sludge is a highly complex matrix composed primarily of proteins, lipids, polysaccharides, humic substances and microbial biomass, with only a minor fraction consisting of identifiable micropollutants. During pyrolysis, these major organic fractions undergo thermal cracking, dehydration and aromatisation reactions, generating low-molecular-weight intermediates (e.g., olefins, alkynes and radicals) that recombine to form primary aromatic species such as benzene, which subsequently act as building blocks for PAH growth through well-established pathways such as hydrogen abstraction–acetylene addition (HACA) (Mendoza-Geney et al. 2022; Pejpichestakul et al. 2019). In particular, humic and fulvic substances represent important reservoirs of partially aromatic carbon, which can readily undergo condensation and structural rearrangement to form polyaromatic structures under pyrolytic conditions (Wycliffe et al. 2025). In parallel, proteins and lipids contribute significantly to PAH formation via radical-mediated fragmentation and recombination, especially in the temperature range of 400 – 600 °C, where volatile release and secondary reactions are maximised (Wycliffe et al.2025). It is well established that PAHs are primarily generated during the incomplete thermal decomposition of organic matter, including biomass and sludge matrices (Wycliffe et al. 2025), rather than from discrete contaminants themselves. Consequently, models that only consider specific organic compounds as precursors will systematically underestimate PAH formation, as they neglect the dominant contribution from the bulk organic carbon pool. Incorporating this broader precursor base is therefore essential for quantitatively reproducing experimentally observed PAH concentrations in sewage sludge-derived biochars.

Hence, the actual potential for generating PAHs during pyrolysis if operated within the temperature range 500 - 600°C is probably significantly higher than predicted by the model that just referred to the PAH precursor pool originating from the microcontaminants.

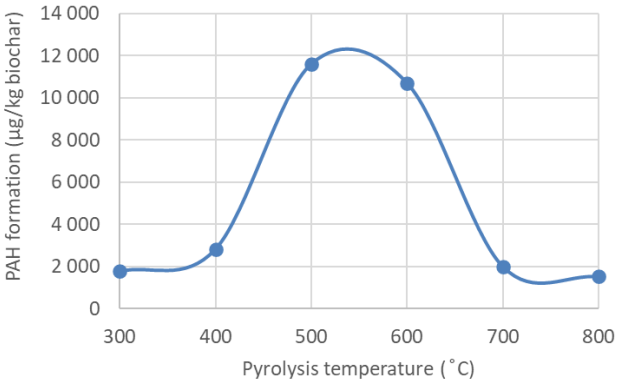


Figure 6.5.4-1. **Concentrations of PAHs in biochar due to in situ formation during pyrolysis at temperatures between 300°C and 800°C as predicted with the pyrolysis simulation model.**

6.5.5 Predicted catalytic formation of PCDD/Fs and PCB during pyrolysis

PCDD/Fs

The model-predicted *in situ* formation of PCDD/Fs at temperatures between 300 °C and 800 °C is shown in **Figure 6.5.5-1**. The concentrations peaked at ca. 2000 ng PCDD/Fs/kg biochar at around 400 °C. The concentrations were apparently several orders of magnitude higher than the concentrations of PCDD/Fs (up to 0.03 ng TEQ/kg biocar) reported by Sørmo et al. (2024) for biochar derived by pyrolysis of Norwegian sewage sludge at 500 – 800 °C (**Table 6.5.2-5**).

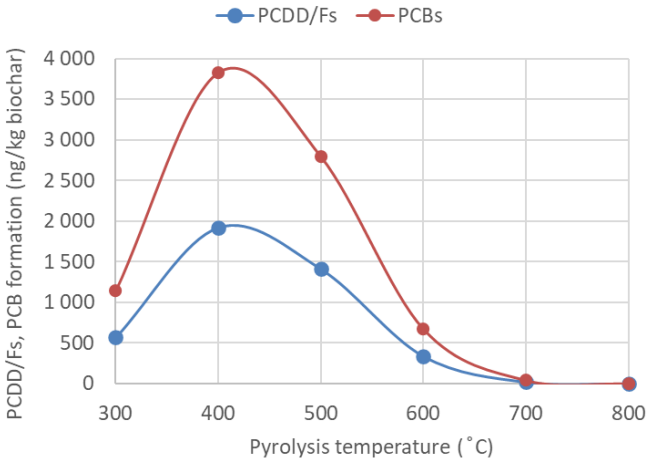


Figure 6.5.5-1. **Concentrations of PCDD/Fs and PCBs in biochar due to in situ catalytic formation during pyrolysis at temperatures between 300 °C and 800 °C as predicted by the pyrolysis simulation model.**

The congeners octachlorodibenzodioxin (OCDD), octachlorodibenzofuran (OCDF), 1,2,3,4,6,7,8-Heptachlorodibenxodioxin (1,2,3,4,6,7,8-HpCDD) and 1,2,3,4,6,7,8-Heptachlorodibenzofuran (1,2,3,4,6,7,8-HpCDF), with toxicity equivalency factors (TEF) of 0.003, 0.001, 0.01 and 0.01, completely dominated the PCDD/F mix reported by Sørmo et al. (2024). Nevertheless, the highest concentration of ∑17 PCDD/Fs was 3.31 ng/kg biochar, about three orders of magnitude lower than predicted by the model. They reported much fewer PCDD/F congeners in the biochars than in the feedstocks (from 14 down to 2-5), and the concentrations were reduced from ca. 300-2000 ng/kg sewage sludge down to ca. 2-3 ng/kg biochar with no apparent dependency on temperature within 500 – 800 °C.

While limited oxygen availability in the pyrolysis reactor is an important factor suppressing PCDD/F formation, the results of Sørmo et al. (2024) show that several additional mechanisms contribute to the extremely low concentrations observed in biochar. First, the process is characterised by spatial separation between an anoxic pyrolysis zone and an oxygen-rich post-combustion chamber operated at 800 – 900 °C, where the oxidative destruction of PCDD/Fs is favoured over formation. Second, the sewage sludge feedstocks (DSS-1, DSS-2 and LSS) contain relatively low chlorine levels, primarily present as inorganic chloride, which limits the availability of reactive chlorinating species required for dioxin synthesis. Third, high sulphur-to-chlorine ratios (up to >400) act as a strong inhibitor of catalytic PCDD/F formation. In addition, rapid transfer of volatilised compounds to the condensate phase, short residence times, and efficient gas–solid separation reduce the opportunity for heterogeneous *de novo*-synthesis. As a result, PCDD/F formation is kinetically and chemically suppressed, while volatilisation and thermal decomposition dominate, leading to a net destruction of 69 – 90 % and >99.9 % removal from the biochar phase. These factors are not captured in simplified catalytic formation models, which therefore substantially overestimate PCDD/F formation under pyrolysis conditions.

PCBs

The model-predicted *in situ* formation of PCBs at temperatures between 300 °C and 800 °C is shown in **Figure 6.5.5-1**. The concentrations peaked at ca. 4.0 µg PCBs/kg biochar at around 400 °C. The concentrations are in the same order of magnitude as the concentrations of ∑PCB7 reported by Sørmo et al. (2024) for biochar derived by pyrolysis of Norwegian sewage sludge at 500 – 800 °C; up to 1.7 µg/kg biochar (**Table 6.5.2-4**). However, the concentrations of PCBs were significantly reduced during pyrolysis in the study reported by Sørmo et al. (2024), from 8-21 µg ∑PCB7/kg sewage sludge to ca. 0.4-1.7 µg ∑PCB7/kg biochar, with no apparent dependency on pyrolysis temperature within 500 – 800 °C.

6.5.6 Overall evaluation

The model represents a balanced compromise between mechanistic detail and computational tractability. By combining structure-based degradation with simplified system-level process representations, it captures key aspects of pyrolysis-driven transformation of organic contaminants. At the same time, the analysis highlights that pyrolysis systems are often destruction- and partitioning-dominated rather than formation-dominated, particularly for highly toxic compounds such as PCDD/Fs. This behaviour is only partially captured by the current model.

Consequently, the model should be positioned as a semi-mechanistic, process-informed framework suitable for exploring relative trends and sensitivities, identifying controlling factors and guiding experimental design rather than as a fully predictive tool for quantitative emission estimation.

6.5.7 Use of model-predicted concentrations in environmental risk assessment

The model-predicted concentrations of organic micropollutants in biochar provide a useful first-order basis for assessing potential environmental impacts, particularly in the absence of comprehensive experimental data for sewage sludge-derived biochars. For soil-living organisms, the model outputs can be interpreted as representing the upper-bound

concentrations embedded within the biochar matrix, while actual bioavailability is likely substantially lower due to strong sorption to the aromatic and porous structure of biochar. This sorption reduces desorption rates and limits uptake via ingestion, although physical ingestion of biochar particles by soil-living organisms may still lead to some exposure. Similarly, plant uptake is expected to be constrained as strongly sorbed hydrophobic contaminants exhibit low mobility in soil pore water, which is the primary pathway for root uptake. For runoff and aquatic exposure, the model results should likewise be interpreted conservatively as most compounds retained in biochar are expected to be poorly leachable; however, a fraction of more polar or weakly bound compounds may still desorb and contribute to transport under certain conditions.

Importantly, the model can also support the evaluation of biochar as a dual-function material, both as a potential contaminant source and as a sorbent that can reduce the bioavailability of contaminants already present in soil. Numerous studies have shown that biochar amendment can decrease the freely dissolved concentrations of hydrophobic organic contaminants through strong adsorption, thereby reducing toxicity and bioaccumulation in soil-living organisms (Zhu et al. 2018; Beesley et al. 2011; Brändli et al. 2008). However, this effect implies a redistribution rather than removal of contaminants, where biochar may become increasingly loaded over time. The model-predicted concentrations should therefore be interpreted in the context of this dynamic equilibrium, where the net environmental risk depends not only on total concentrations but also on bioavailability, desorption kinetics and long-term aging processes. Consequently, while the model provides valuable insight into potential concentration levels and relative trends, its outputs are best suited for screening-level risk assessment and scenario comparison and should ideally be complemented with bioavailability and leaching data for site-specific evaluations.

6.5.8 Other environmental impacts associated with the use of sludge-derived biochar in agriculture

6.5.8.1 Agrochemical and nutrient interactions

A critical and often overlooked risk is the impact of biochar on agricultural efficacy. The high specific surface area of biochar can significantly reduce the effectiveness of agrochemicals, particularly pre-emergent herbicides and pesticides, by fixing them within the carbon matrix (Liu et al. 2018; Varjani et al. 2019; Ni et al. 2020). This may necessitate higher application rates, carrying both economic and environmental consequences (Yang et al. 2006; Graber et al. 2011; Kookana 2010). Furthermore, biochar alters nutrient cycles; while it can increase total soil Nitrogen, it often reduces N and P bioavailability through immobilisation and precipitation, particularly in alkaline soil environments (Rondon et al. 2006; Yao et al 2012; Asai et al. 2009; Chintala et al. 2014; Xu et al. 2016). Inappropriate use may lead to stoichiometric imbalances (C:N ratio) that compromise soil health.

6.5.8.2 Physicochemical risks and i*norganic contaminants*

Biochar application inherently alters soil pH and salinity. While its "liming effect" can be beneficial, in metal-contaminated soils, the resulting increase in pH can mobilise Arsenic (As), leading to elevated concentrations in pore water and potential crop poisoning (Zheng et al. 2012; Beesley et al. 2013). Additionally, risk assessments must account for potentially toxic

elements (PTEs) such as Cr, Cu, Ni, Zn, Pb, Cd, and Hg, which concentrate in biochar during pyrolysis.

6.5.8.3 Direct and indirect impacts on soil biota

Toxicity to soil-living organisms involves both chemical and physical mechanisms. Biochar particles can cause direct physical damage to earthworms by adhering to their bodies, an effect that is independent of chemical contaminants (Schmidt et al. 1999). Furthermore, residual VOCs can act as signalling molecules that disrupt the soil microbiome, alter nitrogen cycling and inhibit fungal growth (Schöller et al. 2002; Chen et al. 2017; Bending and Lincoln 2000). This shift in the fungi-to-bacteria ratio can adversely affect long-term carbon sequestration and soil fertility (Chen et al. 2013; Kelly et al. 2015; Liu et al. 2019).

6.5.8.4 Long-term aging and stability

Biochar is not biologically inert. Over time, physical and chemical aging processes can degrade its immobilisation capacity – sometimes within as little as 2–3 years – potentially leading to a delayed, "ticking clock" release of both organic and inorganic pollutants back into the soil environment (Wang et al. 2021). Therefore, while the current model-predicted data serve as a vital screening tool, site-specific evaluations must weigh these benefits against risks such as increased soil erosion, nutrient immobilisation and long-term pollutant enrichment.

6.6 Organic contaminants in struvite derived from domestic wastewater

Struvite (magnesium ammonium phosphate; $MgNH_4PO_4 \cdot 6H_2O$) is typically obtained at wastewater treatment plants (WWTPs) to alleviate operational challenges, such as the uncontrolled fouling and blocking of sludge return lines, pumps, and valves caused by spontaneous precipitation (Achilleos et al. 2022). Beyond maintenance benefits, it is recovered as a circular economy opportunity to reclaim phosphorus – a finite, EU-classified Critical Raw Material – and nitrogen from nutrient-rich waste streams (Huygens et al. 2019). The production process generally involves controlled crystallisation or precipitation from liquid streams, such as digester supernatant (reject water) or digested sludge, particularly in plants using Enhanced Biological Phosphorus Removal (EBPR), where soluble phosphate concentrations are high (Egle et al. 2016). This is achieved by adding a magnesium source (e.g., $MgCl_2$ or MgO) and adjusting the pH, often via sodium hydroxide addition or CO_2 stripping, to induce a state of supersaturation.

In agricultural settings, struvite is applied as a solid, often granular fertiliser that functions as a slow-release nutrient source; it is relatively water-insoluble but dissolves in response to organic acids exuded by plant roots (González et al. 2021). While currently used primarily in niche sectors such as horticulture, golf courses, and organic farming, it is estimated that by 2030, recovered phosphate salts and ashes could substitute 17 % to 31 % of mined and synthetic phosphorus fertilisers in the EU (Huygens et al. 2019).

In Norway, approximately two-thirds of all sewage sludge is already utilised in agriculture, and the national goal is to use at least 70 % of sludge as a resource under safe conditions. However, due to extensive use of metal coagulants to precipitate phosphorous from wastewater at Norwegian wastewater treatment plants, only a minor fraction of this phosphorous is available for plant uptake (Bøen 2010). Struvite may be a feasible alternative

option to recover inorganic nutrients from wastewater for reuse in agriculture if e.g. the levels of organic micropollutants in treated sewage sludge are considered posing too high a risk.

The potential migration of organic contaminants into recovered struvite is a multi-pathway process involving adsorption, precipitation, and crystallisation (Gao et al. 2023). Unlike direct lattice integration, organic contaminants accumulate through physical adsorption – driven by electrostatic and π-π interactions – and chemisorption, where hydrogen bonding and ligand complexation occur at Mg-OH or P-OH sites. A critical driver of this transport is the formation of ternary complexes (DOM-Metal-Antibiotic), in which multivalent metal cations act as bridges between dissolved organic matter (DOM) and pollutants. During the crystallisation phase, these organic-pollutant complexes or suspended solids (SS) can serve as nuclei or become encapsulated within the mineral matrix as crystals grow and agglomerate (Gao et al. 2023).

A threshold of 3 % organic carbon (OC) in struvite is suggested because organic matter serves as the primary vector for organic contaminants transport (STOWA 2015; Egle et al. 2016). Principal component analysis indicates that DOM content is the primary factor affecting the final concentration of antibiotics in recovered solids, contributing more to residues than pH or wastewater ion composition. Because high-purity mineral precipitation is a clean stoichiometric process, organic contaminants only accumulate in significant quantities when they are adsorbed to or trapped within the organic matrix (Gao et al. 2023). Furthermore, at the alkaline pH levels required for struvite formation, the co-precipitation of unstable, pollutant-laden organic fractions increases as charge balance is destroyed, making the limitation of the scavenger phase (OC) essential for product safety. Restricting OC to 3 % effectively ensures that the resulting material maintains a high safety profile compared to raw manure or sludge, minimizing the potential for long-term enrichment of antibiotics and resistance genes in agricultural soils.

There are very limited data to conduct any thorough risk assessment regarding the application of struvite in agricultural practices. **Table 5.1.2** in **Appendix 5** summarises the typical concentrations of organic contaminants found in struvite derived from different WWTP streams as reported in available studies.

According to current EU regulations (CMC 12 of Regulation (EU) 2019/1009), struvite may only be produced by controlled precipitation from strictly defined wastewater and biowaste streams, excluding animal by-products and biocide-treated inputs, and using limited physical and chemical processing steps; safety with respect to organic contaminants is ensured through source and process control rather than substance-specific concentration limits. The report from the STRUBIAS project (Huygens et al. 2019) suggested that PAH16 must be limited to 6 mg/kg dry matter in precipitated salts such as struvite derived from municipal wastewaters.

6.7 Prioritisation of drugs for the hazard characterisation

Drugs are compounds especially designed to be highly effective in low concentrations in humans and animals. Thus, they have a special position among the other organic contaminants, which possible toxicological effects are unintended side effects. Moreover, in contrast to contaminant groups such as e.g. PCBs, PFAS, and dioxins, which can be assessed as groups, drugs comprise a wide variety of molecular structures that makes it necessary to evaluate their risk potential individually. For the identification of hazards connected to the presence of drugs in soil, plants and animal-derived food products, the drugs were

nevertheless sorted in accordance with the ATC main groups (Anatomical Therapeutic Chemical (ATC) Classification system of the World Health Organisation) to facilitate the recognition of target organs and effect specificity (**Table 6.6-1**).

Table 6.6-1**. Sales of drugs per ATC main group in Norway in 2021 (NIPH 2022).**

ATC main group	Sales in mill DDD*
A - Alimentary tract and metabolism	557
B - Blood and blood forming organs	307
C - Cardiovascular system	936
D - Dermatologicals	7
G - Genito urinary system and sex hormones	243
H - Systemic hormonal preparations, excl. sex hormones and insulins	95
J - Antiinfectives for systemic use	35
L - Antineoplastic and immunomodulating agents	52
M - Musculo-skeletal system	133
N - Nervous system	527
P - Antiparasitic products, insecticides and repellents	2
R - Respiratory system	485
S - Sensory organs	38
V - Various	1
Total human medicines	3,419

*Defined Daily Dose (DDD): assumed average maintenance dose per day for a drug.

The data set for the hazard identification included all drugs that fulfilled one of the following three criteria: (1) detected in sludge sampled at Norwegian wastewater treatment facilities, (2) predicted ecotoxicological potential (RCR_{Q90} > 1), or (3) exceeded 25,000 prescriptions in Norway in 2021 (Data from Norwegian Drug Wholesales Statistics and the Norwegian Prescription Database). Several of the drugs in the data set are no longer used in Norway but were still measurable in sewage sludge and predicted to be environmentally persistent.

All 295 drugs included in the compound priority list (**Appendix II**) were evaluated under consideration of data on frequency in sewage sludge, detected levels (median Q90 UB concentration), predicted half-life in soil/biodegradability, pharmacokinetic data such as bioavailability, distribution in the body, extent of metabolism/amount excreted unchanged, plasma half-life, and acute oral toxicity (data retrieved from drugbank, pubchem and individual literature if necessary) (**Table 6.6-2)**. When several values of the same parameter were obtainable in the literature, the one representing the “worst-case” was chosen for the present evaluation.

Table 6.6-2. **Parameters for the prioritisation of drugs.**

Parameter	Very Low	Low	Intermediate	High/Extensive	Very High
Frequency in sludge (% of analysed samples)	-	<30	30-50	>50	-
Level in sludge Q90 UB (µg/kg dw)	<1	1-10	10-50	50-500	>500

DT_{soil} (d)	-	<50	50-150	>150	-
RCR	<0.1	0.1 - 10	10-50	50-100	>100
BCF_{leaf} (Ås) (mg/kg ww)	<500	500-1000	1000-2000	2000-5000	>5000
Bioavailability (%)	-	<10	10-30	>30	-
Volume of distribution (l/kg bw)	-	< 0.2	0.2-0.6	>0.6	-
Metabolism (amount excreted unchanged %)	-	50-100	10-50	<10	-
Plasma half-life (hours)	-	<4	4-12	>12	-
Acute oral toxicity (LD_{50} rat)	-	>1000	500-1000	<500	-

This selection process based on the ten parameters relevant for the identification of hazards resulted in the reduction from the initially considered 295 drugs to 123 that were subsequently assessed in the hazard characterisation (**Chapter 8.2**).

7 Predicted contaminant concentrations in soil, surface water and plants

This assessment of risks to the environment, animals and humans resulting from the use of sewage sludge as agricultural fertiliser considers different exposure pathways (**Figure 1.5-2**) from soil, numerous crops, grass and food items (**Table 1.5-1**) in different areas of Norway in a number of application scenarios (**Chapter 5**).

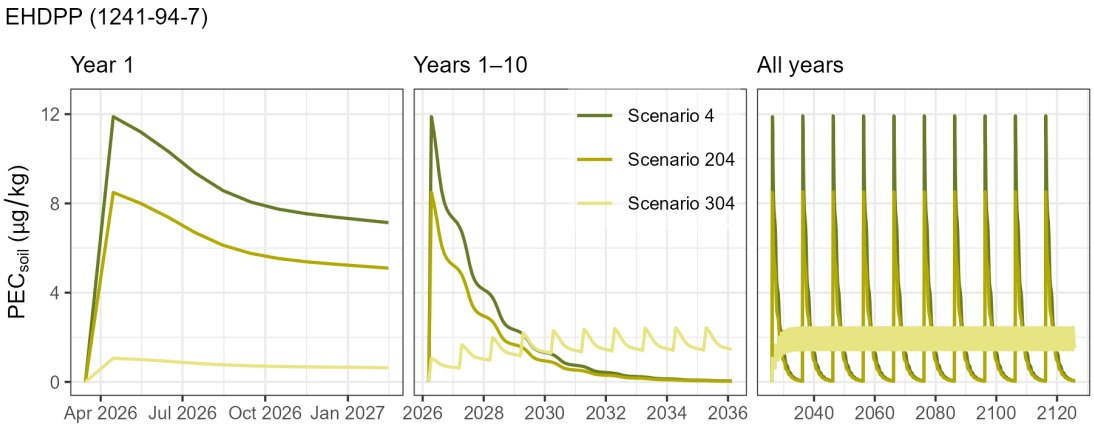
Using measured concentrations in dewatered sewage sludge and physicochemical parameters, predicted environmental concentrations were calculated for soil (PEC_{soil}), surfacewater (PEC_{sw}) and different plant parts (seed, tuber, root, leaf; PEC_{plant}) (Complete PEC tables are available in the Appendix).

Based on the PEC values, BCF for selected edible crops were modelled and applied to estimate whether animals and humans could be exposed to harmful contaminant concentrations in their diet. Likewise, BCF and BMF were used to describe the potential up-concentration of contaminants in freshwater fish.

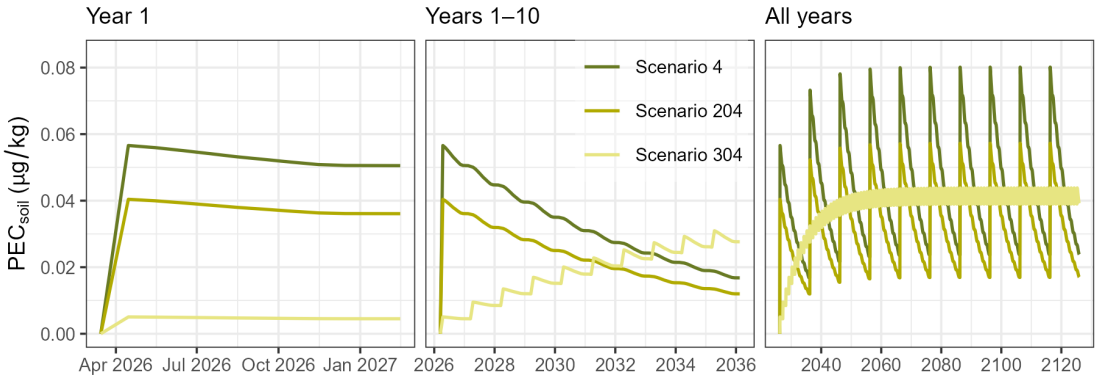
7.1 Predicted environmental concentrations in soil (PEC_{soil})

Changes in PEC_{soil} over time depend on the amount and frequency of the sludge application, the physicochemical properties (degradation (DT_{50}) and mobility (K_{oc})) of the contaminants, and regional differences in soil quality such as the organic content (TOC), pH (for dissociable compounds), soil type influencing the infiltration, temperature, and particularly precipitation.

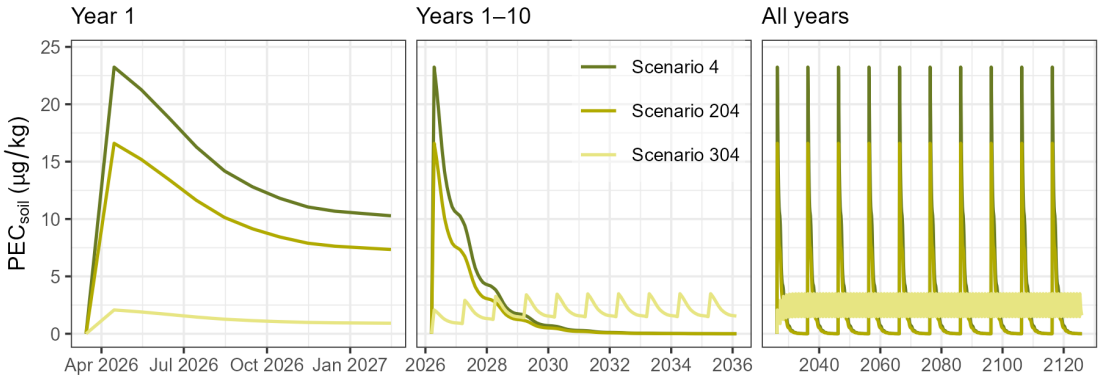
To illustrate this, the changes in PEC_{soil} over 100 years for five selected contaminants (all with $RCR_{soil/peak}$>1) with different properties, application rate are shown below (**Figure 7.1-1**). PEC_{soil} for year 1, for the years 1 to 10, and for all years up to 100 years, after application of sewage sludge with three different frequencies, 11.2 tonnes/ha/10yrs (todays practise corresponding to 250 kg P/10 years and P-limitation in the Norwegian Fertilising Use Regulations), 8 tonnes/ha/10 years and 1 tonne/ha/year, are shown for potato cultivation in Stange (Scenario 4, 204, 304 in ToR2, respectively, **Table 5.1**).



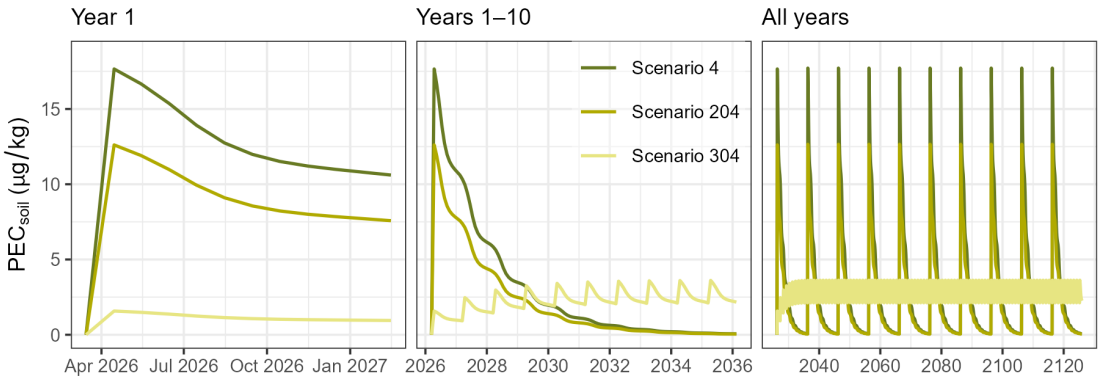
PFOS (1763-23-1)



Carbamazepine (298-46-4)



UV-329 (3147-75-9)



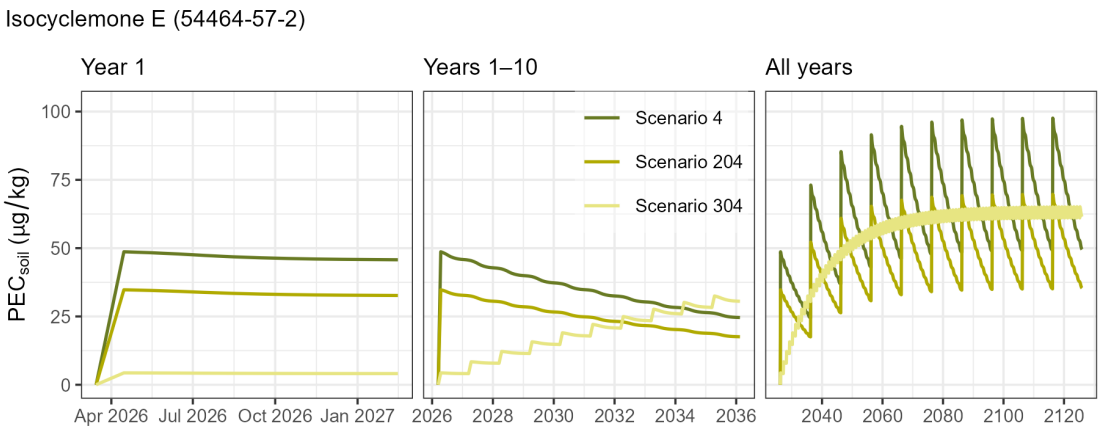


Figure 7.1-1. PECsoil dynamics for 5 representative contaminants in potato production fields in Stange.
Note: **Scenarios 4 and 204 are based on the application of 11.2 or 8 tonnes/ha/10 years of dewatered sewage sludge, respectively. Scenario 304 is based on the application of 1 tonne/ha/year. The scenarios are further described in ToR2a (Scenario 4), ToR2d1 (Scenario 204) and ToR2d2 (Scenario 304).**

There were minimal differences in estimated PEC_{soil} among potatoes, root vegetables (carrots), and cereals across the selected agricultural regions in Norway, with only slightly higher levels observed in Melhus. Likewise, there were negligible differences for the same crops between regions. Therefore, for the sake of brevity, the figures for other crops and regions are omitted.

7.1.1 Predicted background concentration of organic contaminants

In contrast to existing analyses of the background concentrations of a number of heavy metals in agricultural soils (VKM 2014, VKM, 2019, 2022), there are no background concentrations for organic contaminants in agricultural soils. The occurrence of organic contaminants in air, precipitation and soils from urban and remote areas in Norway clearly indicates that there is very likely a background level of many organic contaminants also in agricultural soil, and that the application of sewage sludge is just one of several pollution sources for the soil-food/feed system (**Chapter 4**).

The magnitude and thereby significance of this background level is hard to quantify. In the present risk assessment, background concentrations were not included in the PEC_{soil} calculations, but they are discussed in the risk characterisation (**Chapter 9**) of the individual contaminants or group sums.

Since sewage sludge has been applied to agricultural soils in Norway for about five decades, the predicted contaminant soil concentrations could already include an estimated background level from the previous applications.

The predicted concentration in soil after five applications of sewage sludge (one application every 10^{th} year during the previous 50 years) is assumed to be an appropriate representative for the estimated background concentration ($PEC_{soil\text{-}background}$). This must be considered as an approximate, indicative and conservative value of the soil background in “sludge areas”.

Predicted background concentrations, $PEC_{soil\text{-}background}$, are summarised and compared with the few available measured soil concentrations in urban and remote areas in Norway (**Chapter 4.2**

and Appendix Table 8-1). These values together with information about the number of measured sewage sludge samples, frequency of detections etc, are presented in **Table 7.1.-1**.

Table 7.1-1. Predicted background concentration in soil (PECsoil-background).

CAS	Name	PEC_{soil} peak, 1st appl	$PEC_{soil\ background}$	$DT50_{soil}$	K_{oc}	# samples	# plants w/ data	Freq	Median Q90, sludge
1241-94-7	EHDPP	11.9	0.0408	158	2,491	124	14	1.00	2,070
1763-23-1	PFOS	0.057	0.0237	527,292	821	198	17	0.84	10
298-46-4	Carbamazepine	23.2	0.0030	158	302	143	16	0.98	4,100
3147-75-9	UV-329	17.7	0.0610	158	787	17	3	0.88	3,075
54464-57-2	Isocyclemone E	48.7	48.5	1,582	5,543	82	15	0.99	8,200

Note: PECsoil-background is defined as the predicted soil concentration one month before the 6th application of dewatered sewage sludge with application in accordance with today's practice (11.2 tonnes/ha/10 yrs, ToR2a). All concentrations are in µg/kg dw. Sludge concentration, 'median Q90' is the median of the 90th percentile of sludge concentration across WWTPs with data.

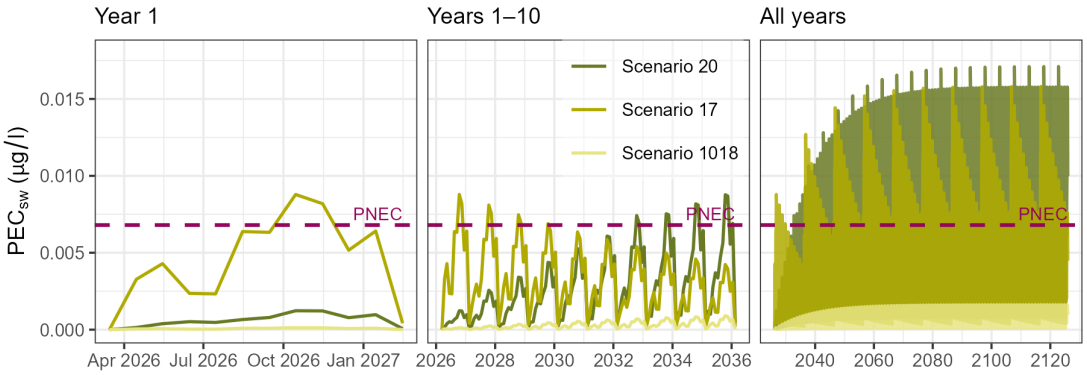
7.2 Predicted environmental concentrations in surface water (PEC_{sw})

Monthly concentrations in surface water (PEC_{sw}) were based on the concentrations in drainage ("effluent") water from the soil profile and standard values for the dilution factor and background concentrations of sediment in surface water. The significance of this number is highest in high order streams, the upper branches of river systems in agriculture-dominated areas. The method is ill-suited for modelling accumulation in slow moving or stagnant water bodies. Monthly effluent, defined as the difference between the sum of rainfall and melting water at the input side and the sum of overland flow and actual evapotranspiration on the output side. This means that concentrations from soil in periods with higher soil moisture surpluses tend to be much more diluted than in drier periods. It should be noted that drainage is assumed to be zero in periods with soil frost, in the model used in this risk assessment.

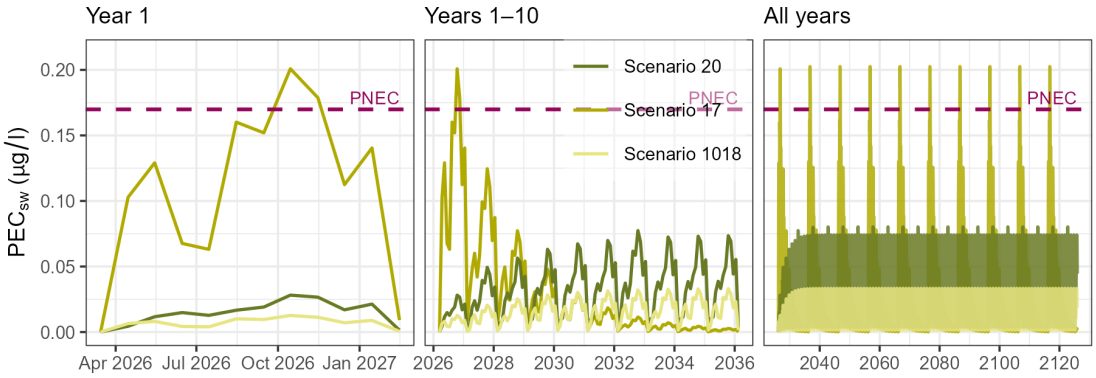
Monthly PEC_{sw} values for five selected compounds and the sum concentration for PCB7 are shown in **Figure 7.2-1** and **Figure 7.2-2**. PEC_{sw} to exhibit not only strong seasonal dynamics, but also different long-term behaviors. The time series patterns for PEC_{sw} differ from PEC_{soil}. While the soil concentrations are a monotonic function of the number of months since the most recent application, PEC_{sw} clearly has two types of peaks, a post-application peak (particularly recognizable in sub-figures for all 100 years) and a peak in periods with little dilution (clearly visible in sub-figures for the first 10 years).

Figure 7.2-1 illustrates effects of different sewage sludge products (dewatered sludge, pellets and liquid sludge product). **Figure 7.2-2** shows effects of regional differences on both seasonal dynamics and long-term patterns.

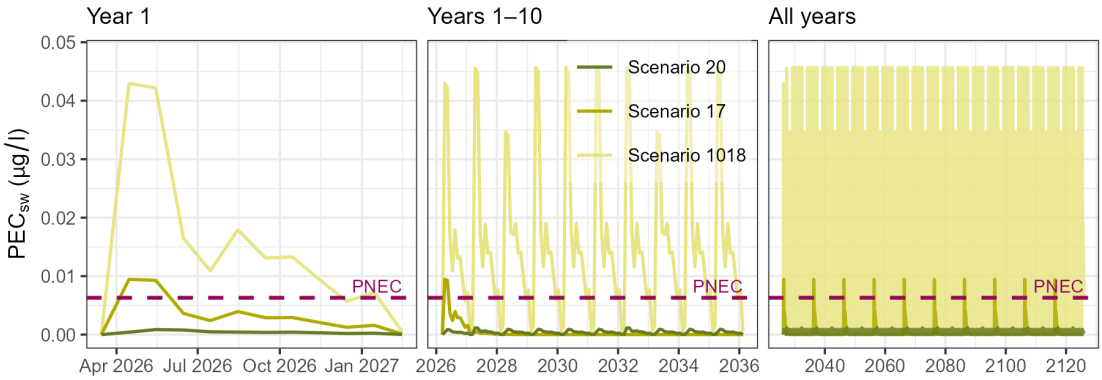
Chlorhexidine (55-56-1)



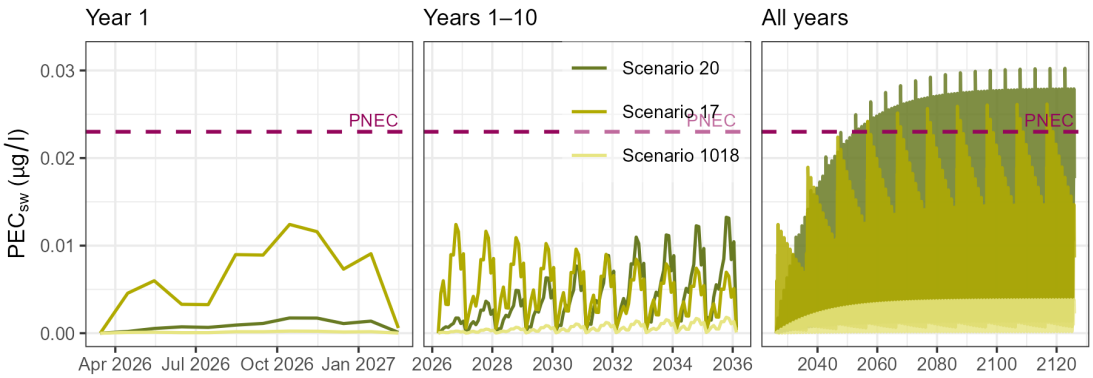
Doxorubicin (23214-92-8)



Fenbendazole (43210-67-9)



Octocrylene (6197-30-4)



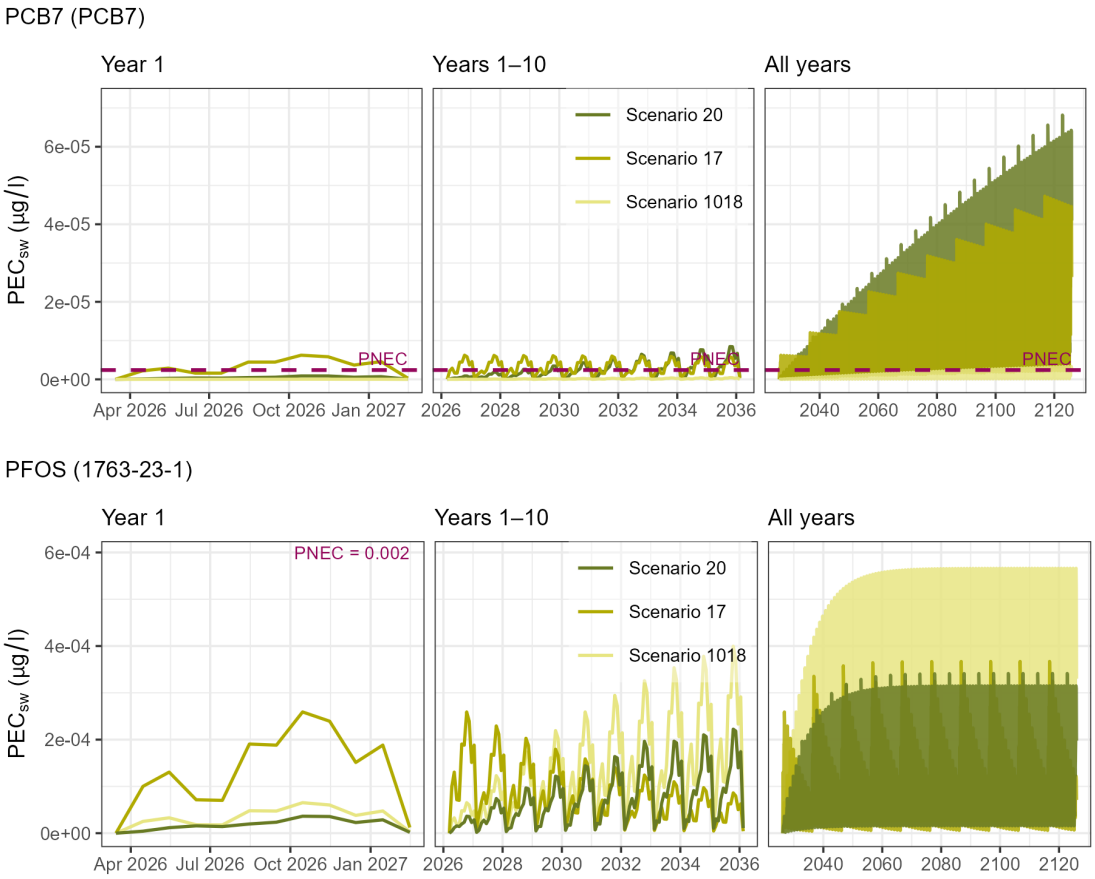
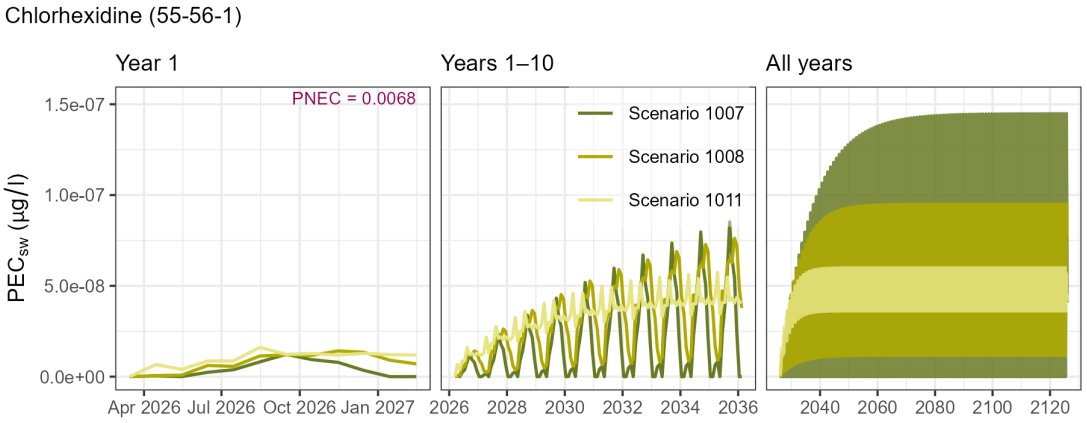
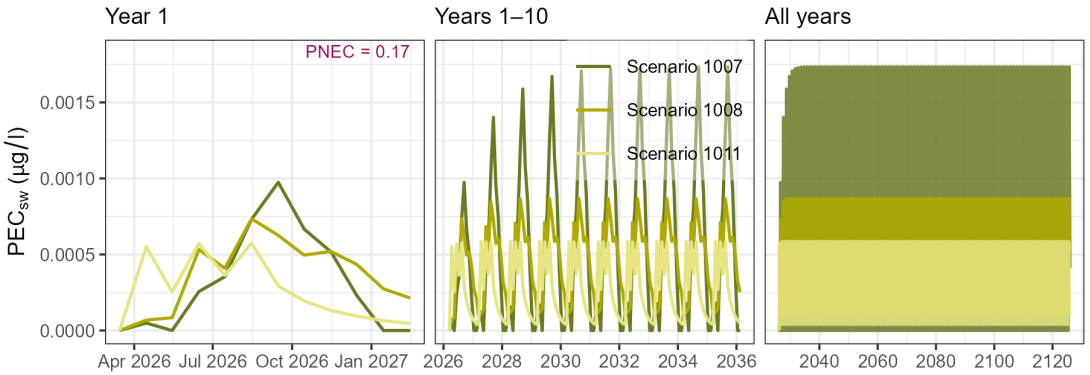


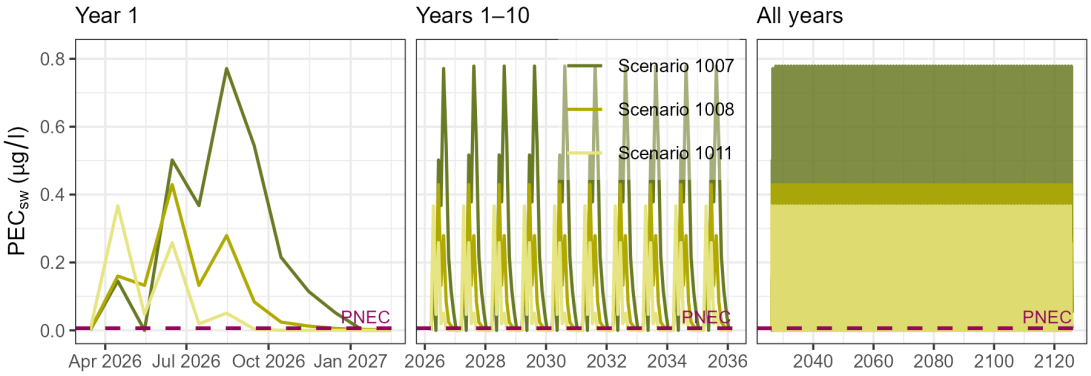
Figure 7.2-1. **Concentration time series for surface water for Stange potato cultivation with different products: dewatered, pellet, and liquid sewage sludge products.**
Note: Scenario 17 calls for application of 11.2 tonnes/ha of dewatered sewage sludge every 10 years, Scenarios 20 calls for annual application of 1.7 tonnes/ha of pallets. Scenario 1018 calls for .5 tonnes/ha of liquid sewage sludge product annually. All application quantities are measured in dry-weight equivalents. For PCB7, EQS is used in place of PNEC. In cases, where PNEC is significantly larger than the range of predicted concentrations, PNEC is identified with a number in the left-most panel of the figures, while otherwise, it is marked graphically with a dashed maroon line. Each compound is identified with a short name and by its CAS number given in parentheses.



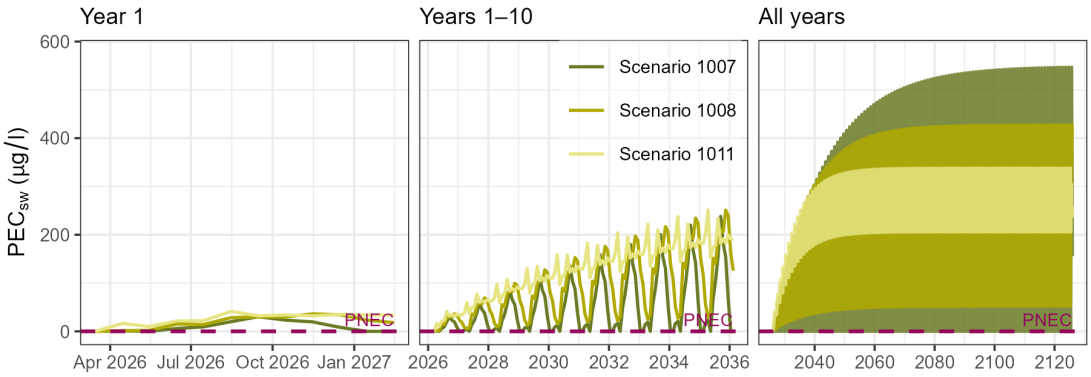
Doxorubicin (23214-92-8)



Fenbendazole (43210-67-9)



Octocrylene (6197-30-4)



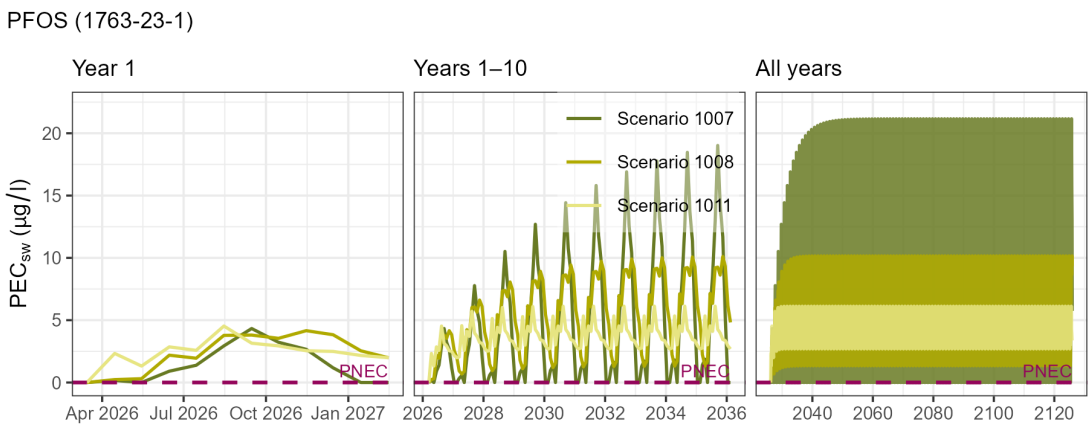


Figure 7.2-2. Concentration time series for surface water for Melhus, Målselv and Time grass cultivation with liquid sewage sludge.
Note: **Scenarios 1007, 1008, and 1011 are for Målselv, Melhus, and Time, respectively. All scenarios call for liquid sewage sludge product application of .7 tonnes/ha annually, in dry-weight equivalent, with the application depth of 5 cm. For PCB7, EQS is used in place of PNEC. In cases, where PNEC is significantly larger than the range of predicted concentrations, PNEC is identified with a number in the left-most panel of the figures, while otherwise, it is marked graphically with a dashed maroon line. Each compound is identified with a short name and (except for PCB7) by its CAS number given in parentheses.**

It should be noted that this risk assessment looks at instantaneous PEC_{sw} value and that accumulation in slow moving water bodies would require information about loading. Though it appears as if persistent pollutants accumulated in water, the long-term positive trend is a product of accumulation in soil, while PEC_{sw} for mobile pharmaceuticals is characterized by immediate acute peaks post application.

Application of dewatered sewage sludge in particular results in a “sawtooth” pattern in concentrations. The pattern stays at stable levels for compounds like fenbendazole, exhibits slowing growth for compounds like chlorhexidine and octocrylene or exhibits strong growth, for example, for PCB7.

For liquid sludge products, despite being applied in smaller annual amounts (0.7 tonnes/ha/year, **Figure 7.2-2**), relative occurrence in liquid product is a function of K_{oc} and, hence, mobility plays a role both in terms of occurrence in the product applied (and thus PEC_{soil}) and in terms of resulting quantities in effluent water and in surface water. Of the compounds presented in **Figures 7.2-1** and **7.2-2**, fenbendazole has relatively much higher concentration (comparing to other contaminant concentrations) in the liquid product than in dewatered sewage sludge, while PFOS and doxorubicin also have greater relative concentrations. When examining post-application acute concentration spikes in the figures, we see they are highest for compounds fenbendazole and PFOS (the two compounds with the highest relative concentrations among those included in the sub-figures).

Figure 7.2-2 shows that there are clear regional differences in seasonal and long-term patterns for PEC_{sw}. The coldest region, Målselv, is consistently characterized by highest seasonal variations with highest acute surface water concentrations over longer-term horizons, while the wettest region, Time, has least variable concentrations with lowest acute concentrations.

7.3 Predicted environmental concentrations in plants (PEC_{plant})

For the prediction of the contaminant concentrations in plants (PEC_{plant}), the PEC_{soil} was used for the time of harvest of the different crops that were included in this assessment ($PEC_{harvest}$).

A set of plant models was used to simulate plant uptake in the different Norwegian regions. Calculated BCF values varied between regions because of their different organic carbon content and pH (**Table 2.2.2-1**). In this paragraph, BCFs are presented only for one region, Stange Hedmark/Innland (soil pH 6.20, orgC 0.03 g/g).

Table 7.3-1 shows the top 16 calculated BCF values for the region Stange Hedmark/Innland (soil pH 6.20, orgC 0.03 g/g). The values are sorted by declining BCF_{leaf}, set for leaf (including grass). Leaves typically show the highest BCF, especially for polar, mobile and non-volatile chemicals, which tend to have the most effective uptake and the highest accumulation in leaves. The highest BCF_{leaf} of all priority contaminants was calculated for iopromide, sulfaguanidine, iopamidol and sucralose. These four chemicals have log K_{ow}-values < 0 and K_d-values < 1 L/kg. Their air-to-water partition coefficients (K_{aw}) are also quite small, between $7x10^{-9}$ and $8x10^{-10}$ L/L, meaning these chemicals are essentially non-volatile and remain in the leaves. Though chemically seen they are weak acids, their pKa are high (acid pKa > 10), so that they are present to 100% in neutral state in Norwegian soils. Their BCF values were thus calculated by the standard model for neutral compounds. The drugs iopromide and iopamidol have molar masses > 700 g/mol, which means that their uptake might be hindered by their molecular size. This is, however, not considered by the standard model, but should be kept in mind. The four contaminants are also taken up into roots (carrots), corn (cereals) and potato, although the BCF values are smaller for these plant parts (**Table 7.3-1**). They are soluble in soil pore water and translocated with the transpiration stream into the leaves, where the water evaporates and leaves the chemicals behind. All contaminants presented in **Table 7.3-1** have similar properties. Several of them are prominent PMT compounds, such as sulfaguanidine, dicyanamide, sulfathiazole and primidone (Neumann and Schliebner 2019).

Table 7.3-1. Contaminants with the highest bioconcentration factor (BCF) for carrot, leaf, cereal and potato in Stange (Innlandet).

Name	BCF_{carrot}	BCF_{leaf}	BCF_{cereal}	BCF_{potato}
Iopromide	2.74*	64.4	3.03	2.33
Sulfaguanidine	2.54	64.0	2.84	2.71
Iopamidol	1.68	42.3	1.88	2.78
Sucralose	1.80	41.4	1.95	1.41
Hydrochlorothiazide	1.61	35.6	1.73	1.30
Meropenem	1.32	33.2	1.47	1.06
Methotrexate	1.25	31.0	1.38	0.98
Oxodolin	1.29	30.5	1.36	1.00
Sulfamerazine	1.22	28.2	1.28	0.97
Sulfathiazole	1.21	28.1	1.26	0.96
Florfenicol	1.22	27.6	1.28	0.94
Dicyandiamid	2.87	21.0	2.66	2.62
Primidone	1.05	20.8	1.05	0.82
Ethylenediaminetetraacetic acid (EDTA)	0.83	20.7	0.92	0.69
4-Acetamidoantipyrine	1.55	17.1	1.51	1.27

4,4'-Diaminodiphenylsulfone	0.75	15.2	0.68	0.53

Note: The rows are ordered by BCF_{leaf} for Stange (Hedmark/Innland region), with soil pH of 6.2 and orgC of 3%. BCF is calculated with the standard model (for neutral chemicals). BCFs are quotes in mg/kg fw.

The 16 contaminants with the predicted lowest BCF-values are shown in **Table 7.3-2**. They include chemicals such as siloxanes, PBDEs, Irgafos 168 and phthalic acid esters with long side chains. All these chemicals have K_d > 100,000 L/kg, some even > 1,000,000 L/kg. These chemicals are strongly bound to soil and not translocated with the transpiration stream into plants. Their uptake pathway is via attachment to soil particles, and the calculated BCF-values thus represent the minimum BCF due to soil attachment: 10^{-2} kg/kg for leaves, 10^{-4} kg/kg for corn and 10^{-3} kg/kg for roots and potatoes (all values based on fresh weight).

Table 7.3-2. Chemicals with the lowest calculated BCF for carrot, leaf, cereal and potato

Name	BCF_{carrot}	BCF_{leaf}	BCF_{cereal}	BCF_{potato}
Dodecamethylcyclohexasiloxane (D6)	0.008	0.01	0.0001	0.0028
Decamethylcyclopentasiloxane (D5)	0.029	0.01	0.0001	0.0076
Bis(2-ethylhexyl)tetrabromophthalate	0.001	0.01	0.0001	0.0010
Dodecamethylpentasiloxane (L5)	0.004	0.01	0.0001	0.0018
Polyphenylmethylsiloxane	0.002	0.01	0.0001	0.0014
PBDE207	0.001	0.01	0.0001	0.0010
Tetradecamethylhexasiloxane	0.002	0.01	0.0001	0.0012
Nonabromodiphenyl ether (NonaBDE)	0.001	0.01	0.0001	0.0010
Tetrabromobisphenol A bis (dibromopropyl ether)	0.001	0.01	0.0001	0.0010
Hexadecamethylheptasiloxane (L7)	0.001	0.01	0.0001	0.0011
Octadecamethyloctasiloxane (L8)	0.001	0.01	0.0001	0.0010
Dinonylphthalate	0.001	0.01	0.0001	0.0010
PBDE209	0.001	0.01	0.0001	0.0010
Decylisoundecylphtalate	0.001	0.01	0.0001	0.0010
UV 360	0.001	0.01	0.0001	0.0010
Tris(2,4-di-tert-butylphenyl)phosphite (Irgafos 168)	0.001	0.01	0.0001	0.0010

Note: The rows are ordered by BCF_{leaf} for Stange (Hedmark/Innland region), with soil pH of 6.2 and orgC of 3%. BCFs are quotes in mg/kg fw.

Bases have mostly low BCF-values. The underlying reasons are that bases adsorb strongest to soil, and bases with pKa around 9 undergo an ion trap effect, which retains them in plant cell vacuoles. This leads to a somewhat higher retention in roots, but less translocation into leaves and corn (Trapp et al. 2023). The base with the highest calculated BCF in grass (leaves) and cereals (corn) is lamotrigine, which has been found in plants during field tests (Nightingale et al. 2025). Acids show better uptake into plants because their adsorption to soil is lower than that of bases (Franco and Trapp 2008). Among the acids with moderate to high BCF are several PFAS, for example PFOA. BCF estimates for the zwitterionic chemicals are highly uncertain. If a measured K_d is unavailable, the predicted value for adsorption in soil is highly uncertain for these chemicals, and the same is true for plant uptake. So far, no model has been developed that would be capable of predicting the uptake and translocation of zwitterionic chemicals. For some, high BCF in leaves have been calculated with the model for neutral chemicals, resulting in BCF > 10 kg/kg for meropenem, methotrexate, ethylenediaminetetra- acetic acid (EDTA), norfloxacin, doxycycline, but these results are not trustworthy.

The BCF values calculated for the five Norwegian agricultural regions are almost the same in ranking, with very little variation due to pH and other soil properties. The calculated BCF values

for Stange, Melhus and Aas are slightly higher than those for Målselv (grass) and Time, because the partitioning between bulk soil (wet weight) and soil pore water depends on the K_d (K_{oc} times orgC), and also on soil density, which is lowest in Time, while Målselv (grass) has the highest orgC, and thus the highest K_d-values.

On the lower end, for 307 chemicals, or 70 % of this dataset, $BCF_{leaves} < 0.1$ kg/kg were calculated for the region Stange. More than 200 of these are just at the minimum BCF (BCF < 0.012 kg/kg), resulting from soil attachment of 0.01 kg/kg for leaves, 0.001 kg/kg for corn, and 0.001 kg/kg for potato and roots, fresh weight-based. This group includes in particular all the lipophilic chemicals with high log K_{ow} and low K_d, such as PBDEs, siloxanes, PAH, PCBs, phthalates, chlorinated pesticides, musk compounds, chlorinated pesticides, DDT and its metabolites. These chemicals show very limited uptake into plants from soil due to their very low solubility; however, contamination from air is more likely (Trapp and Matthies 1995; Trapp 2015).

If uptake from air is neglected, as was done here by setting C_{air} set to zero, the soil resuspension path is the most relevant. However, the amount of attached soil depends highly on meteorological conditions such as rain splash and wind erosion in dry summers. A precise prediction is therefore not possible. Moreover, food processing (washing, peeling, grinding, cooking) will remove attached soil and the chemicals within, except for the fraction that was transferred from attached soil into cuticles and epidermis. The values chosen for this assessment have been retrieved from experiments without food processing and are therefore quite likely at the higher end, i.e. represent a conservative approach.

8 Hazard characterisation of prioritised organic contaminants and exposure in target organisms

8.1 Evaluation of PBT and PMT chemicals

As described in **Chapter 3.2.1**, the physicochemical properties of Persistent, Bioaccumulative and Toxic (PBT) and Persistent, Mobile and Toxic (PMT) chemicals are critical for their categorisation in REACH and in risk assessments. The physicochemical properties also give information about probable fate in the environment and potential exposure pathways. In the present risk assessment, the compound-specific properties and frequency of occurrence in sewage sludge are used to identify contaminants, which pose potential risks to the environment and animal and human health.

The number of PvMT contaminants in sewage sludge with physicochemical properties fulfilling the criteria persistence in soil (the chosen criterion is $DT_{50} \geq 120$ days), mobility into plants (log $K_{oc} < 4$ for mobile chemicals (M) and log $K_{oc} < 3$ for very mobile (vM) - (the latter criterium was chosen as the main filter) - and high plant uptake ($BCF_{leaf} > 1$) is illustrated in a Venn diagram (**Figure 8.1**, left panel). Note, that for many contaminants a (full) classification using the three criteria is not feasible due to missing values. The number of contaminants with missing values is presented in parentheses in the same figure. The contaminants ($PvMT_{leaves}$) in the mid-intersect satisfy all three criteria and have an estimated high uptake into leafy plants such as grass.

Similarly, while considering aquatic toxicity ($PNEC_{aqua} < 10$), contaminants in the mid-intersect fulfilling Persistence, Mobility and Aquatic toxicity criteria ($PvMT_{aq}$) are more likely to pose a risk for aquatic living organisms beacuse these chemicals stay in soil for extended periods of time, have a high mobility, leach into surface water and are highly toxic (**Figure 8.1**, right panel).

A comparable approach was also performed for PvMT fulfilling criteria for uptake into seeds ($BCF_{cereal} > 1$), potatoes ($BCF_{potato} > 1$) and carrots ($BCF_{carrot} > 1$) (not shown). The number of contaminants satisfying these criteria were 25, 22 and 36, respectively.

To identify the contaminants with the highest frequency of detection in dewatered sewage sludge samples, MEC_{sludge} (criterion > 0.5), frequency was considered as an additional criterion. Moreover, information pertinent to the relevance of the different contaminants, considering the total number of samples analysed for a specific contaminant and the number of wastewater treatment plants (WWTPs) where it was detected, is relevant. However, it is important take in mind that for emerging contaminants there are often only a few, if any, measured results in sewage sludge.

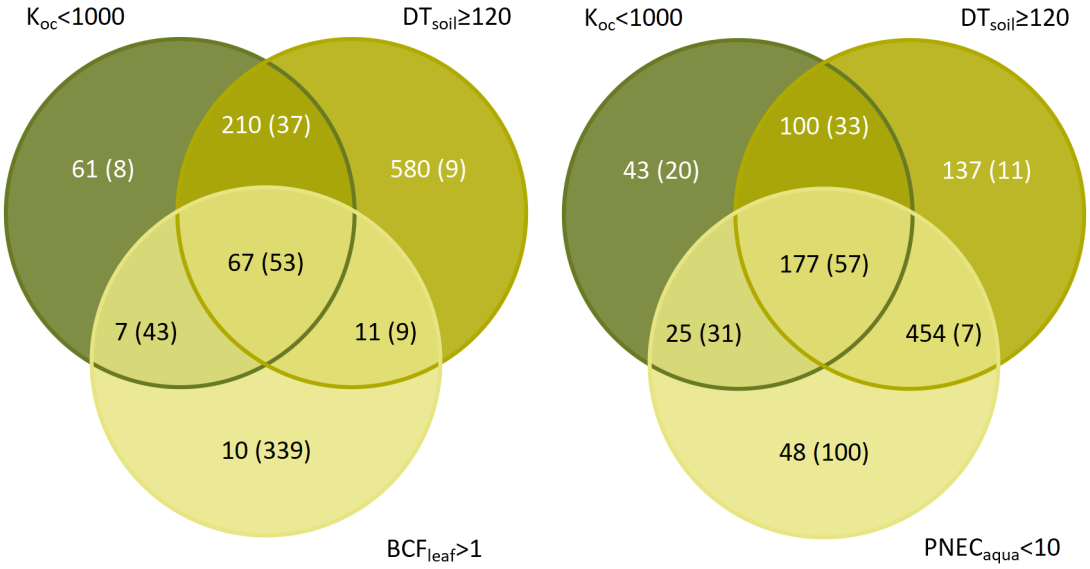


Figure 8.1. Persistent and very mobile chemicals (PvMT).
Note: **Venn-diagrams of persistent (DT_{soil} > 120 days) and very mobile (K_{oc}<1000) contaminants in sewage sludge that also have a predicted high uptake into leaves (left panel, BCF_{leaf} > 1) or are highly toxic for aquatic organisms (right panel, $PNEC_{aqua}$ < 10). The numbers in parentheses indicate the numbers of contaminants with missing values regarding the three criteria applied.**

8.2 Hazards from drugs in sewage sludge

Among the 1,030 prioritised compounds in sewage sludge in this risk assessment (**Chapter 6.1.1**), there were 295 drugs, which were evaluated by the ten-parameter hazard identification step (**Chapter 6.6**). Drugs scoring very low or having low frequency and level in sludge, RCR-Q90, DT_{soil}, oral bioavailability and acute oral toxicity were not included in the hazard characterization dataset for human and animal toxicity. However, exceptions were made for all drugs measured in sewage sludge, even if they are no longer used in Norway or are prescribed to few patients. Additionally, drugs with prescription numbers exceeding 100,000 were included in the toxicity evaluation even if analytical data of measurements in sewage sludge were not available. Finally, drugs without analytical results (n.a.) or high prescription numbers (>25,000 prescriptions per year) were added, when they had high and very high predicted RCR-Q90 or BCF_{leaf} values.

Drugs not fulfilling any of these conditions were excluded from the dataset for the hazard characterisation (see crossed out compounds in the hazard identification tables, **Appendix II**), which reduced the number that had to be considered to 123.

The hazards for health risks in humans from the exposure to drugs in food were characterised by considering the predicted short- and long-term bioaccumulation in soil and plants after using sludge as fertiliser, available data for chronic toxicity in humans and animals (retrieved from repositories by JECFA, EMA and FDA, and from published studies), and guidance values for acceptable daily intake (ADI) in humans and maximum residue levels (MRL) in different foodstuffs by JECFA and national risk assessment authorities. If ADI were not defined by official authorities, a provisional ADIp was created for the present risk evaluation by dividing TDLo (human) or NOAEL (lowest animal value) by a safety factor of 100, or LOAEL (human or animal) by a safety factor of 1,000 (**Table 8.2-1**).

For the evaluation, a worst-case approach was chosen, using the highest predicted values for bioaccumulation between the different scenarios included in this risk assessment. Moreover, the highest predicted value for bioaccumulation in different plant parts (root/potato, seed, leaf) was chosen for the rating of health risks. The rating was performed based on a semi-quantitative matrix, assigning numbers to the individually considered parameters, which were summed up to allow an overall risk characterisation.

Table 8.2-1**. Parameters and ratings used for the hazard characterisation and risk characterisation of drugs occurring in sewage sludge.**

Parameter hazard characterisation	**Very Low**	**Low**	**Intermediate**	**High**	**Very High**
Level in sludge Q90 UB (µg/kg dw)	<1	1-10	10-50	50-500	>500
rating	1	2	3	4	5
Frequency in sludge (% of analysed samples)	<30	<30	30-50	>50	>50
rating	1	1	2	3	3
Parameter	**Unlikely**	**Rather Unlikely**	**Likely**	**Very Likely**	
Bioaccumulation in soil or plants, 100 years, (PEC Y100/PEC Y1)	<0.01	0.01-0.1	0.1-1	1-5	>5
rating	1	2	3	4	5
Upconcentration in plant parts, 1 year (PEC Y1 plant/PEC Y1 soil)	<0.01	0.01-0.1	0.1-1	1-5	>5
rating	1	2	3	4	5
Parameter	**Very Low**	**Low**	**Intermediate**	**High**	**Very High**
Risk to exceed ADI or ADIp (µg/kg bw/d)	>100	50-100	10-50	1-10	<1
rating	1	2	3	4	5
Risk evaluation	**Very low**	**Low**	**Intermediate**	**High**	**Very High**
S ratings					
Risk characterisation	**5-9**		**10-14**	**15-23**	

The results for each of the five parameters included in this rating process are given in the column “Risk evaluation – ratings” for all drugs in the Hazard characterisation tables (**Appendix II**. The final, overall risk rating for every pharmaceutical is presented in the column “Risk characterisation” by a colour code. “Red” indicates that the presence of this pharmaceutical in sewage sludge is of concern for animal and human health and that levels should be monitored. “Yellow” indicates that the respective pharmaceutical could pose a considerable risk and should be included in sludge monitoring, whereas only low risk is expected to be associated with drugs marked with “Green”. For some drugs, individual parameters were missing. This was indicated in the rating sum by “+” since the real number including all parameters would be higher than the current number. Drugs with a summed risk rating below the threshold for the highest risk (15) but marked with “+”, measured at a considerable level in sewage sludge, and drugs with an ADI or ADIp rated as high or very high were included in the list of “high-risk” drugs.

The drugs with the highest predicted risk (in total 56, i.e. 46 % of the drugs considered in the hazard characterisation step) include a high number of compounds affecting the cardiovascular (ATC C), antiinfective (ATC J) and nervous (ATC N) systems. Especially psychopharmaceuticals (ATC N) are highly represented. The list of drugs predicted to have the highest risks in humans and animals are shown in **Table 8.2-2**.

Table 8.2-2. **Drugs with the highest risk score ("red"; ≥15).**

ATC	ATC group	Drug	CAS No.	Risk rating
A	Alimentary tract and metabolism	Loperamide	53179-11-6	16
C	Cardiovascular system	Hydrochlorothiazide	58-93-5	18
C	Cardiovascular system	Bisoprolol	66722-44-9	16
C	Cardiovascular system	Propanolol	525-66-6	15
C	Cardiovascular system	Valsartan	137862-53-4	17
C	Cardiovascular system	Candesartan	139481-59-7	18
C	Cardiovascular system	Telmisartan	144701-48-4	18
C	Cardiovascular system	Atorvastatin	134523-00-5	16
C	Cardiovascular system	Amiodarone	1951-25-3	17
C	Cardiovascular system	Eprosartan	133040-01-4	17
D	Dermatologicals	Ketoconazole	65277-42-1	17
D	Dermatologicals	Tebuconazole	107534-96-3	15
D	Dermatologicals	Benzotriazole	95-14-7	15
G	Sex hormones	Estrone	53-16-7	15
G	Sex hormones	Desogestrel	54024-22-5	11+
G	Sex hormones	Progesterone	57-83-0	15
J	Antiinfectives, systemic	Doxycycline	564-25-0	18
J	Antiinfectives, systemic	Tetracycline	60-54-8	18
J	Antiinfectives, systemic	Oxytetracycline	79-57-2	15
J	Antiinfectives, systemic	Ciprofloxacin	85721-33-1	20
J	Antiinfectives, systemic	Clindamycin	18323-44-9	15
J	Antiinfectives, systemic	Azithromycin	83905-01-5	18
J	Antiinfectives, systemic	Clarithromycin	81103-11-9	17
J	Antiinfectives, systemic	Roxithromycin	80214-83-1	15
J	Antiinfectives, systemic	Erythromycin	114-07-8	15
J	Antiinfectives, systemic	Sulfapyridine	144-83-2	18
J	Antiinfectives, systemic	Benzethonium chloride	121-54-0	15
J	Antiinfectives, systemic	Benzothiazolone	934-34-9	15
L	Antineoplastics	Paclitaxel	33069-62-4	20
L	Antineoplastics	Tamoxifen	10540-29-1	16
L	Antineoplastics	Doxorubicin	23214-92-8	17
M	Anti-inflammatory	Diclofenac	15307-86-5	16
N	Nervous system	Codeine	76-57-3	16
N	Nervous system	Tramadol	27203-92-5	16
N	Nervous system	Lamotrigine	84057-84-1	18
N	Nervous system	Gabapentin	60142-96-3	16
N	Nervous system	Carbamazepine	298-46-4	18
N	Nervous system	Oxcarbazepine	28721-07-5	15
N	Nervous system	Oxazepam	604-75-1	18
N	Nervous system	Haloperidol	52-86-8	15
N	Nervous system	Amisulpride	71675-85-9	16
N	Nervous system	Sertraline	79617-96-2	15
N	Nervous system	Amitriptyline	50-48-6	16
N	Nervous system	Paroxetine	61869-08-7	15
N	Nervous system	Mirtazapine	85650-52-8	16
N	Nervous system	Venlafaxine	93413-69-5	16
N	Nervous system	O-Desmethyl-venlafaxine	93413-62-8	16
N	Nervous system	Citalopram	59729-33-8	14+
N	Nervous system	Trazodone	19794-93-5	15
N	Nervous system	Maprotiline	10262-69-8	18
P	Antiparasitics	Mebendazole	31431-39-7	17
P	Antiparasitics	Fenbendazole	43210-67-9	16
R	Respiratory system	Cetirizine	83881-51-0	17
R	Respiratory system	Fexofenadine	83799-24-0	17
R	Respiratory system	Chlorhexidine	55-56-1	18

V	Various	Ethylenediamine-tetraacetic acid	60-00-4	15

Drugs that are just below the threshold to the highest risk rating (**Table 8.2-3**) should be included in monitoring, because of the uncertainties in analysis and toxicity data, and in the rating approach developed here. Levonorgestrel (rating 12) has been included because it is very much used (ca. 150,000 prescriptions in 2021) in Norway. In total 26 drugs are in this category. Overall, it is noteworthy that of the 1,030 prioritised contaminants in this risk assessment, 8 % (82) are drugs considered to be of high risk to animals and humans consuming feed and food grown in agricultural areas treated with sewage sludge as fertiliser.

Table 8.2-3. Drugs close to highest risk rating ("yellow"; ≥13).

ATC	ATC group	Drug	CAS No.	Risk rating
C	Cardiovascular system	Metoprolol	51384-51-1	11+
C	Cardiovascular system	Carvedilol	72956-09-3	14
C	Cardiovascular system	Irbesartan	138402-11-6	14
C	Cardiovascular system	Fenofibrate	49562-28-9	13
C	Cardiovascular system	Sotalol	3930-20-9	13
C	Cardiovascular system	Lercanidipine	100427-26-7	10+
C	Cardiovascular system	Losartan	114798-26-4	13
D	Dermatologicals	Terbinafine	91161-71-6	13
D	Dermatologicals	Pyrazole	288-13-1	14
D	Dermatologicals	Clotrimazole	2 3593-75-1	14
G	Sex hormones	Levonorgestrel	797-63-7	*12*
J	Antiinfectives, systemic	Trimethoprim	738-70-5	13
J	Antiinfectives, systemic	Sulfamethazine	57-68-1	13
J	Antiinfectives, systemic	Sulfadiazine	68-35-9	13
N	Nervous system	Paracetamol	103-90-2	14
N	Nervous system	Buprenorphine	52485-79-7	10+
N	Nervous system	Orphenadrine	83-98-7	13
N	Nervous system	Memantine	19982-08-2	14
N	Nervous system	Donepezil	120014-06-4	14
N	Nervous system	Entacapone	130929-57-6	14
N	Nervous system	Clonazepam	1622-61-3	13
N	Nervous system	Norsertraline	87857-41-8	14
N	Nervous system	Fluoxetine	54910-89-3	14
N	Nervous system	Clomipramine	303-49-1	13
N	Nervous system	Mianserin	24219-97-4	13
R	Respiratory system	Diphenhydramine	58-73-1	14

8.3 Hazards to the aquatic and terrestrial environment

Pollutants released into the environment pose a wide range of hazards, particularly when they persist, bioaccumulate, or exert toxic effects at low concentrations. Environmental Quality Standards (EQS) are regulatory thresholds established to protect ecosystems and human health by limiting acceptable concentrations of priority substances in water, sediment, or biota. While EQS play an essential role in environmental management, many emerging contaminants—especially pharmaceuticals and high-use consumer chemicals—are not fully covered or are regulated based on incomplete toxicity data. This creates a gap between regulated risks and actual environmental exposure. Recently, the list of EQS was increased from 45 pollutants to 70 groups of pollutants (European Commission, Directive (EU) 2026/805). The EQS are thresholds for groups of contaminants that have posed a challenge for years in the environment, such as PAHs, PCBs, dioxins, chlorinated paraffins, pesticides, etc.

Drugs are of increasing concern because they are designed to be biologically active and are continuously introduced into the environment through wastewater effluent. Even after treatment, many drugs such as antibiotics, antidepressants, and hormones remain detectable in aquatic systems. These compounds can disrupt endocrine systems, alter behaviour in aquatic organisms, and contribute to the development of antimicrobial resistance. Since drugs are typically present in complex mixtures, their combined effects may exceed those predicted by single-compound EQS, raising concerns about mixture toxicity and chronic, low-dose exposure.

Sewage sludge (biosolids), often applied to agricultural land as fertiliser, represents another important source of environmental contaminants. Sludge can accumulate high-use chemicals such as per- and polyfluoroalkyl substances (PFAS), microplastics, personal care product ingredients, and flame retardants. These contaminants can persist in soil, leach into groundwater, or be taken up by crops, creating pathways for entry into food webs. Some substances in sludge are highly stable and resistant to degradation, leading to long-term accumulation and potential ecological effects that are not fully captured by existing EQS frameworks.

In addition, other contaminant groups such as pesticides, industrial chemicals (e.g., plastic additives and flame retardants), and persistent substances like PFAS further complicate the evaluation of environmental risks, particularly because their transformation products and mixture effects are not fully addressed within current EQS frameworks.

In addition to the EQS, PNECs for the environmental components have been described in **Chapter 3.5.**

8.4 Hazards to wildlife from secondary poisoning

In this risk assessment, hazards for wildlife from secondary poisoning with organic contaminants present in sewage sludge were characterised based on already existing reference data (Heimstad et al, 2025) since the compound groups identified as critical corresponded well with those in the list of prioritised contaminants in sewage sludge (**Chapter 3.5**).

The reference data determined substantial bioaccumulation potentials for PFAS (especially PFOS and PFOA) and PCBs, whereas low risks for secondary poisonings in general were reported for chlorinated paraffins (CPs), phthalates, organophosphorus flame retardants (OPFRs), siloxanes, UV compounds and bisphenols although some individual compounds may have BMF > 1.

PFAS, i.e. PFOS and PFOA, were consistently detected in all analysed matrices. Several samples of fieldfare eggs, brown rat liver, and especially badger liver exceeded the $PNEC_{oral}$ and QS_{biota} values for secondary poisoning of predators (e.g., PFOS: $PNEC_{oral}$ 0.033–0.067 mg/kg food; PFOA: $PNEC_{oral}$ 0.0009 mg/kg food).

PCBs were likewise detected in all analysed biota, with the highest concentrations in sparrowhawk eggs. Some PCB congeners (e.g., PCB-153) approached or exceeded $PNEC_{oral}$ (total PCBs: 0.001 mg/kg food; PCB-153: 0.67 mg/kg food).

Chlorinated Paraffins (short-chain (SCCP), medium-chain (MCCP), long-chain (LCCP) poly-chlorinated n-alkanes) were detected in most of the analysed matrices, but not at levels

exceeding the $PNEC_{oral}$ (SCCP (5.5 mg/kg food), MCCP and LCCP (10 mg/kg food)). The highest concentrations were found in the livers of brown rats.

Phthalates, predominantly di(2-ethylhexyl) phthalate (DEHP) and di-isononyl phthalate (DiNP), were detected in soil samples. Additionally, DEHP was found in dog serum. All concentrations were below $PNEC_{oral}$ for secondary poisoning (e.g., DEHP: 3.3 mg/kg food).

Organophosphorus Flame Retardants (OPFRs), i.e. Tris(1-chloro-2-propyl)phosphate (TCPP) and Triethyl phosphate (TEP) were detected in all analysed matrices. However, the concentrations did not exceed $PNEC_{oral}$ (TCPP: 11.6 mg/kg food).

Siloxanes, UV Compounds and Bisphenols were detected in several environmental matrices, but the concentrations were persistently below the respective $PNEC_{oral}$. Thus, thresholds for secondary poisoning were not exceeded.

A more detailed study on PFAS, based on Norwegian data collected between 2013 and 2020 as described in Heimstad et al., 2024, showed that PFOS and long-chain PFCA (e.g., PFNA, PFDA, PFUnDA, PFDoDA) were the most dominant PFAS in all matrices (soil, earthworm, bird eggs, red fox and brown rat liver). Moreover, 6:2 and 8:2 fluorotelomer sulfonates (FTS), precursors for PFOA and other PFCAs, were detected especially in earthworms and bird eggs, with the highest concentrations found at industrial and former landfill sites. Perfluorooctanesulfonamide (FOSA) was found in many samples, with highest concentrations in red fox and brown rat liver (up to 3.3 and 5.5 ng/g ww, respectively). It was also confirmed that the overall PFAS concentrations in all species studied were significantly higher in urban Oslo than in background/reference areas.

Bioaccumulation for PFOS was considerable. High concentrations were detected in earthworms (mean 42.2 ng/g ww, up to 955 ng/g at industrial sites), and the BSAF (biota-soil accumulation factor) for PFOS in earthworms ranged from 11 to 41, indicating strong accumulation. However, it has to be considered that BSAF values must be determined on a case-by-case basis because they depend on many variables and are not universally constant. In Fieldfare eggs, the highest average and median PFOS and sumPFAS concentrations for all analysed bird eggs were detected (mean PFOS 56.3 ng/g ww, up to 601 ng/g). The PFOS and sumPFAS concentrations in Sparrowhawk eggs were comparable to those in Fieldfare eggs, but they were not consistently higher, likely due to dietary and metabolic differences. The livers of Brown rats contained higher PFOS and PFOA levels than those of Red foxes, which with median PFOS concentrations of 10 ng/g ww (max. 144 ng/g) were lower than those in some other European studies.

It is important to be aware that BSAF for earthworms is not a constant value; it varies significantly depending on a range of factors such as the chemical properties of a contaminant. For example, the BSAF for different per- and polyfluoroalkyl substances (PFAS) can vary depending on the number of carbons in the molecule. Furthermore, soil properties such as organic carbon content (fOC), pH, moisture, and texture influence the bioavailability of contaminants. Individual earthworm species (e.g., endogeic (within the earth) vs. anecic (out of the earth)) have different feeding behaviours and accumulate contaminants differently, leading to varying BSAF values. Additionally, the growth rate of the earthworms themselves can influence the kinetics of accumulation and elimination, which in turn affects the BSAF value. The exposure time/steady state can also have an influence because BSAF can change over time, potentially reaching a steady state ($BSAF_{ss}$) after prolonged exposure, which may or may not equal the value calculated at earlier time points (e.g., day 21 or 28). Soil amendments

can be of importance since the addition of compost, bentonite, or activated carbon can alter the bioavailability of metals and other contaminants, thereby changing the BSAF values. Moreover, the co-presence of plants can enhance or decrease the bioaccumulation of certain substances in earthworms, further affecting the BSAF.

Biomagnification (BMF) throughout the food chain earthworm → fieldfare egg → sparrowhawk egg was significant for PFOS with a Trophic Magnification Factor (TMF) of 1.7. Moreover, TMF values ranging from 1.6 to 2.5 for long-chain perfluorocarboxylic acids (PFAs) such as PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA showed significant biomagnification, especially for long-chain congeners. A TMF of 1.8 for 8:2 FTS likewise demonstrated significant BMF. In contrast, PFHxS, PFOA had a TMF < 1, pointing at trophic dilution.

The study showed that Fieldfare eggs and earthworms could be used as bioindicators for urban PFAS contamination due to their wide distribution and accessibility, and the integration of local contamination.

Combined, the data in Heimstad et al. (2024) demonstrated that PFOS and long-chain PFCAs are persistent, bioaccumulative, and biomagnifying in urban terrestrial food webs in Norway. There is a significant risk of secondary poisoning for terrestrial mammals and birds of prey in urban environments, with a significant proportion of prey items exceeding regulatory thresholds. Urban environments act as diffuse and point sources for PFAS, necessitating continued monitoring and mitigation efforts.

8.5 Farm animals – exposure and hazard characterisation

For risk assessment of chemical contaminants in sewage sludge for farm animals, the contaminants had to be analysed for in at least 10 sludge samples collected at minimum two wastewater treatment plants and detected + quantified in at least 10 % of the analysed samples.

Total rations for farm animals were calculated for chemical contaminants with known or estimated BCF in plants and in addition for a few contaminants with data only for soils. The animal rations may consist of compound feed (cereals), forage (grass), as well as soil (and sludge when used digested sewage sludge (Chapter 3.6). The composition of the total rations varies between species and subgroups. The estimated concentrations of contaminants in total rations are given as µg/kg based on dried matter (DM).

The scenarios for use of sewage sludge 11.2 tonnes/ha/10 years in fields for grazing animals and for harvesting forage and cereals for feed production are described in Methodology (chapter 3.6). As a basis for exposure of the contaminants in farm animals, the fate of the same sludge application was estimated from regional and practical conditions at Ås, Stange and Melhus (three scenarios). The exposure levels of the contaminants presented below are from scenario Ås. Comparison with exposure from scenarios Stange and Melhus are summarised in chapter 8.5. A separate scenario for use of digested sewage sludge (1.3 tonnes dm/ha/year on grassland) was estimated from regional and practical conditions at Melhus only.

8.5.1 Determination of contaminant exposure to farm animals

The levels of the various contaminants from sewage sludge are mostly far higher in soil than in the plants, and the levels in leaves are mostly far higher than in cereals. For farm animals, exposure to dewatered sewage sludge-derived contaminants is therefore mostly dominated by their soil intake during grazing, even for contaminants that rather easily move into plants. This became evident, when the relative contaminant intake from gras, cereals (compound feed) and soil was calculated for different exposure pathways (**Table 3.6-2**). Furthermore, the estimated contaminant intake from plants is mostly dominated by the intake of grass/forage.

In high-lactation dairy cows, the daily feed consumption equals on average 4 % of their body weight. At pasture, they eat gras and some soil, and they are additionally fed compound feed. The ratio of gras, soil and compound feed used in the model for dairy cows are 47, 3 and 50 %, respectively (**Table 3.6-2**). Smaller ruminants such as sheep and goats have an even larger feed intake relatively to their body weights and they also usually ingest somewhat more soil. Furthermore, grazing sheep usually do not receive compound feed. For pigs and poultry on grassland/natural area, the estimated intake of soil is relatively high, but they eat less grass and are served more compound feed than ruminants (**Table 3.6-2**).

For animals kept inside or otherwise without access to pasture, intake of soil can be inhibited and usually is negligible. The intake estimations considered an important distinction between grazing animals and animals receiving harvested feed. The grazing animals ingest a certain amount of soil and may additionally receive compound feed at different levels. For animals that receive only harvested feed – forage and compound feed – soil ingestion was set to zero **(Table 3.6-2)**, because it is usually possible to avoid soil contamination in harvested grass and cereals. Thus, the total exposure to contaminants varies considerably between animal species and composition of the total ration and is particularly depending on soil ingestion.

8.5.2 Contaminant exposure from soil ingestion

Organic contaminants like DDTs, PAHs, PCBs, and BDE (and some PFAS) are examples of contaminants that bind strongly to the soil matrix and ingestion of small quantities of soil (3–6 %) will dominate the contaminant level in the total rations of the animals. Strong soil binding, combined with low degradation rates, results in an even higher significance of soil ingestion with time, and the calculated concentrations of organic contaminants in the total rations after 10 applications of sewage sludge are 2 to 10 times higher than those after one application.

The contaminant levels in the total rations are highest for the animals, which are assumed to ingest most soil (here: growing pigs). Soil contributes with about 98 % to the content of the mentioned contaminants in the total ration for fast-growing pigs.

For other organic contaminants with lower K_{oc} and lower DT_{50}, i.e. surfactants or drugs, the significance of soil ingestion is much lower (**Figure 8.5.2-1**). For these contaminant groups, the intake from forage (grass) is the most important for the total rations. After 10 applications of sewage sludge (year 91), the significance of forage for the total ration is still significant for surfactants and drugs (**Figure 8.5.2-1**).

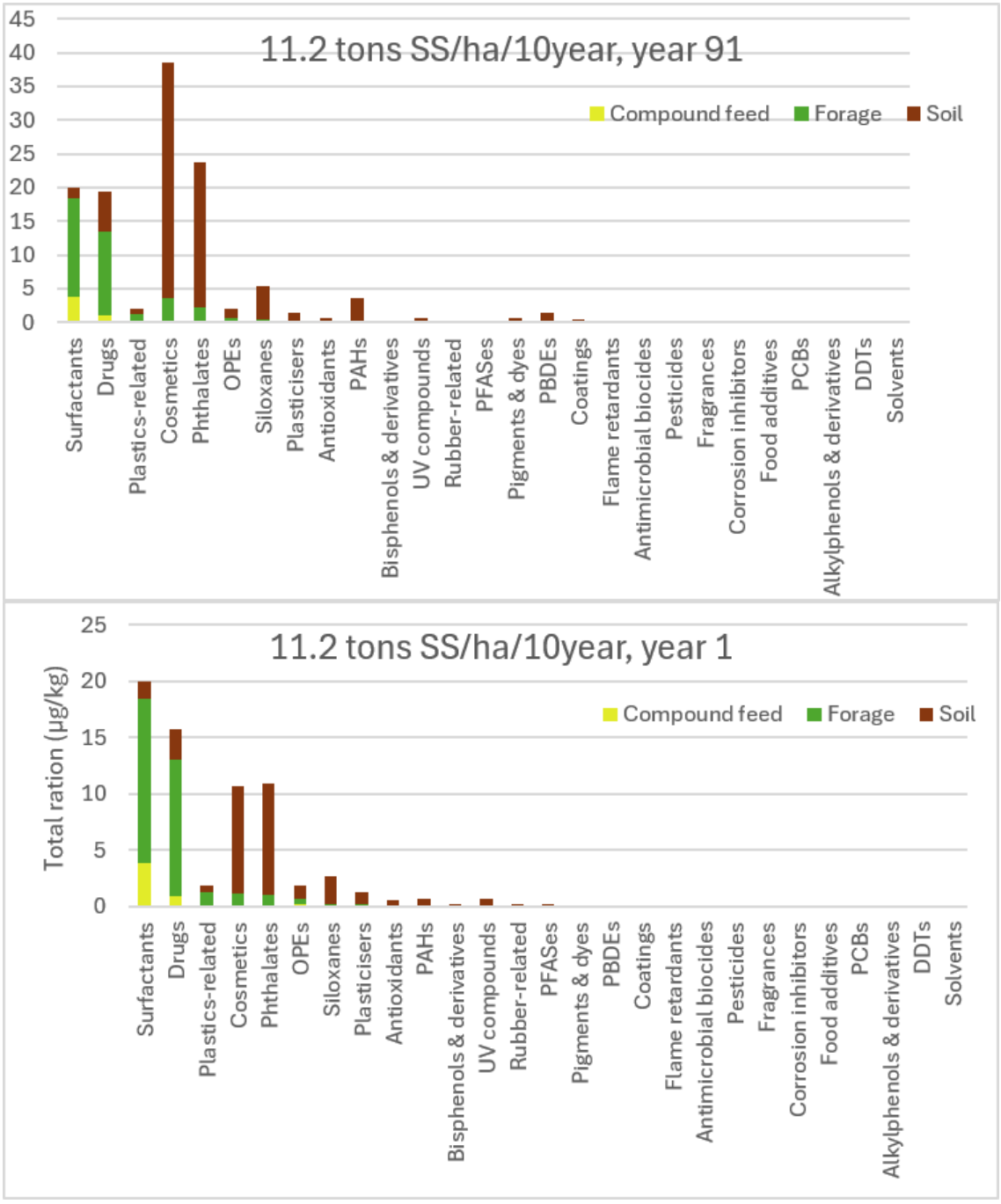


Figure 8.5.2-1. Total rations (µg/kg DM) of contaminants for grazing, high-lactating cows, by chemical groups, after the 1st (lower figure) and 10th (upper figure) application of 11.2 tonnes sewage sludge/ha/10 years. The total rations consist of compound feed, forage and soil.

For most contaminant groups (n=28), the soil is quantitatively the most important contributor to the daily rations (µg/kg DM) for grazing animals, but for drugs, surfactants, plastic-related compounds, bisphenols and their derivatives, and PFAS, forage (grass) contribute more than soil.

For PFAS (n=15), compound feed contributes with nearly 30 % to the daily ration, whereas forage contributes with 45 %.

The groups of contaminants which contribute quantitatively most to the daily rations for animals are cosmetics, drugs, phthalates and surfactants.

8.5.3 Regional differences of contaminants in total rations

Contaminant levels (n=232 contaminants) in total rations were calculated for high-lactating cows, adult sheep with twins, growing pigs, laying hens and high lactating goats for the municipalities Melhus, Stange and Ås. The calculations showed that the amounts of organic contaminants in the total rations of animals on pasture are, e.g., 11 % and 8 % higher at Melhus than at Ås and Stange, respectively.

The percentage differences in the total rations between the regions for all organic contaminants (n=232) considered are on average small, ranging from 1.4 to 11 %. For some contaminants the difference may be higher.

Overall, however, the regional differences in the calculated total rations for the farm animals are small (**Table 8.5.3-1**).

Table 8.5.3-1 Percent difference in sum (n=232 organic contaminants) of total rations between regions Melhus, Stange and Ås. Differences are shown for year 1 (1st application) and year 91 (10th application) for grazing and indoor exposure when applying 11.2 tons SS/ha/10yr. Unit: oercent difference

		Ås-Stange				**Ås-Mel**				**Stange-Mel**			
		Grazing outside		Indoor		Grazing outside		Indoor		Grazing outside		Indoor	
		Year 1	Year91	Year 1	Year91	Year 1	Year91	Year 1	Year91	Year 1	Year91	Year 1	Year91
High lact cows	Min	-42	-42	-46	-46	-38	-38	-57	-57	-18	-18	-44	-44
	Maks	10	10	14	14	12	12	0,9	0,9	29	29	32	32
	Middl	-1,6	-4	-3	-5	-5	-6	-11	-12	-4	-2	-8	-6
	Median	-0,4	-2,9	-1,4	-3,5	-5,1	-6,2	-7,4	-9,1	-4,8	-3,3	-4,9	-4,4
Adult sheep with twins	Min	-41	-41	-46	-46	-38	-38	-58	-58	-18	-18	-45	-45
	Maks	9,9	9,9	14	14	12	12	0,8	0,9	28	28	32	32
	Middl	-1,4	-4,3	-3,0	-5,3	-5,2	-6,1	-11,1	-11,8	-4,0	-2,1	-8,2	-6,7
	Median	-0,4	-2,8	-1,4	-3,2	-5,1	-6,3	-7,4	-9,6	-4,8	-3,4	-4,9	-4,6
Growing pigs	Min	-38	-38	-162	-162	-10	-10	-41	-41	-10	-10	-21	-21
	Maks	2,5	2,5	13	12	12	12	54	54	28	28	82	82
	Middl	-1,7	-4,7	-6,0	-8,9	-3,7	-4,6	-7,0	-7,8	-2,2	-0,2	-4,0	-1,9
	Median	-0,2	-2,9	-0,1	-3,1	-4,9	-5,1	-5,4	-7,4	-4,7	-3,1	-5,1	-4,5

Adult lact goats	Min	-41	-41	-46	-46	-34	-34	-57	-57	-17	-17	-44	-44
	Maks	8,4	8,4	14	14	12	12	0,9	0,9	28	28	32	32
	Middel	-1,6	-4,5	-3,2	-5,5	-4,7	-5,6	-11	-12	-3,3	-1,4	-7,7	-6,2
	Median	-0,3	-2,9	-1,4	-3,5	-5,1	-5,9	-7,4	-9,1	-4,8	-3,2	-4,9	-4,4
Laying hens	Min	-41	-41	-162	-162	-18	-18	-41	-41	-13	-13	-21	-21
	Maks	4,7	4,6	13	12	12	12	54	54	29	29	82	82
	Middel	-1,7	-4,7	-6,0	-8,9	-4,0	-4,9	-7,0	-7,8	-2,5	-0,5	-4,0	-1,9
	Median	-0,2	-2,9	-0,1	-3,1	-5,0	-5,2	-5,4	-7,4	-4,8	-3,1	-5,1	-4,5

8.5.4 Comparison of contaminants in total rations after application of liquid fraction of digestated sewage sludge and dried sewage sludge

When liquid digested sewage sludge is spread on soil surface it is assumed that the digestate will constitute about 1 % of the total intake for all animal groups (**Table 3.6-2**). Since the liquid digestate contains a higher portion of water-soluble (with lower K_d) organic contaminants, which often have a higher plant uptake, the sum of organic contaminants in the total rations increase as compared to applications with dewatered sludge. The calculated total rations for high-lactating cows are 4- to 6-times higher when applying liquid sludge as compared to dewatered sludge (**Figure 8.5.4-1**). The significance of direct ingestion of liquid digestate sticking to grass and the soil surface is dominating the composition of total rations in these calculations.

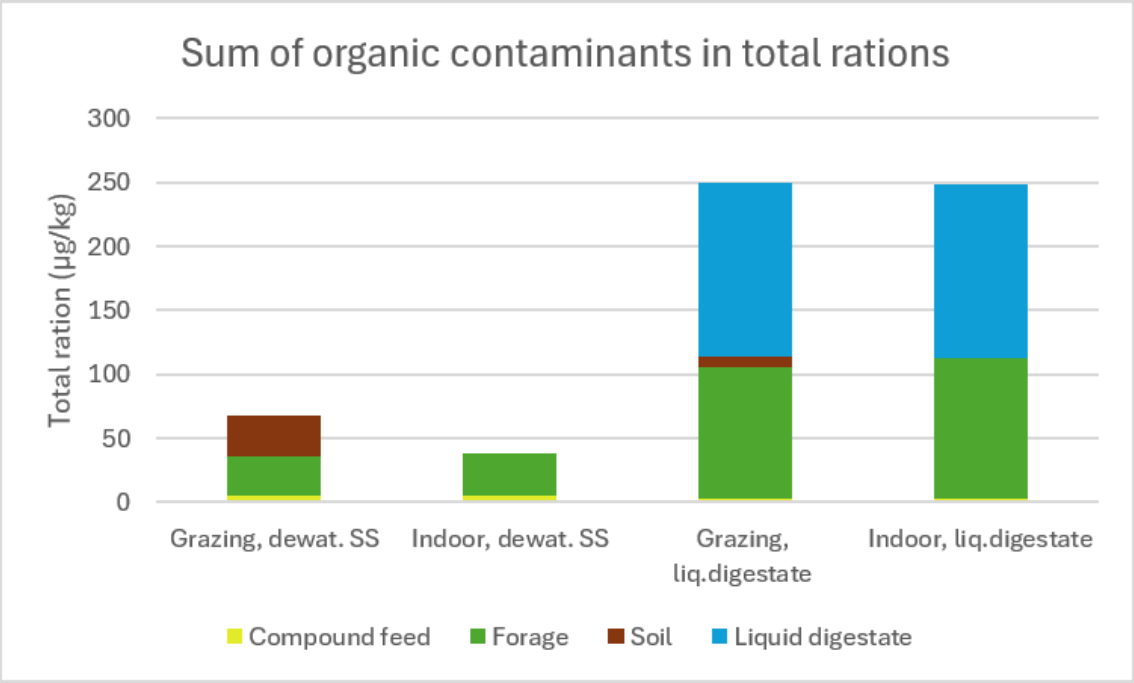


Figure 8.5.4-1. Total rations of the selected organic contaminants (n=232) for high-lactating cows in areas with dewatered sewage sludge application v. liquid fraction of digested sewage sludge application.

As examples, oqrganic contaminants categorized in the groups Drugs, OPEs, Antioxidants, Solvents and Fragrances are significantly higher in liquid fraction of digested sewage sludgecompared to dewatered sewage sludge, while e.g. PAHs, BDEs, PCBs and DDT are much higher in dewatered sludge (**Figure 8.5.4-2**).

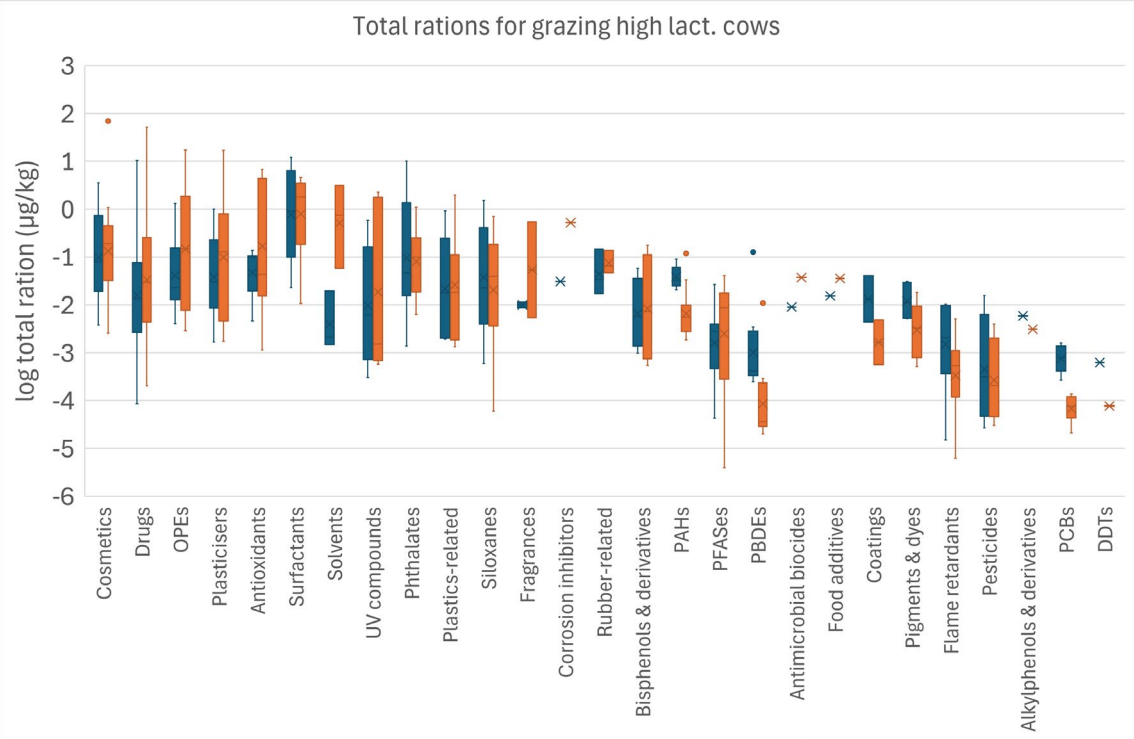


Figure 8.5.4-2**. Total rations (semi-logarithmic, µg/kg dm) for high-lactating cows grazing outside on soils that have been treated with 11.2 tonnes dewatered sewage sludge (blue bars) or 1.3 tonnes (dw) liquid fraction of digested sewage sludge (orange bars).**

8.5.5 Contaminants in total rations for different farm animals

Most of the contaminants are present at far highest concentrations in soil. Secondly, several of the contaminants are also taken up into plants' leaves. Thus, grass/forage may also contain substantial concentrations, whereas cereals were generally less exposed. Of the five farm animal species that have been evaluated in this assessment, adult sheep with twins (forage equals to 94 % and soil 6 % of the total ration) and growing pigs (soil equals to 10 % of the total ration) will be the highest exposed. For grazing adult sheep with twins, the sum of all contaminants in the total ration originates equally from forage and soil (**Figure 8.5.5-1**), while soil contributes to about 85 % of the contaminants in the total ration for pigs. For animals living indoors, the contaminant levels in the total rations are highest for adult sheep with twins, high-lactating cows and adult lactating goats. Forage completely dominates the contaminant level in the total rations, when animals live and are fed indoors without access to soil.

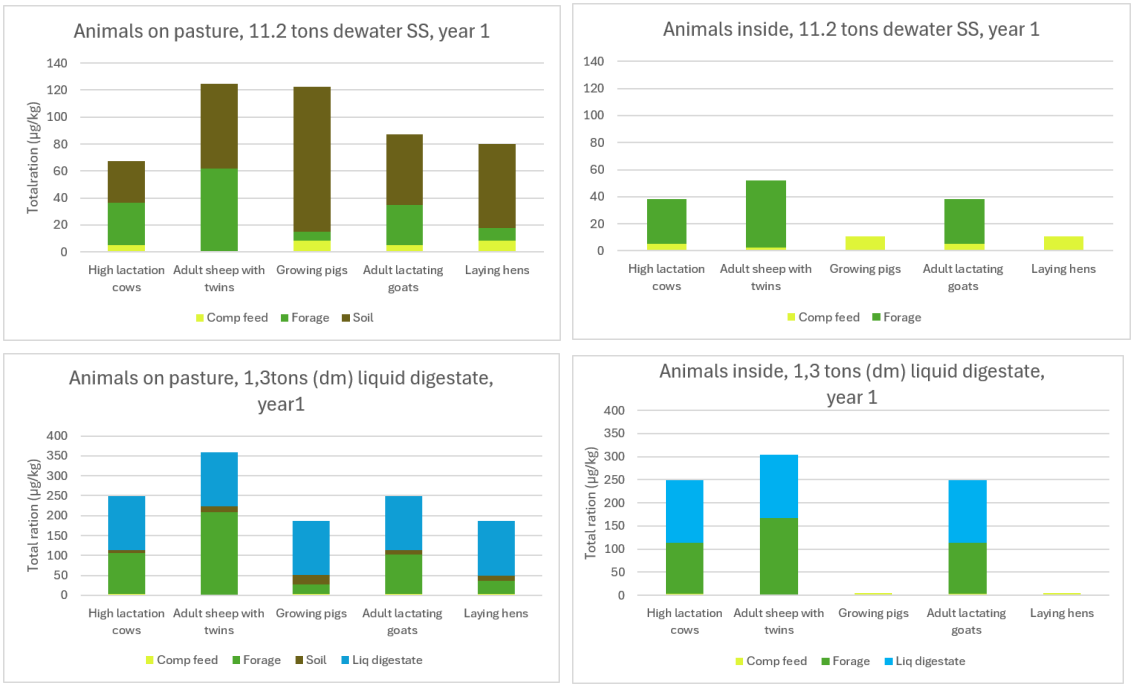


Figure 8.5.5-1. Sum of contaminants (n=232) in the total rations (µg/kg DM) of five animal groups in the first year after the application of 11.2 tonnes dewatered sewage sludge or 1.3 tonnes (dw) liquid fraction of digested sewage sludge.

The contaminant levels in the total rations of the five animal groups are in general higher when liquid fraction of digested sewage sludge is applied as compared to the application of dewatered sewage sludge (**Figure 8.5.5-1**). The total ration for adult sheep with twins has the highest content of contaminants (both for grazing animals and those kept indoors). Ingestion of liquid fraction of digested sewage sludge (1 % of the total ration both for grazing and indoor-living animals) dominates the contaminant levels together with the amount coming from forage.

8.5.6 Hazard characterisation and exposure of the individual contaminants in farm animal rations

This chapter is based on exposure in animal rations after application of 11.2 tonnes/ha of sewage sludge every 10th year.

8.5.6.1 PCBs

Evaluating the exposure of high-lactating cows to PCBs, the model (**Chapter 3.6**) predicted that a single application of sludge on soil area used as pasture the following year and harvested cereals for the production of compound feed in the application year results in a burden from ∑PCB6 of 0.0063 µg/kg in the consumed total ration. Of this, 92 % comes from exposure via soil ingestion. For animals that ingest more soil or have a higher feed consumption than dairy cows, the PCB intake would increase correspondingly. For instance, the corresponding estimated intakes of ∑PCB6 in growing pigs, adult sheep and laying hens at pasture are estimated as 0.019, 0.013 and 0.012 µg/kg total ration, respectively.

∑PCBs accumulate approximately 8-fold in the soil in a 100 year-period with applications of sewage sludge every tenth year, leading to a predicted level of 0.053 µg/kg total ration for the

dairy cows. If the cows received grass harvested as forage together with compound feed, the estimated dietary levels would be 0.00058 and 0.0046 µg/kg total ration, respectively, after the first and tenth sludge application. ∑PCB6 constitute approximately 50 % of the total PCB burden (EFSA, 2005).

Effect studies, both case reports and experimental studies of NDL-PCB in domestic animals have been summarised by EFSA (2005). Technical mixtures and biologically weathered mixtures of PCBs show low acute toxicity in wild and domestic animals, but effects are observed after long time exposure, in particular on reproduction. Studies suitable for establishing tolerable levels are sparse.

Mink is a particularly susceptible species for PCB toxicity, and effects on the reproduction seem to be the critical endpoint. Adverse effects were observed at the lowest dosage 0.64 mg/kg feed (wet weight meat) (Platonow and Karstad, 1973), which can be considered as a LOAEL for wet weight feed, corresponding to 2 mg/kg dried feed. The meat was from cows fed with the technical PCB, Aroclor 1254. However, it must be considered that technical mixtures such as Aroclors and weathered mixtures of PCB may also contain congeners with dioxin-like (DL-) effects, which could have an impact on the observed effect. In mink receiving a diet containing 5.0 mg/kg feed of the NDL-PCBs 136 or 153 for three months (approximately 0.25 mg/kg b.w. per day), no adverse reproductive effects were observed, but slightly altered brain dopamine concentrations were determined.

In laying hens fed a diet for eight weeks containing a weathered mixture of primarily PCBs, with total PCB levels at 0.3 (control), 0.8 and 6.6 mg/kg (measured as sum Aroclors; resulting in an estimated intake of 0.02, 0.05 and 0.40 mg/kg b.w. total PCBs per day), dose-depending effects on the hatching rate and embryo mortality were observed. With increasing dietary PCB levels, the hens hatched more seldom when receiving the high dose, and embryo deformities (e.g. oedema and haemorrhage in the head, neck, abdomen and deformed legs, skull, brain and yolk-sac) were observed at both dose levels. The NOAEL derived from this study was 0.02 mg/kg b.w. (reported by EFSA, 2005). In broiler chicken fed with Aroclor 1254 at concentrations of 0.1, 1, 5, 10 or 20 mg/kg in the diet from hatching to eight weeks of age, dose-dependent, significant growth reduction and increased mortality (10 and 30 % of the animals) were found at 10 and 20 mg/kg diet. These results indicated that the NOAEL for chick mortality was 5 mg/kg diet, corresponding to 0.5 mg/kg b.w. per day (reported by EFSA, 2005).

A few studies have been performed with individual NDL-PCB congeners in farm animals (reported by EFSA, 2005): Pregnant goats were orally administered NDL-PCB 153 or DL-PCB 126 three times a week from day 60 of gestation until delivery (13 weeks) at, respectively, doses corresponding to 98 and 0.049 µg/kg b.w. per day. In the female kids exposed to PCB 153 (the dose equivalent to approximately 1.5 mg/kg in the total daily diet), the pre-pubertal concentration of luteinizing hormone (LH) was lower, puberty was delayed and the progesterone level during the luteal phase of the oestrous cycle was increased. Moreover, the kids had a significantly higher number of white blood cells, neutrophils and lymphocytes at two weeks of age compared to controls. From this study a LOEL of 1.5 mg/kg diet for NDL-PCBs has been derived. Kids exposed to PCB 126 had a significantly lower level of monocytes at eight weeks of age and no effect on the lymphocyte proliferation.

In conclusion, these studies on the effects of NDL-PCBs in farm animals indicated a NOAEL of approximately 1 mg/kg diet. When evaluating risks from the presence of PCBs in animal feed it has, however, to be considered that congener patterns in feed, particularly that of plant origin

and in the edible tissue of animals, may differ considerably. Due to the different sources of contamination and the great variety of origins of feed and food commodities, there is generally no correlation between the concentrations of NDL-PCB and DL-PCB Toxic Equivalents (TEQ), or the total TEQ (polychlorinated dibenzo-p-dioxins (PCDD), polychlorinated dibenzofurans (PCDF) and DL-PCB).

Dioxins/furans and dioxin-like PCBs
For individual polychlorinated dioxins, furans and dioxin-like (dl) PCBs analytical results in Norwegian sewage sludge are deficient. Individual congeners are only available from two samples of sewage sludge from two plants. Despite few data, they are included in the present evaluation due to the importance of these toxicants. Sum toxicological equivalents (TEQ) of seven four-eight chlorinated dioxins are 0.46 and 1.14 ng/kg. Corresponding sums of ten four-eight chlorinated furans are 0.26 and 0.64 ng/kg, and of four four-six chlorinated non-ortho PCBs are 0.16 and 0.61 ng/kg. Mean of the two samples for dioxins, furans and dl-PCBs are respectively 0.80, 0.45 and 0.39 ng TEQ/kg, and mean of all groups of the dioxin-related compounds are 1.6 ng TEQ/kg. As a rough estimate we consider the fate of the sum of the dioxin-related compounds rather similar as for ∑PCB6, which was estimated in sewage sludge in the present assessment to be 24.3 µg/kg. Total ration for lactating cows grazing on pasture treated with standard amounts of sewage sludge and where the animals also were supplied with compound feed from cereal field treated with standard amount of sludge, was estimated to contain 0.0063 µg/kg of ∑PCB6 after one sludge application. Thus, estimated concentration of sum dioxin-related compounds for grazing lactating cows after one sludge application is 0.41 pg TEQ/kg total ration. If we consider an 8-fold accumulation over 100 years (ten sludge applications), the total ration for the lactating cows would contain 3.3 pg TEQ/kg of the sum dioxin-related compounds. Another example, for laying hens at pasture, the estimated concentration of sum dioxin-related compounds after one sludge application is 0.79 pg TEQ/kg total ration and after 100 years 6.3 pg TEQ/kg.

For laying hens, a NOAEL of 5.6 ng/kg b.w. per day of TCDD and corresponding LOAEL of 1.1 µg/kg bw per day was identified, showing that egg production had ceased after 12 days of treatment with a high dose of TCDD (referred by EFSA 2018). These data correspond to NOAEL 93 ng/kg and LOAEL 18 µg/kg diet for the laying hens. In chicks, a NOAEL of 0.1 µg TCDD/kg b.w. per day was observed, a 10-fold higher dose showing mortality. TEQ for TCDD = 1.

For mink, a NOAEL of 2.1 ng/kg b.w. per day of TCDD and lowest LOAEL of 4.6 ng/kg b.w. per day was observed in a two-generation study following oral exposure to TCDD, showing proliferation of the squamous gingival epithelium in the mouth of juveniles (EFSA, 2018).

8.5.6.2 DDTs

The model for high-lactating cows used in this risk assessment predicted that the intake level of ∑DDTs from grazing on a pasture in the year following a single application of sewage sludge and from compound feed prepared from cereals harvested in the application year would amount to 0.0035 µg/kg total ration. Of this, 91 % would come from the uptake of soil under grazing. For animals that ingest even more soil or eat relatively more than dairy cows, the ∑DDT intake would increase correspondingly. For instance, for growing pigs and adult sheep, the corresponding ∑DDT intake levels are estimated to 0.011 and 0.070 µg/kg total ration respectively.

According to the model predictions, the concentrations of ∑DDT in soil will have increased 6- to 7-fold after 100 years of repeated sewage sludge applications, leading to an intake level of 0.023 µg/kg total ration. If the cows received only foraged grass and compound feed, the estimated ∑DDT exposure would be 0.00031 and 0.0019 µg/kg total ration, respectively, after the first and tenth sludge applications.

The sensitivity to DDT exposure varies with species, strain, age, gender, health status and fat depot. Lean animals are more susceptible to intoxications than fat animals, since the lipophilic contaminants are deposited in the body fat. Acute toxicity occurs from stimulations of the central nervous system. Symptoms can vary considerably but are predominantly neuromuscular. The onset of clinical signs depends on the dose ingested (Humphreys, 1988). The symptoms of chronic toxicity are similar to those of acute toxicity but usually develop more gradually, and tremors, convulsions and depression may persist for weeks. Liver enlargement and necrosis are common, and also hormonal tissues, reproduction, foetal development and the immune system get frequently affected (Humphreys, 1988).

No clinical or reproductive effect was observed in dairy cows and heifers fed with doses up to 600 mg DDT/kg diet (17mg/kg b.w. per day) for two months before expected parturition (EFSA, 2006). Effects on reproduction were neither observed in ewes at doses of 10 mg o,p'-DDT/kg diet (0.3 mg/kg b.w. per day). However, sheep fed daily with 250 mg technical DDT/kg diet (7 mg/kg b.w. per day) for 10 or 16 weeks had increased liver microsomal enzyme activity (EFSA, 2006).

In chicken, the adrenal cortical function and liver glycogen level were decreased by technical DDT at a level of 5 mg/kg diet (0.5 mg/kg b.w. per day). Studies in laying hens showed reduced egg production and eggshell thickness, and the derived NOAELs were between 0.5 to 18 mg/kg b.w. per day (7.5 to 300 mg/kg DM diet) (EFSA, 2006). In ducks, a NOAEL for 10 mg p,p'-DDT/kg diet (0.6 mg/kg b.w. per day) and LOAELs for p,p'-DDE and DDD at 10 mg/kg diet (0.6 mg/kg b.w. per day) were determined based on reproductive effects. Considering the mineral composition of the eggshell, the NOAEL for p,p'-DDE was 1 mg/kg diet (0.06 mg/kg b.w. per day) (EFSA, 2006).

In conclusion, birds are relatively more sensitive to DDT exposure than other farm animals, with a NOAEL of about 1 mg/kg diet. The absorption from the gut is almost complete at low doses (< 1 mg/kg b.w.) in all investigated species if there is fat in the diet, which acts as a carrier (EFSA, 2006). The accumulation ratio calculated for the sum of p,p'-DDT and p,p'-DDE residues in adipose tissue relative to the p,p'-DDT levels in feed varied from 2.2 in sheep to 6 - 30 in broilers. The reported values in beef cattle for p,p'-DDT only were in the 0.7 - 0.9 range, whereas they were in the 11 - 26 range for p,p'-DDE (EFSA 2006).

8.5.6.3 Other chlorinated pesticides (Hexachlorobenzene, HCB)

The prediction model for high lactation cows indicated that the intake level of HCB from grazing on a pasture in the year following a single application of sewage sludge and from compound feed prepared from cereals harvested in the application year would amount to 0.00034 µg/kg total ration. According to the model predictions, the HCB concentrations in soil will have increased 2-fold after 100 years of repeated sewage sludge applications, leading to an intake level of 0.00059 µg/kg in cows' total ration consisting of grass, soil and compound feed. If the cows received only foraged grass and compound feed, the estimated HCB exposure would be close to zero since the main intake results from soil uptake under grazing.

HCB toxicity is mainly recognisable by disturbances of the nervous and hormonal systems, and the liver. The NOEL for lambs has been set to 0.1 mg/kg diet based on hepatic enzyme induction. In growing pigs, a NOAEL of approximately 1 mg/kg diet based on hepatic effects was derived. In broiler cockerels, 10 mg/kg diet did not show any adverse hepatic and adrenal effects. The lowest feed concentration (125 mg/kg diet) given to laying hens elicited adverse hepatic effects and was thus considered as LOAEL (EFSA Journal 2006).

In conclusion, the NOAEL for farm animals is about 1 mg HCB/kg diet.

8.5.6.4 Chlorinated paraffins

Three groups of chlorinated paraffins are measured and detected in sewage sludge – short chain (SCCPs), middle chain (MCCPs) and long chain chlorinated paraffins (LCCPs). Estimated concentrations in the total ration for grazing high lactating cows after a single application of sludge are 0.30, 1.4 and 0.74 µg/kg, respectively. Soil intake constitutes the major contribution to the ration, estimated to constitute 73, 75 and 76 %. The corresponding estimated intake of these chemicals for non-grazing cows are 0.07, 0.35 and 0.13 µg/kg, respectively. The chlorinated paraffins accumulate in soil, and an 8-fold increase would be expected after 100 years (10 sludge applications) based on similar levels in the sludge in the future.

EFSA (2020) has assessed chlorinated paraffins in feed and food and did not identify studies of adverse effects in ruminants and pigs, but two relevant studies in poultry are reported. In a study in broiler chickens, the diet was supplemented with SCCPs up to 100 mg/kg feed for 31 days. Significantly lower mean live weights and higher relative spleen weights at the highest dosage level were observed, and 100 mg/kg feed was considered as the LOAEL. Laying hens were fed with a diet supplemented with SCCPs up to 100 mg/kg feed for 8 weeks and performance and relative organ weights were monitored. No significant effects were observed, and 100 mg/kg feed was considered as the NOAEL. In developmental and reproductive studies in rabbits, NOAEL were identified for SCCPs at 10 mg/kg b.w. per day (developmental effects) and for MCCPs at 100 mg/kg b.w. per day (developmental and maternal effects), and furthermore a NOEL for LCCPs at 1000 mg/kg b.w. per day was defined. For rats, EFSA (2020) identified reference points based on BMDL10 of 2.3 mg/kg b.w. per day for increased incidence of nephritis in male rats for SCCPs, and of 36 mg/kg b.w. per day for increased relative kidney weights in male and female rats for MCCPs.

8.5.6.5 Brominated flame retardants (BFRs)

The prediction model for high lactation cows indicated that the intake level of BFR, measured as the sum of six brominated diphenyl ethers, ∑BDE6, from grazing on a pasture in the year following a single application of sewage sludge and from compound feed prepared from cereals harvested in the application year would amount to 0.0072 µg/kg total ration. Of this, 94 % would come from the uptake of soil under grazing. For animals that ingest even more soil or eat relatively more than dairy cows, the ∑BDE6 intake would increase correspondingly. For instance, for growing pigs and adult sheep, the corresponding ∑BDE6 levels are estimated to 0.023 and 0.014 µg/kg total ration, respectively.

According to the model predictions, the soil concentrations of ∑BDE6 will have increased 9-fold after 100 years of repeated sewage sludge applications, leading to an intake level of 0.067 µg/kg total ration. If the cows received only foraged grass and compound feed, the estimated

∑BDE6 exposure would be 0.00045 and 0.0037 µg/kg total ration, respectively, after the first and tenth sludge applications.

The total exposure to BFRs comprises a huge number of other compounds than BDE6, of which several are also found in sewage sludge. Of these, PBDE-209, decabromo-diphenyl-ethane and tetrabromo-bisphenol A are all expected to occur at higher levels in animal diets produced on areas treated with sludge than ∑BDE6. The exposure was estimated to, respectively, 0.121, 0.0099 and 0.0093 µg/kg total ration for grazing dairy cows in the first year after a single application of sludge. Accordingly, exposure to the sum of the 20 BFRs, for which quantitative data in soil and plants exist, in grazing dairy cows was estimated to 0.16 µg/kg total ration after a single sludge application. After 100 years (10 applications), the corresponding sum of 20 BFRs was predicted as 1.4 µg/kg total ration.

Health effects of BFRs in farm animals are sparsely known (EFSA, 2024), but the effect profiles of these compounds seem to be rather similar to those of PCBs, affecting the nervous, endocrine, reproductive and immune systems. The differences in the neurotoxic potency of BDEs and PCBs are apparently small, and additive effects have been suggested (Kodavanti et al. 2018). Since relevant toxicological data for farm animals for the determination of a tolerable level for the chronic dietary intake of BFRs are lacking, the same NOAEL at 1 mg/kg feed as for PCBs is applied here.

8.5.6.6 Perfluorinated chemicals (PFCs)

The prediction model for high lactation cows indicated that the intake level of PFC, measured as the sum of four per- and polyfluoroalkyl substances ∑PFAS4 (PFOS, PFOA, PFHxS, PFNA), to high lactation cows, from grazing on a pasture in the year following a single application of sewage sludge and from compound feed prepared from cereals harvested in the application year would amount to 0.021 µg/kg total ration. Of this, 25 % would come from uptake of soil under grazing. For animals that ingest even more soil or eat relatively more than dairy cows, the PFAS intake would increase correspondingly, but far less than for PCBs, DDTs and BFRs. For instance, for growing pigs or adult sheep, the corresponding ∑PFAS4 levels are estimated to 0.035 and 0.022 µg/kg total ration, respectively. The PFCs are extremely persistent, and as a group, their half-life in soil is almost infinite.

According to the model predictions, the soil concentrations of ∑PFAS4 will have increased 2-fold after 100 years of repeated sewage sludge applications, leading to an intake level of 0.041 µg/kg total ration. If the cows received only foraged grass and compound feed, the estimated ∑PFAS4 exposure would be 0.016 and 0.033 µg/kg total ration, respectively, after the first and tenth sludge applications.

Not all congeners included in the more comprehensive ∑PFAS22 were detected in the analysed Norwegian sewage sludge samples. According to the prediction model, the ∑PFAS22 levels in soil, grass and compound feed would be about twice as high as the ∑PFAS4 levels. Considering all 14 PFCs detected in the sewage sludge (including ∑PFAS4), the dietary exposure in grazing dairy cows was estimated at 0.065 and 0.16 µg/kg total ration, after, respectively, one and ten sludge applications.

Furthermore, some PFCs are not expected to transfer into plants but are taken up by grazing dairy cows through soil ingestion. The sum of 13 PFCs from this category contributed an additional exposure of 0.0064 and 0.048 µg/kg total intake after, respectively, the first and

tenth sludge applications. Notably, PFCs with high affinity to soil showed also a somewhat higher potential for bioaccumulation in soil.

There are currently no data on the toxicological effect potency and tolerable levels of PFCs in farm animals (Kodavanti et al. 2018; Peritore et al. 2023). In the EFSA evaluation on human health risk from the dietary exposure to PFOS and PFOA (congeners in ∑PFAS4), which sums up toxicological developmental and longtime studies performed in laboratory animals (EFSA, 2018; EFSA, 2020), PFOS and PFOA exert developmental neurotoxic effects in rodents already at doses of 0.1 to 0.3 mg/kg b.w. per day. A dose of 1 mg/kg diet can thus not be considered as safe for rodents, and consequently neither for farm animals. Because the group of PFCs is very large and chemically heterogenous, the effect patterns and potencies may vary considerably, and the uncertainty for tolerance in farm animals is enormous.

8.5.6.7 Polycyclic aromatic hydrocarbons (PAHs)

The exposure of farm animals to PAHs was calculated based on ∑PAH8 or ∑PAH16. Using the prediction model established in this risk assessment, the intake levels in high-lactation cows from grazing on a pasture in the year following a single application of sewage sludge and from compound feed prepared from cereals harvested in the application year would amount to, respectively, 0.24 and 0.65 µg/kg total ration. Of these, 90-91 % would come from the uptake of soil under grazing. For animals that ingest more soil or eat relatively more than dairy cows, the PAH intake would increase correspondingly. For instance, for grazing growing pigs and adult sheep, the corresponding estimated intake of ∑PAH16 would be 1.99 and 1.31 µg/kg total ration, respectively. If the cows received only foraged grass and compound feed, the estimated ∑PAH16 exposure would be 0.063 µg/kg total ration after the first sludge application.

PAHs are generally predicted to accumulate in soil, and ∑PAH16 soil concentrations will have increased about 5-fold after 100 years of repeated sewage sludge applications, leading to an intake level of 3.4 µg/kg total ration for dairy cows. ∑PAH8 constitute 36 % of the ∑PAH16 level in soil after one application, and 55 % after 100 years, indicating that some of the most persistent PAHs belong to ∑PAH8.

Exposure PAHs can lead to a variety of adverse effects in animals, including carcinogenic, teratogenic, genotoxic, immunotoxic, neurotoxic as well as reproductive- and endocrine-disrupting effects (Sun et al., 2021). The effect pattern and potency of the individual compounds appear to be different, and safe levels in farm animals have not been determined. Based on carcinogenic effects in mice, the BMDL10 for PAH8 was set to 0.49 mg/kg b.w. per day. This value was used as point of departure for human risk characterisation (reported by EFSA, 2008). Based on an approximate feed intake of 13 % related to their respective body weights, this would correspond to a level of 3.5 - 4 mg/kg feed. However, cancer is not the most critical effect in relatively short-lived farm animals, and neither are data from mice the best basis for predicting adverse effects, but in lack of other data, the BMDL10 was used as an indicative value in this risk assessment.

8.5.6.8 Phosphate plasticisers and flame retardants

Various phosphate compounds used as plasticisers or flame retardants were detected in sewage sludge. Stabilities, accumulation potentials and uptake kinetics in plants vary considerably between individual compounds.

Using the prediction model established in this risk assessment, the intake levels of tri-1-chloro-2-propyl-phosphate (tris-chloropropyl-phosphate; TCPP) and tris-2-butoxyethyl-phosphate (TBEP) in high-lactation cows from grazing on a pasture in the year following a single application of sewage sludge and from compound feed prepared from cereals harvested in the application year would amount to, respectively, 1.3 and 0.95 µg/kg µg/kg total ration. Of these, respectively 57 and 82 % would come from the uptake of soil under grazing. The estimated intake levels in non-grazing cows have thus been calculated to, respectively, 0.55 and 0.18 µg/kg total ration after a single sludge application. The estimated half-lives in soil are about 0.5 and 4 years, respectively, and neither have a significant potential for accumulating in soil.

2-Ethyl-hexyl-diphenyl-phosphate has an estimated intake level of 0.38 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 93 %. For non-grazing cows, the intake level is 0.026 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

Dibutyl-phosphate has an estimated intake level of 0.14 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 65 %. For non-grazing cows, the intake level is 0.047 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

Triphenyl-phosphate has an estimated intake level of 0.078 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 78 %. For non-grazing cows, the intake level is 0.018 µg/kg total ration. It is expected that the compound accumulates in soil during 100 years of repeated sewage sludge applications by 50 %.

Tri-1,3-dichloro-2-propyl-phosphate has an estimated intake level of 0.058 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 81 %. For non-grazing cows, the intake level is 0.011 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

Tri-2-chloro-ethyl-phosphate has an estimated intake level of 0.046 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 52 %. For non-grazing cows, the intake level is 0.022 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

Tri-isobutyl-phosphate has an estimated intake level of 0.035 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 75 %. For non-grazing cows, the intake level is 0.0091 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications.

Tri-isopropyl-phenyl-phosphate has an estimated intake level of 0.022 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 89 %. For non-grazing cows, the intake level is 0.0023 µg/kg total ration. The predicted half-life in soil is about 40 years. It is expected that the compound accumulates 8-fold in soil during 100 years of repeated sewage sludge applications.

2-Isopropyl-phenyl-diphenyl-phosphate has an estimated intake level of 0.020 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.002 µg/kg total ration. It is

expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications.

Tetraphenyl-resorcinol-di-phosphate has an estimated intake level of 0.017 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 88 %. For non-grazing cows, the intake level is 0.0018 µg/kg total ration. The predicted half-live in soil is about 40 years. It is expected that the compound accumulates 7-fold in soil during 100 years of repeated sewage sludge applications.

Diphenyl-phosphate has an estimated intake level of 0.015 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 67 %. For non-grazing cows, the intake level is 0.0049 µg/kg total ration. The predicted half-life in soil is relatively short (6 months). No significant accumulation in soil is expected from repeated sludge applications.

Tri-propyl-phosphate has an estimated intake level of 0.0076 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 63 %. For non-grazing cows, the intake level is 0.0029 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

Bis-2-butoxy-ethyl-hydrogenphosphate has an estimated intake level of 0.0041 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 61 %. For non-grazing cows, the intake level is 0.0016 µg/kg total ration. The predicted half-life in soil is relatively short (6 months). No significant accumulation in soil is expected from repeated sludge applications.

Tri-o-cresyl-phosphate has an estimated intake level of 0.0016 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 94 %. For non-grazing cows, the intake level is 0.00012 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

Furthermore, dibutyl-phenyl-phosphate has been detected in sewage sludge, but an uptake into plants is not expected according to the model predictions. The intake level from soil in grazing dairy cows has been estimated to 0.0011 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

Chemicals within this group may elicit various toxic effects, including endocrine disruption, in experimental animals but at relatively high levels. The chemical of quantitative dominance in animal ration – tris-chloropropyl-phosphate (TCPP) – is studied for subchronic and chronic toxicities in rats (2.5 – 20 g/kg diet) and mice (1.25 – 20 g/kg diet) (NTP, 2023). Concentration-related effects on weight gain, organ weights and microscopic changes were observed in rats and mice from 2.5 g/kg diet. In two-year studies, increased incidences of carcinomas, particularly in liver, were observed in rats and mice at 20 and 10 g/kg diet, respectively.

For tris-2-butoxyethyl-phosphate (TBEP), toxicity studies in experimental animals have shown that liver is the major target organ. Based on an 18-week repeated dose study in rats, the NOEL for liver effects was reported to be 15 mg/kg b.w. per day, while LOEL was 150 mg/kg b.w. per day (WHO, 2000).

2-Ethyl-hexyl-diphenyl-phosphate has been shown to induce dose-response related liver toxicities and lung oxidative stress and pyroptosis in poultry chicks exposed by gavage from

age 7 days for up to 42 days (Yang et al. 2022; Sun et al., 2025). The doses were 800, 1600 and 3200 mg/kg bw per day, compared with controls.

Triphenyl-phosphate was administered via dosed feed at 0, 1, 3, 10 or 15 g/kg diet to rats from gestation day 6 through postnatal day 28 and offspring were given similarly dosed feed further on to postnatal day 56 (Witchey et al. 2023). Dose-related effects on body weight in dams and offspring and delays in pubertal endpoints were observed at lowest dosage level and above.

Due to their estimated long half-lives and accumulation, tri-isopropyl-phenyl-phosphate and tetraphenyl-resorcinol-di-phosphate are also hazard evaluated.

Tri-isopropyl-phenyl-phosphate (isopropylated triphenyl phosphate; IPP) was fed to rats for 90 days in diets estimated to deliver daily doses of 0, 5, 20, 70 and 140 mg/kg b.w per day (Wade et al. 2019). The exposure caused a dose-related increase in liver and adrenal gland weight. Cells in the zona fasciculate (ZF) of the adrenal cortex were filled with droplets that were suggested to contain neutral lipid, but there was no change in basal or stress-induced serum levels of their major secreted ZF product corticosterone, suggesting cell function was not altered. There were no effects on responses to glucose or insulin challenge, but serum levels of fructosamine were elevated by the exposure, suggesting a slight tendency of exposed animals to be hyperglycemic. Serum levels of total cholesterol and high-density lipoprotein cholesterol were significantly elevated at the two highest doses. The study indicated that the exposure causes hypertrophy and neutral lipid accumulation in adrenal cortex ZF cells but not impaired corticosterone production. In a study of reproductive and developmental toxicity, IPP was administered via dosed feed at 0, 1, 3, 10 or 15 g/kg diet to rats from gestation day 6 through postnatal day 28 and offspring were given similarly dosed feed further on to postnatal day 56 (Witchey et al. 2023). Dose-related effects on body weight in dams and offspring and delays in pubertal endpoints were observed at lowest dosage level and above.

Data for tetraphenyl-resorcinol-di-phosphate are from Environmental Agency 2009: In a 28-day mouse oral toxicity study with particular emphasis on immune toxicity, treatment with tetraphenyl resorcinol diphosphate at up to 5 g/kg b.w. per day did not elicit any treatment-related changes suggestive of general toxicity or immunotoxicity, and this level was therefore considered to be the oral NOAEL in mice. For rats there were lack of effects in studies of reproductive and developmental toxicity in rats with up to 20 g/kg diet. In a developmental study on rabbits, no treatment-related effects were observed in dams or fetuses dosed with up to 1 g/kg b.w. per day. Thus, a NOAEL for developmental toxicity for tetraphenyl resorcinol diphosphate is greater than 1 g/kg b.w. per day, corresponding to approximately 10 g/kg total ration.

8.5.6.9 Other organophosphates

Other organophosphates present in sewage sludge with potential availabilities in rations for farm animals are the following chemicals with use for various technical purposes such as lubricant additives, hydraulic fluids, pesticides, coatings, finishings, inks, and oil well drilling defoamer.

Bis-2-ethylhexyl-phosphate (BEHP) has an estimated intake level of 4.9 µg/kg total ration in grazing dairy cows. For non-grazing cows, the intake level is 4.6 µg/kg total ration. Grass/forage and cereals are considered as the main sources, and the contribution from soil ingestion for grazing dairy cows is 10 %. No accumulation in soil is expected.

Tri-butyl-phosphate (TBP) has an estimated intake level of 0.016 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 99 %. For non-grazing cows, the intake level is 0.00014 µg/kg total ration. The predicted half-life in soil is rather short (some days). No significant accumulation in soil is expected from repeated sludge applications.

4-Isopropyl-phenyl-diphenyl-phosphate has an estimated intake level of 0.011 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 91 %. For non-grazing cows, the intake level is 0.0012 µg/kg total ration. The predicted half-life in soil is about 4 years. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications.

Bis-2-ethylhexyl-phosphate (BEHP) acts as a corrosive. Rats were administered BEHP by gavage for 28 days at 20, 60 and 180 mg/kg b.w. per day (Pelletier et al. 2020). Effects on haematology and clinical chemistry were mostly limited to the 180-mg/kg-group, but epithelial cell apoptosis and necrosis accompanied by hyperplasia and hyperkeratosis were unambiguously observed in the non-glandular forestomach of both males and females at the 60-and 180-mg/kg dose levels. Based on this salient but most likely transitory and reversible response to this mildly corrosive chemical accompanied with impaired weight gains observed in males from the same treatment groups, the NOAEL was estimated at 20 mg/kg b.w. per day.

Tri-butyl-phosphate (TBP) was administered in the diet at 0, 200, 700 and 3000 mg/kg to rats for two years (Auletta et al. 1998). Body weight gain decreased at 3000 mg/kg, and a dose-related increase in the incidence and severity of urinary bladder hyperplasia and the incidence of urinary bladder papillomas was evident at 700 and 3000 mg/kg diet. The NOEL for chronic toxicity was 200 mg/kg diet. TBP was negative in genotoxicity tests, suggesting that the tumours were induced by nongenotoxic mechanisms. In male mice, TBP at 50 and 100 mg/kg b.w. per day decreased sperm count and motility, damaged testicular structure, and induced apoptosis after 35 days of oral gavage (Wang et al. 2025). In addition, TBP caused inflammation in the mouse small intestine and led to gut microbiota dysbiosis and metabolic profile alterations and increased the abundance of *Prevotellaceae,* which are negatively associated with sperm motility.

8.5.6.10 Other flame retardants

Pentachlorobenzene has an estimated intake level of 0.00039 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. The half-life in soil is with about 400 years extremely long. It is expected that the compound accumulates 6-fold in soil during 100 years of repeated sewage sludge applications.

Dechlorane 604 and dechlorane 602 have estimated intake levels of, respectively, 0.00033 and 0.0000075 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contributions from soil amount to, respectively, 91 and 90 %. Their half-lives in soil are with more than 1000 years extremely long. It is expected that the compounds accumulate 10-fold in soil during 100 years of repeated sewage sludge applications.

Dechlorane Plus Anti and dechlorane Plus Syn have both been detected in sewage sludge, but they are not expected to be taken up into plants. The intake levels from soil have been estimated as, respectively, 0.0012 and 0.00028 µg/kg total ration in grazing dairy cows. It is expected that the compounds accumulate 9-fold in soil during 100 years of repeated sewage sludge applications.

2,4,6-Tribromanisole has an estimated intake level of 0.000014 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 93 %. For non-grazing cows, the intake level is 0.0000014 µg/kg total ration. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications.

Pentachlorbenzene have shown neurotoxic effects in rat pups where their mothers were fed 250 mg/kg or more in the diet (Linder et al. 1980). Dechlorane Plus was studied for clinical, pathological and reproductive effects in rats given repeated oral doses by gavage, where the NOEL was 5 g/kg b.w. per day Brock et al. 2010). For 2,4,6-tribromanisole, NOAEL for oral study with rats was determined to be 1000 mg/kg b.w. per day (Koschier et al. 2011).

8.5.6.11 Phthalates

Phthalates occur regularly in sewage sludge, and some congeners are estimated to be present at high levels in soil. The estimated plant uptake is low, and accidental intake with soil is the major contributor to the exposure in grazing animals. Phthalates are used as plasticizers in the manufacturing of flexible vinyl, which is widely used in consumer products. The lowest-molecule weight phthalates are commonly used in personal care products and as solvents and plasticizers for technical and pharmaceutical products.

The phthalate congener with the highest level in the sewage sludge samples is bis-2-ethylhexyl-phthalate (DEHP). Using the prediction model established in this risk assessment, the intake level in high-lactation cows from grazing on a pasture in the year following a single application of sewage sludge and from compound feed prepared from cereals harvested in the application year would amount to 9.6 µg/kg total ration. Of these, 90 % would come from the uptake of soil under grazing. For animals that ingest more soil or eat relatively more than dairy cows, the DEHP intake would increase correspondingly. For instance, for growing pigs and adult sheep, the corresponding estimated intake level of would be 29.0 and 19.1 µg/kg total ration, respectively.

According to the model predictions, the soil concentrations of DEHP will have increased 2-fold after 100 years of repeated sewage sludge applications, leading to elevated levels in farm animals. The half-life of DEHP in soil is about 4 years.

For decyl-isoundecyl-phthalate, di-cyclo-hexyl-phthalate, dibutyl-phthalate, butyl-benzyl-phthalate, diiso-butyl-phthalate, 2-ethylhexyl-hydrogen-phthalate and bis-2-ethyl-hexyl-tetrabromo-phthalate, the estimated intake levels for grazing dairy cows are estimated to be 0.68, 0.051, 0.048, 0.041, 0.038, 0.0015 and 0.00099 µg/kg total ration, respectively. Of these, respectively, 93, 97, 99, 88, 99, 99 and 90 %, would come from soil ingestion. Only bis-2-ethyl-hexyl-tetrabromo-phthalate is expected to accumulate (8-fold) over a period of 100 years with repeated sewage sludge applications.

Thus, estimated intake levels of bis-2-ethyl-hexyl-phthalate (DEHP), decyl-isoundecyl-phthalate, di-cyclo-hexyl-phthalate, dibutyl-phthalate, butyl-benzyl-phthalate, diiso-butyl-phthalate, 2-ethylhexyl-hydrogen-phthalate and bis-2-ethyl-hexyl-tetrabromo-phthalate in non-grazing dairy cows after one sludge application are estimated to 0.97, 0.047, 0.0013, 0.00033, 0.0053, 0.00015, 0.00002 and 0.0001 µg/kg, respectively.

The phthalates are endocrine disrupters, mainly classified as antiandrogens. The most critical effects caused by phthalates concern reproduction. Tolerance levels for farm animals are lacking. A group-TDI for phthalates in humans, expressed as DEHP equivalents, has been

proposed at 50 µg/kg b.w. per day (EFSA Panel on Food Contact Materials, 2019). With DEHP being predicted to have the highest intake levels in animals after sewage sludge applications, the human TDI can also be considered as relevant for farm animals. For dairy cows with a daily feed intake equivalent to about 4 % of their body weight this would correspond to an intake level of 1.3 mg/kg total ration per day.

8.5.6.12 Bisphenols

Bisphenols are a group of chemicals commonly used in the production of plastics and epoxy resins. They are generally taken up into plants at considerable levels, particularly into grass/forage. They have rather short half-lives (approximately 6 months) in soil and are not expected to accumulate after repeated sewage sludge application, there are, however, exceptions for some bisphenols.

Bisphenol A has an estimated intake level of 0.85 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 42 %. For non-grazing cows, the intake level is 0.52 µg/kg total ration.

Bisphenol S has an estimated intake level of 0.51 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts only to 5 %. For non-grazing cows, the intake level is 0.51 µg/kg total ration.

Bisphenol F has an estimated intake level of 0.22 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 43 %. For non-grazing cows, the intake level is 0.14 µg/kg total ration.

2,2'-Bisphenol F has an estimated intake level of 0.052 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to only 19 %. For non-grazing cows, the intake level is 0.044 µg/kg total ration.

2,4'-Bisphenol F has an estimated intake level of 0.0077 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 42 %. For non-grazing cows, the intake level is 0.0047 µg/kg total ration.

Bisphenol E has an estimated intake level of 0.0018 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 29 %. For non-grazing cows, the intake level is 0.0014 µg/kg total ration.

Bisphenols with lower plant uptake ($t_{1/2\_soil}$ about *4 years, accumulation in soil possible)*
Bisphenol AF has an estimated intake level of 0.0036 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 88 %. For non-grazing cows, the intake level is 0.00046 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

Bisphenol G has an estimated intake level of 0.0022 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 89 %. For non-grazing cows, the intake level is 0.00023 µg/kg total ration. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications.

Bisphenol B has an estimated intake level of 0.00092 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 72 %. For non-

grazing cows, the intake level is 0.00028 µg/kg total ration. It is expected that the compound accumulates 1.5-fold in soil during 100 years of repeated sewage sludge applications.

Sum of these bisphenols has an estimated intake level of 1.6 µg/kg total ration in grazing dairy cows and 1.2 µg/kg total ration for non-grazing cows. For dairy cows with a daily feed intake equivalent to about 4 % of their body weight these figures correspond to respectively 64 and 49 ng/kg b.w. per day.

Bisphenol A is an endocrine disrupting chemical with oestrogen-like and anti-androgenic properties (Tarafdar et al., 2022; EFSA, 2023). However, the toxicity of bisphenol A and other bisphenols is multifaced with comprehensive data from experimental studies in rodents and *in vitro*, primarily for bisphenol A (BPA), but data from farm animals are lacking. The immune system has been identified as most sensitive with a BMDL 8.2 ng/kg b.w. per day for BPA in mice. Recognising the uncertainties, a TDI of 0.2 ng/kg b.w. per day was established. Also, the toxic potential of other bisphenols may be significant and some of the analogues are shown to exhibit oestrogenic or anti-androgenic activities like or even greater than that of bisphenol A (Chen et al. 2016).

Thus, the estimated exposure of bisphenols in grazing and no-grazing dairy cows are respectively 8 and 6 times higher than the BMDL level for immune effects in mice.

8.5.6.13 Other plasticisers

2,2,4-Trimethyl-1,3-pentanediol-di-isobutyrate (TPIB) has an estimated intake level of 0.013 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 72 %. For non-grazing cows, the intake level is 0.0046 µg/kg feed. No significant accumulation in soil is expected from repeated sludge applications.

Hexabromo-benzene has an estimated intake level of 0.0018 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 94 %. For non-grazing cows, the intake level is 0.00012 µg/kg feed. No significant accumulation in soil is expected from repeated sludge applications.

Toxicity of TPIB has been reviewed by the Risk Science Center, University of Cincinnati, USA (RSC, 2018). TPIB caused kidney toxicity in rats after exposure ranging from 28 days to 90 days. Observed effects included increased kidney weight, CPN and hyaline droplet accumulation in male rats, but not in female rats, at 750 mg/kg b.w. per day. Decreased total litter weight and litter size, and decreased number of implants and number of corpora lutea were reported in a reproductive/developmental toxicity screening assay. The NOAEL for reproductive or developmental toxicity was identified at the mid dose, 276 mg/kg b.w. per day for males and 359 mg/kg b.w. per day for females.

8.5.6.14 Rubber-related compounds

Abietic acid and dehydroabietic acid are natural tricyclic diterpenoids, used in various industrial applications such as stabilizer in synthetic rubber. Abietic acid and dehydroabietic acid have estimated intake levels of 0.14 and 0.080 µg/kg total ration in grazing dairy cows after one application of sewage sludge. Their contribution from soil amounts to 88-90 %. For non-grazing cows, the intake levels are 0.014 and 0.0099 µg/kg total ration. Their estimated half-life in soil is about 4 years but no significant accumulation in soil is expected from repeated sludge applications.

1,3-Diphenyl-guanidine has an estimated intake level of 0.031 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 31 %. For non-grazing cows, the intake level is 0.022 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications.

2-Mercapto-benzo-thiazole has an estimated intake level of 0.017 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 88 %. For non-grazing cows, the intake level is 0.0017 µg/kg total ration. The estimated half-life in soil is about 6 months but no significant accumulation in soil is expected from repeated sludge applications.

Abietic acid and dehydroabietic acid have several bioactive properties but rather low toxicity in mammals (EFSA, 2023; Hao et al. 2022). EFSA considers a NOAEL for rats for abietic acid above 25 mg/kg b.w. per day (EFSA, 2023). For 1,3-diphenyl-guanidine, rats fed 1500 mg/kg diet or more and mice fed 750 mg/kg diet and more showed reduced feed intake and body weights (NTP, 1995).

For 2-mercapto-benzo-thiazole, 13-week gavage studies in rats and mice showed a LOAEL of 188 mg/kg b.w. per day for rats on the basis of increased relative liver weights, and a NOAEL of 188 mg/kg b.w. per day for mice on the basis of lethargy, and at the next dose level of 375 mg/kg b.w. per day for developing rough coats (reported by Health Canada (2025)).

8.5.6.15 Corrosion inhibitors

Benzotriazole has an estimated intake level of 0.16 µg/kg total ration in grazing dairy. The contribution from soil amounts to 61 %. For non-grazing cows, the intake level is 0.066 µg/kg total ration. The estimated half-life in soil is only 6 months. No significant accumulation in soil is expected from repeated sludge applications.

5-Methyl-benzotriazole (tolyltriazole) has an estimated intake level of 0.030 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 93 %. For non-grazing cows, the intake level is 0.0019 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

The toxicities of benzotriazole and tolyltriazole are characterised by Health Canada (2025). For benzotriazole, the NOAEL for systemic toxicity in rats was 30 mg/kg b.w. per day based on kidney effects in adult females at higher doses, while the NOAEL for reproductive and developmental effects was 300 mg/kg b.w. per day. For tolyltriazole, the NOAEL for systemic toxicity in rats was 150 mg/kg b.w. per day based on haematological and clinical biochemical effects at higher doses.

8.5.6.16 Technical UV-chemicals

The following UV-chemicals are phenolic benzotriazoles used as light stabilisers in industrial products for technical purposes.

UV-329 has an estimated intake level of 0.56 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 94 %. For non-grazing cows, the intake level is 0.039 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications.

UV-328 has an estimated intake level of 0.0059 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.00060 µg/kg total ration. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications.

UV-327 has an estimated intake level of 0.0016 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 94 %. For non-grazing cows, the intake level is 0.00017 µg/kg total ration. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications.

UV-320 has an estimated intake level of 0.00029 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 94 %. For non-grazing cows, the intake level is 0.000020 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications.

The toxicities of the phenolic benzotriazoles UV-329 and -320 have been characterised by Health Canada (2025). The NOAEL for chronic exposure in rats was 0.1 mg/kg b.w. per day based on blood and liver effects in male rats. Phenolic benzotriazoles exhibit diverse toxicological profiles and mechanisms, including AHR activation leading to disrupted xenobiotic metabolism and endocrine signalling (Ling et al., 2025). Endocrine disruption arises from ER/ERR agonism and antiandrogenic activity, notably potent oestrogenic effects from UV-P. Oxidative stress underlies tissue damage and inflammation. Additional mechanisms involve disrupted lipid metabolism, mitochondrial dysfunction, and caspase-mediated apoptosis.

8.5.6.17 Pigments and dyes

Pigment Orange 13, pigment Red 14, pigment Red 112, and pigment Red 146 have estimated intake levels of, respectively, 0.029, 0.028, 0.0071 and 0.0049 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amount to 90 %. For non-grazing cows, the levels of intake are thus approximately 1/10 lower. The estimated half-lives in soil are about 40 years. It is expected that the compounds accumulate 8-fold in soil during 100 years of repeated sewage sludge applications.

The toxicity of these pigments is very low and totally outside the scope as hazard for farm animals exposed via sewage sludge.

2-Methyl-antraquinone and 4-methoxy-N-phenyl-o-toluidine have estimated intake levels of, respectively, 0.016 and 0.0048 µg/kg µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contributions from soil amount to, respectively, 49 and 33 %. For non-grazing cows, the intake levels are, respectively, 0.0082 and 0.0033 µg/kg total ration. The half-life of the compounds in soil are about 6 months. No significant accumulation in soil is expected from repeated sludge applications.

For antraquinone, a NOAEL of 470 mg/kg diet (31 mg/kg b.w. per day) in subchronically exposed rats based on absence of liver histopathology was identified (Dodd et al., 2013). No corresponding toxicity data have been identified for 2-methyl-antraquinone, and neither for 4-methoxy-N-phenyl-o-toluidine.

8.5.6.18 Solvents

Toluene has been detected in sewage sludge but is not expected to be taken up into plants. The intake level from soil has been estimated as 0.022 µg/kg total ration in grazing dairy cows. No significant accumulation in soil is expected from repeated sludge applications.

p-Xylene and o-xylene have both been detected in sewage sludge, but they are not expected to be taken up into plants. The intake levels from soil have been estimated as, respectively, cows 0.0023 and 0.0017 µg/kg total ration in grazing dairy cows. No significant accumulation in soil is expected from repeated sludge applications.

Ethylbenzene has been detected in sewage sludge but is not expected to be taken up into plants. The intake level from soil has been estimated as 0.0021 µg/kg total ration in grazing dairy cows. No significant accumulation in soil is expected from repeated sludge applications.

The solvents have short half-lives and the estimated levels in soil available for animals at the time for grazing are very low. Only the hazard of toluene has been characterised here. When toluene was given to rats and mice by gavage at doses of 0, 312, 625, 1,250, 2,500 or 5,000 mg/kg of b.w. per day for 5 days a week for 90 days (RAIS, 1994), increases in liver and kidney weights and neurological effects were observed at high doses. NOAELs were set to 312 mg/kg b.w. in rats and 1250 mg/kg b.w. in mice.

8.5.6.19 Antioxidants

n,n'-Diphenyl-1,4-phenylene-diamine (DPPD) has an estimated intake level of 0.13 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 35 %. For non-grazing cows, the intake level is 0.086 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

4-tert-Butylphenol has an estimated intake level of 0.038 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 53 %. For non-grazing cows, the intake level is 0.018 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

4,4'-Methylene-bis-2,6-ditert-butylphenol has an estimated intake level of 0.038 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 92 %. For non-grazing cows, the intake level is 0.0041 µg/kg total ration. The estimated half-life in soil is about 40 years. It is expected that the compound accumulates 8-fold in soil during 100 years of repeated sewage sludge applications.

Butylated hydroxytoluene has an estimated intake level of 0.019 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 87 %. For non-grazing cows, the intake level is 0.002 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

2,4,6-Tri-tert-butylphenol has an estimated intake level of 0.0044 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 91 %. For non-grazing cows, the intake level is 0.00045 µg/kg total ration. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications.

4,4'-Butane-1,1-diylbis-2-tert-butyl-5-methylphenol has an estimated intake level of 0.0042 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 88 %. For non-grazing cows, the intake level is 0.00044

µg/kg total ration. The estimated half-life in soil is about 40 years. It is expected that the compound accumulates 8-fold in soil during 100 years of repeated sewage sludge applications.

For DPPD, the NOAELs in rats after repeated oral dose toxicity and reproduction/developmental toxicity were considered to be 1000 and 8 mg/kg b.w. per day, respectively (Matsumoto et al. 2013). The other antioxidant compounds were detected at lower concentrations in sewage sludge, far lower than those that are shown to elicit adverse effects in rats.

8.5.6.20 Phenolic disinfectants

Cresols are phenolic disinfectants with are irritant and corrosive at sufficient concentrations. m-Cresol, o-cresol and p-cresol have estimated intake levels of, respectively, 0.12, 0.11 and 0.12 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contributions from soil amount to 99 %. For non-grazing cows, the intake levels are, respectively, 0.0010, 0.00082, and 0.0010 µg/kg µg/kg total ration. Cresols have a short half-life in soil and are not expected to accumulate from repeated sludge applications.

The concentrations are considered to be far lower than those that can elicit health damage in farm animals (Humphreys 1988).

8.5.6.21 Surfactants

Chemicals grouped as surfactants have been detected in sewage sludge at considerable levels and are expected to occur in animal rations at relatively high concentrations. Grass/forage is considered the main source for the quantitatively dominating compounds, with smaller contributions from cereals and soil. However, there are also detected surfactants that do not transfer into plants at a substantial ratio. Half-lives in soil can range between 6 months and 4 years, but significant accumulation in soil is not expected from repeated sludge applications every tenth year for 100 years. Surfactants can have topical effects by irritating skin and damaging mucous membranes after ingestion.

Sodium p-n-dodecylbenzene sulfonate (SDDBS) has an estimated intake level of 11.7 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to only 3 %. For non-grazing cows, the intake level is 12.0 µg/kg total ration. The compound is not expected to accumulate significantly in soil.

Sodium p-n-decylbenzene sulfonate has an estimated intake level of 1.9 µg/kg total ration in grazing dairy cows. Also, for non-grazing cows, the intake level is estimated to 1.9 µg/kg total ration. The contribution from soil amounts to only 5 %. No accumulation in soil is expected.

Rats given SDDBS orally at a varying dosage of 2.5-5.0 mL/kg b.w. per day of a 15 % formulation (corresponds to 375-750 mg/kg b.w. per day) for 22 weeks showed decrease in growth rate and mild necrosis of intestinal mucosa and hemosiderosis of the spleen, liver and kidneys. No lesions were observed in rats given SDDBS at 0.5 mL/kg b.w. per day (corresponds to 75 mg/kg b.w. per day) (reported by The American College of Toxicology, 1993). Dogs exposed with 10 to 1000 mg/kg b.w. per day of 15 % SDDBS in the diet for 6 months developed haemorrhagic necrosis of the intestine and infiltration of inflammatory cells at 10 mg/kg and hemosiderosis of the liver and spleen at 100 and 1000 mg/kg (reported by The American College of Toxicology, 1993). There were minimal data available on sodium decylbenzene sulfonate, but the Expert Panel determined that due to the chemical similarity of sodium

dodecylbenzene sulfonate (SDDBS) and sodium decylbenzene sulfonate, the data concerning SDDBS that were presented in the report were applicable in assessing the safety of sodium decylbenzene sulfonate (The American College of Toxicology, 1993).

Nonylphenol-diethoxylate (NP2EO) is a chemical in the group nonylphenol ethoxylates which are non-ionic surfactant, used as ingredient in detergents, in personal care products and in industrial processing, such as polymerisation and polymer stabilisation. NP2EO has an estimated intake level of 0.17 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.019 µg/kg total ration. The estimated half-life in soil is about 40 years. It is expected that the compound accumulates 7-fold in soil during 100 years of repeated sewage sludge applications.

4-Nonyl-phenol is a starting component in NPE production and is also a component in polymer production. It has an estimated intake level of 0.0056 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.00056 µg/kg total ration. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications.

Other related phenolic chemicals, 4-Tert-octylphenol monoetoxylate (OP1EO) and 4-tert-octylphenol have been detected at lower concentrations, mainly in soil.

Nonylphenols and their ethoxylates have xenoestrogenic effects in mimicking oestrogen and are irritating at high concentrations (Chokwe et al. 2017). Oral toxicity studies (90-days) exist for nonyphenol ethoxylates in rats and dogs (reported by Nielsen et al. 1999). NOAELs ranging between 40 and 160 mg/kg b.w. per day for rats and a NOEL of 40 mg/kg b.w. per day for dogs were set. For nonyl-phenol, a LOAEL of 15 mg/kg b.w. per day in developmental/reproductive studies in rat was identified.

8.5.6.22 Technical biocides

Hexadecyl-trimethyl-ammonium has been detected in soil but is not expected to transfer into plants. Based on the estimated soil intake, an intake level of 1.5 µg/kg total ration has been predicted in grazing dairy cows. No significant accumulation in soil is expected from repeated sludge applications.

Dimethyl-dioctyl-ammonium (DDAC) has an estimated intake level of 0.47 µg/kg total ration in grazing dairy cows. The uptake in plant is considered neglectable, so non-grazing cows receiving forage are hardly exposed. For animals that ingest even more soil or eat relatively more than dairy cows, the DADMAC-C8 intake would increase correspondingly. For instance, for growing pigs and adult sheep, the corresponding intake levels are estimated to, respectively, 1.6 and 0.95 µg/kg total ration respectively. The half-life in soil is short (approximately 2 weeks) and the compound does not accumulate.

Benzyl-dimethyl-dodecyl ammonium (benzodedecinium) has an estimated intake level of 0.23 µg/kg total ration in grazing dairy cows. Soil is the main source of exposure (74 % contribution) so that non-grazing cows receiving forage are much less exposed (0.061 µg/kg total ration). For animals that ingest even more soil or eat relatively more than dairy cows, the compound intake would increase correspondingly. For instance, for growing pigs and adult sheep, the corresponding benzyl-dimethyl-dodecyl ammonium intake levels are estimated to,

respectively, 0.61 and 0.42 µg/kg total ration respectively. The compound is not expected to accumulate significantly in soil.

Chloroxylenol has an estimated intake level of 0.0084 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 55 %. For non-grazing cows, the intake level is 0.0039 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications.

Hexadecyl-trimethyl-ammonium, dimethyl-dioctyl-ammonium (DDAC) and benzyl-dimethyl-dodecyl ammonium (benzodedecinium) are quaternary ammonium compounds (QACs) which are irritating chemicals which can elicit systemic toxicity at certain doses (Camagay & Connolly, 2023), but NOAELs or other tolerance levels for oral exposure are not identified for the chemical detected. Effective concentrations of QACs against microorganisms are considered considerably higher (ppm-levels) (Boyce, 2023), than those estimated in rations for animals produced with sewage sludge.

The safety of chloroxylenol was assessed by The American College of Toxicology (1985). Rats fed 60 or 120 mg/kg b.w. per day for 13 weeks had increased salivation, haematological changes and increased liver and kidney weights. Dogs given 6, 12, 60 or 120 mg/kg b.w. showed a dose related increase in liver weight. Minimum inhibitory concentrations *in vitro* were 0.10, 0.004 and 0.01 % (equivalent to 1, 0.04 and 0.1 g/L) for, respectively, *P. aeruginosa*, *B. subtilis* and *A. niger*.

8.5.6.23 Siloxanes

Siloxanes are used as emulsifiers or lubricants in cosmetics but also in technical products such as house paint. Deca-methyl-cyclo-penta-siloxane (D5), dodeca-methyl-cyclo-hexa-siloxane (D6), octa-methyl-cyclo-tetra-siloxane, dodeca-methyl-penta-siloxane (L5), deca-methyl-tetra-siloxane (L4), hexa-methyl-di-siloxane and poly-phenyl-methyl-siloxane, octamethyl-tri-siloxane and hexa-methyl-cyclo-tri-siloxane have been determined in sewage sludge at different levels. Their half-lives in soil range from about 4 to 400 years but as rather volatile chemicals, their accumulation is low or absent.

Deca-methyl-cyclo-penta-siloxane (D5), dodeca-methyl-cyclo-hexa-siloxane (D6), dodeca-methyl-penta-siloxane (L5), deca-methyl-tetra-siloxane (L4) and poly-phenyl-methyl-siloxane have estimated intake levels of, respectively, 1.5, 0.68, 0.18, 0.022 and 0.004 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contributions from soil amount to about 90 to 93 %. For non-grazing cows, the intake levels are reduced to about 1/10. The estimated half-lives in soil are about 4 years. It is expected that the compounds accumulate 2-fold in soil during 100 years of repeated sewage sludge applications.

Octa-methyl-cyclo-tetra-siloxane (D4), hexa-methyl-di-siloxane and octamethyl-tri-siloxane have estimated intake levels of, respectively, 0.23, 0.014 and 0.004 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contributions from soil amount to about 90 to 93 %. For non-grazing cows, the intake levels are reduced to about 1/10. The estimated half-lives in soil are about 4 years but no significant accumulation in soil is expected from repeated sludge applications.

Hexa-methyl-cyclo-tri-siloxane has an estimated intake level of 0.0000017 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts

to 100 % so that non-grazing cows are only exposed to trace amounts. The estimated half-life in soil is 400 years, but the model did not find it to accumulate in soil.

Most toxicological studies of siloxanes were based on inhalation, but there are some oral studies, which are considered more relevant for exposure in farm animals via sludge application. For deca-methyl-cyclo-penta-siloxane (D5), orally administered to rats for 5 days/week over 4 weeks, the NOAEL in males was 100 mg/kg b.w. per day, but no NOAEL was identified in females (< 25 mg/kg b.w. per day) based on increased liver weight (Dekant & Klaunig, 2016). For dodeca-methyl-cyclo-hexa-siloxane (D6), a NOAEL of 1500 mg/kg b.w. per day was established in a repeated dose toxicity study after oral administration to rats (Ko et al. 2024). For octa-methyl-cyclo-tetra-siloxane (D4), a 14-day repeated oral dose study by gavage in rats resulted in a NOAEL of 100 mg/kg b.w. per day based on increased liver weight at higher doses (Andersen 2022). Based on the available data, dodeca-methyl-penta-siloxane (L5) is not expected to cause severe adverse health effects following repeated oral exposure (IMAP, 2018).

8.5.6.24 Other technical chemicals

2,7-Diisopropylnafthalene and 2,6-diisopropylnafthalene are substitutes of PCBs used in carbonless copy paper etc. They have estimated intake levels of, respectively, 0.017 and 0.015 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contributions from soil amount to 90 %. For non-grazing cows, the intake levels are, respectively, 0.0018 and 0.0015 µg/kg total ration. The half-lives of the compounds in soil are about 4 years. It is expected that the compounds accumulate 2-fold in soil during 100 years of repeated sewage sludge applications. The toxicity of these compounds is considered very low (Hoke & Zellerhoff, 1998).

Dioctyl-tin has an estimated intake level of 0.0034 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 89 %. For non-grazing cows, the intake level is 0.00038 µg/kg total ration. The estimated half-life in soil is about 40 years. It is expected that the compound accumulates 7-fold in soil during 100 years of repeated sewage sludge applications. The NOAEL for various toxicological effects in rats after a 6-week oral exposure study with dioctyl tin was 5 mg/kg b.w. per day (ATSDR 2005).

8.5.6.25 Cosmetics

Fragrances

Several fragrances used in perfumes, cosmetic creams, soaps and detergents have been detected in sewage sludge – some at rather high concentrations, with considerably long half-lives in soil and the potential to be transferred into plants.

Galaxolide has an estimated intake level of 3.4 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.36 µg/kg total ration. The estimated half-life in soil is about 40 years. It is expected that the compounds accumulate 6.5-fold in soil during 100 years of repeated sewage sludge applications, leading to an intake level of 22 µg/kg total ration in grazing cows.

Galaxolidone has estimated intake levels of 1.4 µg/kg µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amount to 90 %. For non-grazing cows, the intake levels are reduced to 1/10. The half-life in soil is about 4 years. It is

expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications.

Galaxolide is agonist for androgen receptor. Subchronic reproductive toxicity studied in mature male rats show reduced sperm concentration and motility, increased sperm deformity, and atrophy of the seminiferous tubules in the testicles (Li & Wang, 2023). Furthermore, galaxolide exposure reduced testosterone level, and induced luteinizing hormone, and follicle-stimulating hormone levels in rat serum. Compared with the control group, the levels of oxidative stress markers in the serum and testicular tissue increased. Galaxolide also inhibited expression of the genes involved in androgen synthesis in testicle. In a developmental toxicity study pregnant rats were dosed galaxolide by gavage at 0, 50, 150 and 500 mg/kg b.w. per day on days 7-17 of pregnancy (reported by IMAP, 2019). The reported maternal NOAEL was 50 mg/kg bw per day based on reductions in body weight gain during the dosing period. The developmental NOAEL was 150 mg/kg bw per day based on skeletal malformations at the highest dose. In a 90-day oral study, rats received galaxolide via diet resulting in an average daily intake of 5, 16, 52 or 155 mg/kg bw per day (reported by IMAP, 2019). Reported NOAEL was 155 mg/kg b.w. per day.

Galaxolidone is a metabolite of galaxolide and a fragrance that seem to be less toxic for mammals, but relevant hazard data is lacking.

Isocyclemone E has estimated intake level of 1.6 µg/kg µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amount to 90 %. For non-grazing cows, the intake levels are reduced to 1/10. The half-life in soil is about 4 years. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge application.

Isocyclemone E and related chemicals (OTNE) are considered of low toxicity in mammals (Scognamiglio et al. 2013).

Tonalide has an estimated intake level of 0.88 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 93 %. For non-grazing cows, the intake level is 0.061 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications.

Tonalide was fed to rats for 13 weeks where NOAEL of 5 mg/kg bw per day was reported based on dose-dependent changes in haematological and biochemistry parameters at 15 and 50 mg/kg bw per day (referred by IMAP, 2019)

Cashmeran has an estimated intake level of 0.13 µg/kg µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is reduced to 0.013 µg/kg total ration. The half-life of the compound in soil is about 4 years. It is expected that the compounds accumulate 1.5-fold in soil during 100 years of repeated sewage sludge applications. Cashmeran is considered to have low toxicity to mammals and no potential to act as an endocrine disruptor (Tayal et al. 2024).

Methyl-2,6,6-trimethyl-cyclohexene-1-carboxylate has an estimated intake level of 0.0072 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 98 %. For non-grazing cows, the intake level is 0.00016 µg/kg total ration. The estimated half-life in soil is about 1.5 months. No significant accumulation in soil is expected from repeated sludge applications. The chemical has low toxicity.

Traseolide and celestolide have estimated intake levels of, respectively, 0.0065 and 0.0040 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contributions from soil amount to about 90 %. For non-grazing cows, the intake levels are reduced to 1/10. The half-lives of the compounds in soil are about 4 years. It is expected that the compounds accumulate 2-fold in soil during 100 years of repeated sewage sludge applications. Phantolide has an estimated intake level of 0.0037 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.00037 µg/kg total ration. The estimated half-life in soil is short. No significant accumulation in soil is expected from repeated sludge applications.

Traseolide, celestolide and phantolide are synthetic polycyclic fragrances with assumed low mammalian toxicity, but they are lipophilic with potential for bioaccumulation. Potential to act as endocrine disrupters are not clarified (Washam, 2005; IMAP, 2017).

UV-filters
Octocrylene has an estimated intake level of 1.5 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.15 µg/kg total ration. The estimated half-life in soil is about 4 years. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications.

For octocrylene, the NOAEL from a 90-day rat dietary toxicity study was 175 mg/kg b.w. per day, based on liver, thyroid, and pituitary effects at higher dose levels that produced hepatic enzyme induction (Norman et al. 2025). The NOAEL for parental systemic, reproductive, and developmental toxicity from an extended one-generation reproductive toxicity study in rats was 153/163 mg/kg b.w. per day (males/females).

Octyl-methoxy-cinnamate, 4-Methoxy-cinnamate and 2-ethyl-hexyl-trans-4-methoxy-cinnamate have different CAS-numbers but seem to be the same chemical or their names are mixed in scientific literature and often commonly called octinoxate. They have estimated intake levels of, respectively, 0.085, 0.049 and 0.047 µg/kg total ration in grazing dairy cows. The corresponding intake of the sum of them are 0.18 µg/kg total ration. The contributions from soil are close to 100 % so that non-grazing cows are only exposed to trace amounts. The half-lives of the compounds in soil are only approximately 2 weeks. No significant accumulation in soil is expected from repeated sludge applications.

Octinoxate is considered not to be toxic in mammalian studies, but studies of endocrine related toxicity are inconclusive (IMAP 2017). Danish Environmental and Food Ministry (2015) referred toxicity data and reported a NOAEL at 450 mg/kg b.w. per day in rats subchronically fed with octinoxate.

Benzofenone-3 has an estimated intake level of 0.031 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 42 %. For non-grazing cows, the intake level is 0.019 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications.

Benzofenone-3 shows low toxicity in mammals (Danish Environmental and Food Ministry (2015; Ghazipura et al., 2017). In rat studies, NOAEL are reported for oral subchronic toxicity at 411 mg/kg b.w. per day, for development and maternal toxicity at 200 mg/kg b.w. per day and for reproductive toxicity at 400 mg/kg b.w. per day (referred Danish Environmental and Food Ministry (2015).

4-Metyl-benzyliden-kamfer has an estimated intake level of 0.015 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 92 %. For non-grazing cows, the intake level is 0.0012 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications.

Toxicity studies of 4-Metyl-benzyliden-kamfer with repeated oral exposure have been conducted in rats, referred by the Danish Environmental and Food Ministry (2015). The lowest NOAEL at 25 mg/kg b.w. per day was based on thyreoidea effects.

Cosmetic biocides
The cosmetic biocides triclosan and triclocarban have estimated intake levels of, respectively, 0.37 and 0.036 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contributions from soil amount to about 89 %. For non-grazing cows, the intake levels are, respectively, 0.04 and 0.004 µg/kg total ration. The half-lives of the compounds in soil are, respectively, 4 and 40 years. It is expected that the compounds accumulate, respectively, 2- and 7-fold in soil during 100 years of repeated sewage sludge applications.

Triclosan may elicit a diversity of toxic effects including endocrine disruption. Several studies have demonstrated oestrogenic activity and anti-androgenic activity of triclosan (SCCS, 2022). A NOAEL of 8 mg/kg b.w. per day for triclosan from reproductive toxicity studies in rats is identified.

A NOAEL of 25 mg/kg b.w. per day for triclocarban based on a 2-year chronic feeding study in rats is identified (SCCS, 2022).

Microbial resistance and cross-resistance from biocides such as triclosan in sewage sludge cannot be excluded but these effects are more likely to occur in microorganisms in soil directly exposed to sewage sludge than at far lower concentrations in farm animals.

Cosmetic preservatives
Methylparaben has an estimated intake level of 0.34 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.044 µg/kg total ration. The estimated half-life in soil is only 2 weeks. No significant accumulation in soil is expected from repeated sludge applications. Subchronic and chronic oral studies indicate that parabens such as methylparaben are practically nontoxic (Andersen, 2008).

8.5.6.26 Bioactive compounds in food

Caffeine has an estimated intake level of 0.015 µg/kg total ration in grazing dairy cows. The contribution from soil amounts to 93 %. For non-grazing cows, the intake level is 0.0011 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications.

Caffeine is not assumed to elicit health effects in farm animals at this level.

8.5.6.27 Drugs

Hazards with the dietary exposure to drugs in animals and humans are characterised in **Chapter 8.2**. Data for the individual drugs are available in **Appendix II**. In the evaluation of drugs, both the intended pharmacological effect and potential adverse side effects have been considered as both are undesirable regarding dietary exposure from food and feed. Moreover, drugs are especially designed to be effective at low levels. However, in the evaluation of

specific hazards to farm animals, with focus on high-yielding lactation cows, performed in the present **Chapter 8.5**, only drugs were considered that were analysed in at least 10 sewage sludge samples collected at in minimum two water treatment plants and were quantified in at least 10 % of the samples. Considering that lactating cows consume a feed amount equivalent to 4 % of their b.w. (**Table 8.5.1-1**), daily doses of feedborne drugs were estimated. These were compared to the acceptable daily intake (ADI) defined for humans (**Appendix II**) since toxicity data for farm animals are generally lacking. As previously, the drugs are sorted according to the ATC system. The short descriptions about pharmacological and toxicological effects have been retrieved from Drugbank (**Table 1.4.2-1**).

ATC A - Alimentary tract and metabolism
Loperamide is a long-acting anti-diarrheal drug, affecting opioid receptors in intestinal muscles. Chronic ingestion can cause cardiac effects that can become life-threating at high doses. Loperamide has an estimated intake level of 0.0053 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.00058 µg/kg total ration. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications, reaching an intake level comparable to a daily dose of 0.00042 µg/kg b.w., which is below the predicted ADIp of 1.3 µg/kg b.w./day in humans.

ATC C - Cardiovascular system
Hydrochlorothiazide is a diuretic and antihypertensive drug that is used to treat oedema and hypertension. Adverse effects include hypotension and respiratory impairment cause ion imbalances, especially hypokalemia, hypochloremia and hyponatremia. Hydrochlorothiazide has an estimated intake level of 0.018 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 83 %. For non-grazing cows, the intake level is 0.0036 µg/kg total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 2.5 µg/kg b.w./day in humans.

Bisoprolol is used to prevent myocardial infarction and heart failure, and to treat mild to moderate hypertension. Adverse effects connected to this β-blocker include hypotension, congestive heart failure and bradycardia. Bisoprolol has an estimated intake level of 0.00097 µg/kg total ration in grazing dairy cows after one application of sewage sludge. Grass/forage is the major source of exposure. For non-grazing cows, the intake level is 0.0007 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be far below the predicted ADIp of 1.4 µg/kg b.w./day in humans.

Propranolol is a β-antagonist mainly used to treat hypertension. Adverse effects include hypotension and hypoglycaemic seizures. Propranolol has an estimated intake level of 0.0096 µg/kg total ration in grazing dairy cows after one application of sewage sludge. Grass/forage and soil are major sources of exposure. For non-grazing cows, the intake level is 0.005 µg/kg total ration. The estimated half-life in soil is 4 years. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications. However, the daily dose after a sludge application is still expected to be far below the predicted ADIp of 32 µg/kg b.w./day in humans.

Valsartan is an angiotensin II receptor blocker used to manage hypertension. Common adverse effects hypotension, abdominal pain and hyperkalemia. Valsartan has an estimated intake level of 0.36 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 75 %. For non-grazing cows, the intake level is 0.096 µg/kg total ration. The estimated half-life in soil is about 400 years. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications, resulting in a daily dose that is still expected to be below the predicted ADIp of 40 µg/kg b.w./day in humans.

Candesartan is also an angiotensin-receptor blocker for the treatment of hypertension. Adverse side effects include hypotension, decreased kidney and liver functions, and hyperkalemia. Candesartan has an estimated intake level of 0.096 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 67 %. For non-grazing cows, the intake level is 0.034 µg/kg f total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 0.5 µg/kg b.w./day in humans.

Telmisartan is another angiotensin-receptor blocker for the treatment of hypertension. Common adverse side effects are hypotension, dizziness and tachycardia. Telmisartan has an estimated intake level of 0.099 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.01 µg/kg total ration. The estimated half-life in soil is 40 years. It is expected that the compound accumulates 7-fold in soil during 100 years of repeated sewage sludge applications, resulting in an intake level of 0.73 µg/kg total ration, comparable to a daily dose of 0.03 µg/kg b.w., which is below the predicted ADIp of 0.3 µg/kg b.w./day in humans.

Irbesartan is also an angiotensin receptor blocker used to treat hypertension, delay progression of diabetic nephropathy and treat congestive heart failure. Side effects include hypotension, tachycardia or bradycardia. Irbesartan has an estimated intake level of 0.017 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the estimated ADIp of 300 µg/kg b.w./day in humans.

Atorvastatin is a lipid-lowering statin inhibiting the endogenous production of cholesterol in the liver by inhibiting the hydroxymethylglutaryl-coenzyme A reductase. Adverse side effects include liver damage and seizures. High doses applied in carcinogenic studies in mice have caused liver carcinoma. Atorvastatin has an estimated intake level of 0.065 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 92 %. For non-grazing cows, the intake level is 0.0047 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the TDI of 1 µg/kg b.w./day in humans.

Rosuvastatin is another lipid-lowering statin. Possible adverse side effects are muscle and abdominal pain, and hepatotoxicity. Rosuvastatin has an estimated intake level of 0.00085 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 96 %. For non-grazing cows, the intake level is 0.00003 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge

applications. The daily dose after a sludge application is expected to be far below the predicted ADIp of 40 µg/kg b.w./day in humans.

Fenofibrate lowers plasma cholesterol by altering the lipid metabolism through activation of the peroxisome proliferator activated receptor alpha. Reported side effects include digestive issues, headaches, back pain and photosensitivity. Fenofibrate has an estimated intake level of 0.002 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 85 %. For non-grazing cows, the intake level is 0.00025 µg/kg total ration. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications, resulting in a daily dose that is still expected to be below the predicted ADIp of 100 µg/kg b.w./day in humans.

Sotalol is a methanesulfonanilide beta adrenergic antagonist used to treat life-threatening ventricular arrhythmias and to maintain sinus rhythm. Side effects include bradycardia, hypotension, bronchospasm, and hypoglycemia. Sotalol has an estimated intake level of 0.0099 µg/kg total ration in grazing dairy cows after one application of sewage sludge. For non-grazing cows, the intake level is 0.0056 µg/kg total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be far below the predicted ADIp of 34 µg/kg b.w./day in humans.

Diltiazem is a calcium channel blocker used to treat hypertension and to manage chronic stable angina. Side effects effects include bradycardia, hypotension, heart block, and cardiac failure. Diltiazem has an estimated intake level of 0.00094 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 79 %. For non-grazing cows, the intake level is 0.00021 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be far below the predicted ADIp of 680 µg/kg b.w./day in humans.

Metoprolol is beta-blocker used in the treatment of hypertension and angina. Side effects include bradycardia, hypotension, bronchospasm and cardiac failure. Metoprolol has an estimated intake level of 0.0025 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 100 %. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be far below the predicted ADIp of 170 µg/kg b.w./day in humans.

Verapamil is a non-dihydropyridine calcium channel blocker used in the treatment of angina, arrhythmia, and hypertension. Side effects include hypotension, bradycardia and arrhythmia. Verapamil has an estimated intake level of 0.0024 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 100 %. It is expected that the compound accumulates 8-fold in soil during 100 years of repeated sewage sludge applications, resulting in a daily dose that is still expected to be below the predicted ADIp of 140 µg/kg b.w./day in humans.

ATC D Dermatologicals

Terbinafine is an allylamine antifungal used to treat dermatophyte infections in nails and the skin. Adverse side effects include nausea, vomiting, abdominal pain, dizziness, rash, frequent urination, and headache. Terbinafine has an estimated intake level of 0.035 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 94 %. For non-grazing cows, the intake level is 0.0024 µg/kg total ration. The

estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 70 µg/kg b.w./day in humans.

ATC G Sex hormones
Six sex hormones, consisting of two synthetic progestins, one synthetic oestrogen and three natural oestrogens, have been identified in sewage sludge samples and were included into the assessment of risks for farm animals.

Levonorgestrel is a synthetic progestin used to prevent pregnancy and as an emergency contraceptive. It inhibits ovulation. Side effects include nausea and bleeding. Levonorgestrel has an estimated intake level of 0.035 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 13 %. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application (0.0014 µg/kg b.w./day) is expected to be only slightly below the predicted ADIp of 0.003 µg/kg b.w./day in humans.

When levonorgestrel was given orally to mice for three days at doses of 25, 250 and 2500 µg/kg b.w. per day (Kim et al. 2015), uterus enlargement and ovarian dropsy were detected in mice given 250 µg/kg b.w. and above.

Norethisterone is a synthetic second-generation progestin used to prevent pregnancy and hormone replacement therapy in menopause. It acts similarly to endogenous progesterone but with a much higher potency. Side effects include nausea, bleeding, and there is a risk for the development of breast cancer. Norethisterone has an estimated intake level of 0.0011 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 31 %. No significant accumulation in soil is expected from repeated sludge applications. The animal exposure is considered clearly below predicted ADI.

Ethinylestradiol (EE2) is a synthetic oestrogen used to prevent pregnancy, treat symptoms of menopause and prevent postmenopausal osteoporosis. It inhibits ovulation. Side effects include bleeding, nausea, vomiting, breast tenderness, abdominal pain, drowsiness and fatigue. Ethinylestradiol has an estimated intake level of 0.00044 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 82 %. No significant accumulation in soil is expected from repeated sludge applications. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications. The daily dose after a sludge application is expected to be below the ADI in humans that are given in the range of 0.001 to 0.007 µg/kg b.w./day.

Ethinylestradiol administered at exposure concentrations of 2, 10, or 50 µg/kg diet in a low phytoestrogen diet to rats in a multigenerational reproductive toxicology study showed clear biological activity including potentially adverse effects (NTP, 2010). Both preweaning and postweaning body weights of males and females were decreased during periods of direct exposure to the experimental feed. Ethinylestradiol accelerated the attainment of puberty in females under continuous exposure conditions (F1 and F2) and of animals, where dosing was terminated at weaning (F3). Perturbation of the oestrous cycle in young females after vaginal opening and prior to mating was observed in the F1 and F2 generations. In males, statistically significant inductions of male mammary gland hyperplasia (F0 through F3 generations) and mild mineralisation of renal tubules (F1 and F2 generations) were observed. The majority of these effects were observed at 50 µg EE2/kg diet, but significant effects on body weight

reduction and male mammary gland hyperplasia were observed already at the lowest exposure concentration (2 µg EE2/kg diet).

When a combination contraceptive containing 0.15 mg/kg b.w./day levonorgestrel and 0.03 mg/kg b.w./day ethinylestradiol were given to adolescent rats for 7-21 days (Amedu et al. 2025), significantly increased oxidative stress, as evidenced by elevated MDA levels and reduced SOD activity, were observed after 21 days.

Estrone (E1) is a natural oestrogen used to treat perimenopausal and postmenopausal symptoms. Its oestrogenic potency is one third that of estradiol. Side effects include nausea, breast tenderness, fluid retention and oedema and headaches. Estrone has an estimated intake level of 0.025 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 34 %. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application (0.001 µg/kg b.w./day) is expected to be below the ADI of 0.007 µg/kg b.w./day in humans, but with a small safety margin.

Estradiol (E2) is a natural oestrogen used to manage conditions associated with estrogen deficiency, such as to treat symptoms of menopause, low estrogen, breast cancer and advanced prostate cancer, and to prevent postmenopausal osteoporosis. Side effects include nausea, vomiting, abdominal pain, breast tenderness, venous thrombosis and vaginal bleeding. Estradiol has an estimated intake level of 0.001 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 85 %. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the ADI of 0.05 µg/kg b.w./day in humans.

Estriol (E3) is a natural oestrogen, produced by the placenta during pregnancy. It is used to manage conditions associated with estrogen deficiency. Side effects include headaches, hypertension, dizziness, and blood clots. Estriol has an estimated intake level of 0.0082 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 21 %. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the ADI of 0.007 µg/kg b.w./day in humans.

Hazards connected to residues of natural oestrogens in sewage sludge are most relevant for organisms that are in direct contact with the sludge. Health effects in farm animals are less likely at the present level of these hormones. However, the knowledge is deficient (Wojnarowski et al. 2021).

Moreover, combination effects of different hormone drugs and, also of endocrine disrupting chemicals should be considered. Regarding the predictions of hormone levels in sewage sludge in the present evaluation, it can be expected that the combined concentrations in soil are already close or above the established ADI in humans for ethinylestradiol and estrone. In addition, no sewage sludge data were available for desogestrel, which is a contraceptive widely used in Norway. Accumulation in soil is predicted after repeated sludge applications, and the predicted ADIp is 0.005 µg/kg b.w./day.

ATC J Antiinfectives, systemic

Sulfapyridine is a sulfonamide antibiotic previously used to treat certain skin diseases. It is no longer prescribed, but there are still relatively high levels measurable in sewage sludge. Side effects include blood disorders, skin reactions and liver and kidney toxicity. Sulfapyridine has

an estimated intake level of 0.18 µg/kg total ration in grazing dairy cows after one application of sewage sludge. It transfers almost completely into plants. For non-grazing cows, the intake level is therefore also 0.18 µg/kg total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the ADI of 10 µg/kg b.w./day in humans.

Sulfadiazine is a sulfonamide antibiotic used for urinary tract infections and trachoma. Side effects include blood disorders, skin reactions and liver and kidney toxicity. Sulfadiazine has an estimated intake level of 0.0056 µg/kg total ration in grazing dairy cows after one application of sewage sludge. It transfers almost completely into plants. For non-grazing cows, the intake level is therefore also 0.0049 µg/kg total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the ADI of 20 µg/kg b.w./day in humans.

Sulfamethoxazole is an oral sulfonamide antibiotic, mostly given in combination with trimethoprim, used to treat infections of the urinary tract, respiratory system and gastrointestinal tract. Side effects include bowel issues, blood disorders, liver problems and skin reactions. Sulfamethoxazole has an estimated intake level of 0.0021 µg/kg total ration in grazing dairy cows after one application of sewage sludge. For non-grazing cows, the intake level is 0.0012 µg/kg total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the ADI of 50 µg/kg b.w./day in humans.

Benzothiazolone is a substituted derivative of benzothiazole and used as a scaffold for novel antibiotics with activity against multidrug-resistant pathogens. Adverse effects include gastrointestinal problems, dermal toxicity and respiratory irritation. This compound class has tested positive in gene toxicity assays and is potentially carcinogenic. Benzothiazolone has an estimated intake level of 0.18 µg/kg total ration in grazing dairy cows after one application of sewage sludge. For non-grazing cows, the intake level is 0.15 µg/kg total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 14 µg/kg b.w./day in humans.

Benzothiazol-2-yl-amine is used in the textile industry and as a scaffold for novel antibiotics. Adverse effects include irritation of the skin, eyes and upper respiratory tract. Benzothiazol-2-yl-amine has an estimated intake level of 0.011 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 60 %. For non-grazing cows, the intake level is 0.0051 µg/kg total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 14 µg/kg b.w./day in humans.

Azithromycin is a broad-spectrum macrolide antibiotic used for the treatment of respiratory, enteric and genitourinary infections. Side effects include liver and renal toxicity. Azithromycin has an estimated intake level of 0.13 µg/kg total ration in grazing dairy cows after one application of sewage sludge. For non-grazing cows, the intake level is 0.088 µg/kg total ration. The estimated half-life in soil is 40 years. It is expected that the compound accumulates 3-fold in soil during 100 years of repeated sewage sludge applications, resulting in intake levels of 0.33 and 0.23 µg/kg total ration in, respectively, grazing and non-grazing cows. However, the

corresponding daily doses (µg/kg b.w./day) are expected to be below the acceptable daily exposure (ADE) of 12 µg/kg b.w./day in humans.

Clindamycin is a lincosamide antibiotic used in the treatment of a variety of serious infections and topically for acne vulgaris. Side effects include abdominal pain, nausea, vomiting, and diarrhoea. Clinadmycin has an estimated intake level of 0.0087 µg/kg total ration in grazing dairy cows after one application of sewage sludge. For non-grazing cows, the intake level is 0.007 µg/kg total ration. The estimated half-life in soil is 4 years. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications, resulting in intake levels of 0.013 and 0.0053 µg/kg total ration in, respectively, grazing and non-grazing cows. The corresponding daily doses (µg/kg b.w./day) are expected to be below the predicted ADIp of 30 µg/kg b.w./day in humans.

Clarithromycin is a macrolide antibiotic used for the treatment of acute otitis, pharyngitis, tonsillitis, respiratory tract infections and uncomplicated skin infections. Side effects include diarrhoea, nausea, abnormal taste, dyspepsia, abdominal discomfort, liver toxicity and allergic reactions. Clarithromycin has an estimated intake level of 0.0069 µg/kg total ration in grazing dairy cows after one application of sewage sludge. For non-grazing cows, the intake level is 0.0029 µg/kg total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the ADI of 0.2 µg/kg b.w./day in humans.

Trimethoprim is an antifolate antibiotic used to treat urinary tract infections, or in combination with e.g. sulfamethoxazole to treat eye, lung, and gastrointestinal infections. Side effects include nausea, vomiting, dizziness, headaches, confusion and bone marrow depression. Trimethoprim has an estimated intake level of 0.0008 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 83 %. For non-grazing cows, the intake level is 0.00015 µg/kg total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the ADI of 4.2 µg/kg b.w./day in humans.

ATC L Antineoplastics

Doxorubicin is an anthracycline used to treat various cancers. The drug is mutagenic in *in vitro* assays. Side effects include reduced fertility and cardiovascular dysfunction. Doxorubicin has an estimated intake level of 2.6 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is small (19 %) resulting in an intake level of 2.2 µg/kg total ration in non-grazing cows. No significant accumulation in soil is expected from repeated sludge applications. The level in cows' total ration, equivalent to 0.09 µg/kg b.w. per day, is above the predicted ADIp of 0.05 µg/kg b.w. per day in humans.

Tamoxifen is a selective oestrogen receptor modulator used to treat breast cancer. Side effects include respiratory difficulties and convulsions. Tamoxifen has an estimated intake level of 0.0023 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.00023 µg/kg total ration. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications. N-desmethyltamoxifen is an active metabolite of tamoxifen that should be included into the hazard characterisation. However, the daily dose after the sludge application is expected to be below the predicted ADIp of 0.05 µg/kg b.w./day in humans.

ATC M Anti-inflammatory

Diclofenac is a phenylacetic acid derivative and non-steroidal anti-inflammatory drug (NSAID) used to treat arthritis. Side effects include lethargy, nausea, vomiting and gastrointestinal bleeding. Diclofenac has an estimated intake level of 0.054 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 94 %. For non-grazing cows, the intake level is 0.0035 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the ADI of 0.5 µg/kg b.w./day in humans.

Naproxen is a nonsteroidal anti-inflammatory drug used to treat arthritis, joint inflammation and mild to moderate pain. Side effects include increased blood pressure, upper gastrointestinal bleeding, lethargy, nausea and risk of premature closure of the foetal ductus arteriosus when taken during pregnancy. Naproxen has an estimated intake level of 0.023 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 95 %. For non-grazing cows, the intake level is 0.0016 µg/kg total ration. The estimated half-life in soil is 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 400 µg/kg b.w./day in humans.

ATC N Nervous System

Codeine is an opioid analgesic used to treat moderate to severe pain. Side effects include confusion, somnolence, shallow breathing, constricted pupils, nausea, vomiting, constipation and a lack of appetite. Codeine has an estimated intake level of 0.01 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 54 %. For non-grazing cows, the intake level is 0.005 µg/kg total ration. The estimated half-life in soil is about 40 years. It is expected that the compound accumulates 0.5-fold in soil during 100 years of repeated sewage sludge applications. The daily dose after a sludge application is expected to be below the ADI of 2 µg/kg b.w./day in humans.

Tramadol is a centrally acting opioid agonist used for the management of moderate to severe pain. Side effects include nausea, dizziness, constipation, headaches, and drowsiness. In laboratory animals, embryotoxicity and foetotoxicity have been observed. Tramadol has an estimated intake level of 0.0063 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 60 %. For non-grazing cows, the intake level is 0.0027 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 8 µg/kg b.w./day in humans.

Carbamazepine is an anticonvulsant drug and analgesic drug used to control seizures. Side effects include cardiovascular, neurological, respiratory, urinary, neuromuscular and mild cardiac symptoms. Carbamazepine is one of the chemicals with highest estimated level in gras/forage. It has an estimated intake level of 9.4 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is low so that for non-grazing cows, the intake level is only slightly lower. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications. The estimated daily dose of 0.4 µg/kg b.w/day after a sludge application is expected to be below the ADI of 15.9 µg/kg b.w./day in humans; however, the safety margin is rather small. Furthermore, two metabolites of carbamazepine have been detected in sewage sludge and thus can be expected to occur in soil: 10,11-dihydro-10,11-dihydroxy-carbamazepine and 10,11-dihydrocarbamazepine. The metabolites are not expected to be taken up into plants but the

intake levels in grazing cows from in soil are estimated to 0.0012 and 0.000085 µg/kg, respectively. The metabolites are not expected to accumulate.

Lamotrigine is a phenyltriazine antiepileptic used to treat some types of epilepsy and bipolar I disorder. Side effects include ataxia, nystagmus, increased seizures and decreased levels of consciousness. Lamotrigine has an estimated intake level of 0.1 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is low so that for non-grazing cows, the intake level is only slightly lower. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 3 µg/kg b.w./day in humans.

Gabapentin is a structural analogue of the inhibitory neurotransmitter gamma-aminobutyric acid and used as anticonvulsant to treat certain types of seizures and nerve pain. Side effects include central nervous system (CNS) depression and gastrointestinal symptoms. Gabapentin has an estimated intake level of 0.012 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 90 %. For non-grazing cows, the intake level is 0.00036 µg/kg total ration. The estimated half-life in soil is short (a few days). No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 29 µg/kg b.w./day in humans.

Amisulpride is a dopamine D2 receptor antagonist used in the treatment of acute and chronic schizophrenia. Side effects include cardiovascular and neuropsychiatric symptoms. Amisulpride has an estimated intake level of 0.23 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is low. For non-grazing cows, the intake level is 0.21 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 43 µg/kg b.w./day in humans.

Oxazepam is a 3-hydroxybenzodiazepine used in the treatment of alcohol withdrawal, anxiety, panic disorders and insomnia. Side effects include mild to severe CNS depression. Oxazepam has an estimated intake level of 0.074 µg/kg total ration in grazing dairy and non-grazing cows after one application of sewage sludge since exposure comes mainly from grass/forage. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 0.2 µg/kg b.w./day in humans.

Sertraline is a selective serotonin reuptake inhibitor used to treat major depressive disorder, social anxiety disorder and other psychiatric conditions. Side effects include somnolence, vomiting, tachycardia, nausea, dizziness, agitation and tremor. Sertraline has an estimated intake level of 0.072 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. The estimated half-life in soil is about 4 years. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 20 µg/kg b.w./day in humans.

Norsertraline is the desmethyl-metabolite of sertraline. It has an estimated intake level of 0.035 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The

contribution from soil is high so that the exposure in non-grazing cows is low. The estimated half-life in soil is about 4 years. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 300 µg/kg b.w./day in humans.

Venlafaxine is a selective serotonin and norepinephrine reuptake inhibitor used to treat major depression, anxiety disorder and panic disorder. Side effects include somnolence, paresthesia of the extremities, dizziness, nausea, vomiting, cardiovascular symptoms and liver damage. In pregnant woman, preeclampsia and post-partum haemorrhage have been observed. Venlafaxine has an estimated intake level of 0.017 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 5.4 µg/kg b.w./day in humans.

O-desmethylvenlafaxine is a major, active metabolite of venlafaxine, but also prescribed as drug to treat mood disorders such as depression. Side effects are similar to those observed for venlafaxine. O-desmethylvenlafaxine has an estimated intake level of 0.013 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 8 µg/kg b.w./day in humans.

Citalopram is a selective serotonin reuptake inhibitor used to treat depression. Side effects include cardiovascular effects such as hypotension, hyponatremia, and CNS symptoms. Exposure of pregnant woman can lead to persistent pulmonary hypertension of the newborn and poor neonatal adaptation. In exposed pregnant laboratory animals, reduced foetal weight gain has been observed at increased doses. Citalopram was mutagenic in *in vitro* assays and caused small intestine carcinoma in rats. Moreover, a decrease of fertility was found. Citalopram has an estimated intake level of 0.035 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 1.5 µg/kg b.w./day in humans.

N-desmethylcitalopram is a major, less active metabolite of citalopram. N-desmethylcitalopram has an estimated intake level of 0.03 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 120 µg/kg b.w./day in humans.

Trazodone is is a serotonin uptake inhibitor used to treat major depressive disorder. Side effects include decreased memory, alertness and cognition, as well as priapism, hypotension, cardiovascular and respiratory symptoms. Trazodone has an estimated intake level of 0.0012 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 50 %. For non-grazing cows, the intake level is about 0.0006 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 4 µg/kg b.w./day in humans.

Amitriptyline is a tricyclic antidepressant used to treat symptoms of depression and anxiety. Side effects include low blood pressure, confusion, convulsions, eye problems, disturbed concentration, drowsiness, hallucinations and cardiovascular problems. Amitriptyline has an estimated intake level of 0.048 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. The estimated half-life in soil is about 400 years. It is expected that the compound accumulates 10-fold in soil during 100 years of repeated sewage sludge applications, but the daily dose is still expected to be below the predicted ADIp of 20 µg/kg b.w./day in humans.

Maprotiline is a tetracyclic antidepressant used to treat depression, bipolar disorder, and anxiety. Side effects include neuromuscular symptoms, hypotension, tachycardia and disturbances of consciousness. Maprotiline has an estimated intake level of 0.017 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. The estimated half-life in soil is about 400 years. It is expected that the compound accumulates 8-fold in soil during 100 years of repeated sewage sludge applications, but the daily dose is still expected to be below the predicted ADIp of 4 µg/kg b.w./day in humans.

Mirtazapine is a tetracyclic antidepressant used to treat major depression and insomnia, and to increase appetite. Side effects include hypotension and sedating effects. Mirtazapine is carcinogenic in mice studies causing hepatocellular tumours and thyroid follicular adenoma. It decreases fertility and induces loss of pregnancy in rats. Mirtazapine has an estimated intake level of 0.013 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 1.5 µg/kg b.w./day in humans.

Mianserin is a tetracyclic antidepressant used to treat depression and anxiety. Side effects include drowsiness and haematological problems. Mianserin has an estimated intake level of 0.0071 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 12 µg/kg b.w./day in humans.

Clomipramine is a tricyclic antidepressant used to treat obsessive compulsive disorders and other mood disorders. Side effects include cardiac dysrhythmias, severe hypotension, convulsions and CNS depression. Clomipramine has an estimated intake level of 0.0017 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is high so that the exposure in non-grazing cows is low. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 1 µg/kg b.w./day in humans.

Oxcarbazepine is an anti-epileptic used to treat seizure disorders. Side effects include respiratory and CNS depression, movement-related disorders, nausea and hyponatremia. Oxcarbazepine has an estimated intake level of 0.0063 µg/kg total ration in grazing dairy cows after one application of sewage sludge. For non-grazing cows, the intake level is 0.0059 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 10 µg/kg b.w./day in humans.

Haloperidol is a first-generation antipsychotic used to treat schizophrenia and behavioural issues. Side effects include movement disorders, hyperpyrexia, muscle rigidity, altered mental status, tachycardia and kidney damage. Haloperidol has an estimated intake level of 0.0028 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 86 %. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 0.2 µg/kg b.w./day in humans.

Donepezil is an acetylcholinesterase inhibitor used to treat the behavioural and cognitive effects of Alzheimer's Disease and other types of dementia. Side effects include nausea and vomiting, bradycardia, hypotension, perspiration, seizures, muscle weakness and respiratory depression. Haloperidol has an estimated intake level of 0.0011 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 86 %. The estimated half-life in soil is about 4 years. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications, but the daily dose is still expected to be below the predicted ADIp of 10 µg/kg b.w./day in humans.

Memantine is an N-methyl-D-aspartate receptor antagonist used to treat moderate to severe dementia in Alzheimer's. Side effects include reduced neuronal synaptic plasticity, dizziness, headache, confusion, constipation, sleepiness, nausea, diarrhoea, weight gain and hypertension. Memantine has an estimated intake level of 0.00054 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 75 %. The estimated half-life in soil is about 1.5 years. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 10 µg/kg b.w./day in humans.

Orphenadrine is a muscarinic antagonist used to treat muscle pain and discomfort. Side effects include dry mouth, drowsiness, dizziness, blurry vision and constipation. Orphenadrine has an estimated intake level of 0.000082 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 88 %. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 5 µg/kg b.w./day in humans.

Acetaminophen (paracetamol) is an analgesic used to treat pain and reduce fever. Side effects include kidney and liver damage, and allergic reactions. At high concentrations, evidence of carcinogenic activity has been demonstrated in rats. Acetaminophen has an estimated intake level of 0.017 µg/kg total ration in grazing dairy cows after one application of sewage sludge. For non-grazing cows, the intake level is 0.013 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the ADI of 50 µg/kg b.w./day in humans.

ATC P Antiparasitics

Since in this hazard characterisation for high-lactating cows, a cut-off was employed considering only drugs that were analysed in at least 10 sewage sludge samples collected at in minimum two water treatment plants and quantified in at least 10 % of the samples, none of the drugs in ATC P were evaluated.

ATC R Respiratory System

Chlorhexidine is an antiseptic used to sterilise hands and to treat gum disease. Side effects include gastric distress, nausea and allergic reactions. Chlorhexidine has an estimated intake level of 0.4 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 70 %. For non-grazing cows, the intake level is about 0.13 µg/kg total ration. The estimated half-life in soil is about 4 years. It is expected that the compound accumulates 2-fold in soil during 100 years of repeated sewage sludge applications, but the daily dose is still expected to be below the ADI of 5 µg/kg b.w./day in humans.

Fexofenadine is a selective histamine H1 antagonist used to treat allergic symptoms. Side effects include sedation, dizziness, drowsiness, and dry mouth. Fexofenadine has an estimated intake level of 0.34 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 88 %. For non-grazing cows, the intake level is about 0.045 µg/kg total ration. The estimated half-life in soil is 40 years. It is expected that the compound accumulates 6-fold in soil during 100 years of repeated sewage sludge applications resulting in an intake level of 2.0 µg/kg total ration in grazing cows. However, the corresponding daily dose of 0.08 µg/kg b.w./day is expected to be below the predicted ADIp of 30 µg/kg b.w./day in humans.

Cetirizine is a selective histamine H1 antagonist used to treat symptoms of allergies. Side effects include drowsiness, dry mouth, headache and fatigue. Cetirizine has an estimated intake level of 0.1 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is low. For non-grazing cows, the intake level is about 0.087 µg/kg total ration. The estimated half-life in soil is about 6 months. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 8 µg/kg b.w./day in humans.

Meclozine is a histamine H1 antagonist used to treat nausea, vomiting, and dizziness associated with motion sickness. Side effects include drowsiness, dry mouth, headache, fatigue and constipation. Meclozine has an estimated intake level of 0.0072 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 93 %. For non-grazing cows, the intake level is about 0.00054 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 50 µg/kg b.w./day in humans.

Diphenhydramine is a histamine H1 antagonist used to treat allergic reactions. Side effects include drowsiness, hyperpyrexia, mydriasis, fever, agitation, tremor and cardiovascular symptoms. Diphenhydramine has an estimated intake level of 0.0021 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 81 %. For non-grazing cows, the intake level is about 0.00045 µg/kg total ration. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application is expected to be below the predicted ADIp of 7 µg/kg b.w./day in humans.

ATC V Various

Since in this hazard characterisation for high-lactating cows, a cut-off was employed considering only drugs that were analysed in at least 10 sewage sludge samples collected at in minimum two water treatment plants and quantified in at least 10 % of the samples, none of the drugs in ATC V were evaluated.

8.5.7 Effects on grazing animals from sewage sludge-treated grass

Several studies observing sheep that graze on sewage-treated pastures are available, starting as early as from 1982, when effects on male sheep were examined, showing increased relative weight of the testis after 152 days (Hogue et al., 1984). However, cadmium was the only contaminant analysed in sewage sludge in this study. Since then, the numbers and amounts of chemicals used for all kind of applications have changed substantially, and the composition and load of chemical contaminants in the sludge in 1982 is unlikely to be comparable to the current situation.

8.5.7.1 Tissue and milk residues from sheep grazing on sewage sludge-treated pastures

In a study in ewes and lamb grazing on pasture treated with sewage sludge containing alkylphenols and phthalates twice a year in 3 years, slightly increased phthalate tissue concentrations were determined, while the concentrations of alkylphenols (DEHP and total alkylphenol) did not differ from those in control sheep grazing on non-sludge treated pasture (Rhind et al., 2005). The concentrations of alkylphenols and phthalates in milk from ewes and lamb grazing on pasture treated with sewage sludge twice a year over 3 years were analysed by Rhind et al. (2007). They found that although the levels of alkylphenols and even more so of phthalates varied considerably in these milk samples, they were not statistically different from those in milk samples of animals grazing on soil treated with inorganic fertilisers.

8.5.7.2 Biological effects in sheep grazing on sewage sludge-treated pastures

Biological effects of sheep grazing on pastures treated with sewage sludge twice a year (2.25 tonnes dry weight/hectare) for several years or with mineral fertiliser over years have been reported in a number of studies (**Table 8.5.7-1**). The sheep were not allowed to graze on the pasture for three weeks after the application of sewage sludge. Observed effects in these studies have been published in a series of papers and reviewed in Evans et al., 2014 and Bellingham et al., 2025. The sludge and/or soil in these studies had been analysed for a range of chemical contaminants with known endocrine disrupting effects such as alkylphenols, phthalates, some pesticides, as well as for some well-known contaminants such as PBDEs, PCBs and PAHs. Several heavy metals were also included in the analyses (Rhind et al., 2002; Rhind et al., 2013; Zhang et al., 2015). These studies clearly demonstrated a range of effects in the offspring of ewes that had been grazing on sewage-treated pastures for at least one month prior to mating and until delivery and weaning. The effects described included behaviour changes as well as alterations in testicles, alterations in gonadotropin-releasing hormones and neuroendocrine systems and in the hypothalamus-pituitary gonadal axis (**Table 8.5.7-1)**. Male foetuses appeared to be more sensitive than female. Moreover, cardiovascular diseases observed in adult sheep that had been exposed *in utero* were possibly caused by these contaminants (Khan et al., 2025).

Overall, these studies clearly document that exposure during gestation to contaminants occurring in sewage sludge through grazing of the mother sheep on treated pastures affects the foetal, neonatal and pubertal development as well as reproductive and metabolic functions in adult life (Evans et al., 2014; Bellingham et al., 2025). Based on the available studies, it is not possible to attribute the biological effects to specific contaminants in the sludge. According to the authors of the original papers as well as the review papers, the concentrations of each single component was considered to be too low to have any impact on

the grazing animals, and hence the effects were considered to be a result of the mixture of contaminants present in the sludge (Evans et al., 2014; Bellingham et al., 2025).

Table 8.5.7-1. Studies observing effects in sheep grazing on pastures treated twice yearly for 3 years with sewage-sludge as fertiliser.

Animals	n	Observed effects	References
Pregnant ewes and newborn lamb	40 males, 40 females	Altered behaviour, demasculinisation of male behaviour	Erhard et al., 2004
Male foetuses of pregnant ewes (D110)	12	Decreased testis growth, number of Sertoli cells, Leydig cells and plasma testosterone	Paul et al., 2005
Female foetuses of pregnant ewes (D110)	8	Reduced weight, reduced expression of growth differentiation factor, induced myeloid leukaemia cell differentiation protein, reduced expression of pro-apoptotic BAX, a range of proteins differentially expressed from controls	Fowler et al., 2005
Male and female foetuses from pregnant ewes	17	Decreased expression of KiSS-1 in hypothalamus, fewer kisspeptin immunopositive cells co-localised with LHβ and ERα in the pituitary gland. (KiSS-1 is involved in secretion of GnRh)	Bellingham et al., 2009
Offspring of ewes exposed from conception to weaning (male) or slaughter (female)	12 males, 12 females	Increased mineral density and reduced the cross-sectional area and periosteal circumference of the femur. The female femur was slightly less physical resistant to fracture than the control	Lind et al., 2009
Adult from 5 months – 4-6 years, Foetuses from conception to day 110)		Adult ewes: reduced size, mineral content and bone density in the metaphyseal part of femur Female foetuses: reduced size and marrow cavity area of the mid-diaphyseal part of femur. Male foetuses: Increased bone mineral content in mid-diaphyseal part of the femur.	Lind et al., 2010
Male foetuses exposed in utero and postnatally	12 males	Reduced number of germ cells, more Sertoli-cell only tubules, in a subset of animals	Bellingham et al., et al., 2012
Female foetuses exposed *in utero* and postnatally		Altered ovary development and gene expression in foetus from ewes from sewage-treated soil	Bellingham et al., et al., 2013
Pre and post conceptual foetus of sweep	72	Disrupted thyroid development at D 110 of gestation.	Hombach-Klonisch et al., 2013
Female foetuses exposed *in utero* and post-natally		Exposure pre and/or post conception altered expression of key neuroendocrine. Male foetuses more affected than female and expressing more “female-like mRNA profiles	Bellingham et al., 2016
Female foetuses of ewes exposed for 80 days during pregnancy (1 single		Exposure during early, mid or late gestation reduced early stage foetal follicles. The exposure altered foetal liver chemical profiles, morphology and altered expression of foetal genes and proteins	Lea et al., 2016
Ewes exposed to sludge-treated pasture throughout breeding lives. Female F1 maintained on same grazing area, male maintain on same	10 females and 12 female foetuses	Altered expression of detoxification enzymes, altered liver proteome,	Filis et al., 2019

grazing until 7 months, thereafter control			
Male newborn lambs from ewes grazing on sludge treated pastures 1 months, control rams	17	Lower plasma testosterone concentrations, a greater proportion of Sertoli cell-only seminiferous tubules, fewer gonocytes, altered testicular mTOR signalling, altered transcriptome.	Elcombe et al., 2021
Male offspring (1 day – 11 months) lambs from ewes grazing on sludge treated pastures	10-15	Reduced number of Sertoli cells, reduced CYP17A1, reduced b.w., adrenal and testis mass, AGD, testosterone.	Lea et al., 2022
Male offspring from ewes grazing on sewage-sludge treated soil during pregnancy and lactation	11	Reduced number of germ cells, increased proportion of Sertoli-cells only tubules, altered transcriptome, including HIFa.	Elcombe et al., 2022
Male offspring from ewes grazing on sewage-sludge treated soil (age 1 day – 11 months)		Altered testicular development although at least partially recovered post-exposure	Elcombe et al., 2023
Male and female offspring from ewes grazing on sewage treated pastures to week 55		Reversible reduced male peripubertal b.w., early pubertal onset in male, delayed puberty in female,	Evans et al., 2022
Pregnant ewes grazing on sewage treated pasture	15	Changes in metabolome in pregnant ewes mid-gestation. Changes dependent on sex of foetus	Thangaraj et al., 2023a
Pregnant ewes grazing on sewage treated pasture	15	Increased concentrations of mineralocorticoids and ROS and reduced levels of cytokines in maternal blood	Thangaraj et al., 2023b
Adult male offspring from ewes grazing on sewage treated pastures.		Altered gene expression, particularly in hypothalamus, but also liver and adipose tissues. Altered b.w., plasma triglyceride levels in a subset of male offspring	Ghasemzadeh-Hasankolaei et al., 2024
Adult offspring from ewes grazing on sewage treated pastures.		Increased left ventricular fibrosis. Upregulation of genes for apoptosis and inflammatory markers in males but not females	Khan et al., 2025

Note: AGD: Anus-genital distance; D110: Day 110 in pregnancy

8.6 Humans (general population, subgroups) - exposure and hazard characterisation

Humans can potentially be exposed to contaminants occurring in sewage sludge used as fertiliser by the consumption of plants such as vegetables and cereals, as well as animal-derived food products such as milk, meat, eggs, freshwater fish and drinking water (**Figure 1.5-2**).

A complete intake estimation in humans from food for all contaminants in sewage sludge based on food consumption data and dietary habits was not feasible within the framework of the present risk assessment and not required in the terms of reference provided by the Norwegian Food Safety Authority. Thus, a simplified and pragmatic approach has been used.

Contaminants originating from sewage sludge application on fields may leach from soil into waterways. In the water, the contaminants are diluted in a large water volume in rivers or lakes, and they may be taken up by fish. There are only very few commercial fisheries in freshwaters in Norway. They are mostly restricted to either large lakes with a large water volume or to lakes in high mountain areas with very limited agriculture. Human consumption

of freshwater fish affected from application of sewage sludge will therefore be limited mainly to self-caught fish from waterways in the close vicinity of fields, on which sewage sludge has been applied. The mean consumption of these fish is estimated as close to none but could be significant for the part of the population that is actively fishing. However, data on the consumption of self-caught fish are very limited.

For estimating contaminant exposure, potential increase in food plants as well as in animal-derived food items following the application of sewage sludge was calculated (**Chapter 7**). For contaminants, for which the concentrations in plants or fish were not expected to change following the application of sewage sludge to agricultural soils, the use of sewage sludge was considered as to not constitute an additional risk to human health. If, however, the concentrations in the edible parts of plants, animals or animal-derived food items were expected to increase, we have considered the contribution of these foods to the current total dietary intake and the relative size of the increase caused by sludge application. Finally, the significance of any change in the dietary intake of a contaminant was evaluated by comparing the current intake (dose per kg b.w./day) to relevant Health-Based Guidance Value (HBGV) such as TDI or ADI and determined if additional exposure might cause health risks.

The hazard characterisation of contaminants that could pose a risk to humans through dietary exposure has in this evaluation been only performed for compounds, 1) detected in the sludge at levels above the LOQ in at least one sample, and 2) increased in food items as a consequence of sewage sludge applications, according to the modelling performed in this evaluation. The hazard characterisation for humans performed here is based on available toxicity and exposure data, risk assessments and available TDI or corresponding values (ADI, MOE). For a substantial number of compounds in this report, the required information was not available and therefore, a simplified approach for risk assessment without a hazard characterisation has been used. This approach is based on e.g. changes is the exposure following the use of sewage sludge.

Generally, the same contaminant groups that have been considered in the hazard characterisation for farm animals (**Chapter 8.5.6**) are relevant for humans. However, while in the evaluation performed for farm animals the focus was on contaminant levels in grass/forage, cereals and soil, for humans also tubers and roots have to be taken into account.

Many chemical contaminants have low plant uptake, e.g. the BCF_{plant} is low. This means that human exposure is limited to those contaminants that accumulate in plant parts, reducing the number considerably (C**hapter 7.3**). The predicted plant concentrations for contaminants in the different compound groups (**Chapter 6.1.3**) were compared to the available HBGV assuming a high intake of the crop plants. The results are shown in **Supplementary materials 3** (Table 8.6-1 Assessment of human exposure and risk) (enclosure) and summarised in the following.

8.6.1 Hazards to humans from prioritised contaminants

Humans are exposed to contaminants in sludge by consumption of food produced on the areas where the sludge was applied or if the areas are used for cultivation of gras for feed production. Crop plants like cereals, potatoes and vegetables may potentially absorb contaminants from the soil. Plants, are, however, rather selective in their uptake from soil, and most organic contaminants are poorly absorbed, but with exceptions. The contaminants absorbed in plants may also be transferred to food products from animals. In this report the

transfer to meat and milk has been included in the assessment of food intake. For most compounds this transfer is low, but there are important exceptions. It is well documented that dioxins and PCBs are transferred to fat-containing animal derived food. Also, PFAS is transferred to milk and meat. Of the chemicals evaluated, particularly the siloxanes are modelled to reach the highest levels in meat, and concentrations exceeding the specific migration limit (SML) in the regulation of siloxanes in food contact materials. Transfer to meat and milk are discussed in the evaluation of the groups of contaminants below.

8.6.1.1 Perfluorinated chemicals (PFCs)

EFSA has decided to base their risk assessment for PFCs on the sum of four PFAS, i.e. PFOA, PFNA, PFHxS and PFOS (s. also **Chapter 8.5.6.6**), which in general add up to about 50% of the analysed PFAS in food. EFSA has set a TWI of 4.4 ng/kg b.w./week for this group sum. The currently estimated intake from food in Europe already exceeds the TWI, even when lower bound (LB) occurrence data are used in the predictions. VKM estimated mean intakes of the sum of four PFASs ranged from 6.5 to 18 ng/kg bw/week, which is already exceeding the TWI (VKM 2022).

Since the use of sewage sludge as fertiliser is predicted to increase the level of ΣPFAS4 in cereals and vegetables by 0.043 and 0.024 µg/kg, respectively, the TWI would be exceeded considerably more. Fruit and fruit products, vegetables and vegetable products were among the main contributors for some PFAS, but vegetables were not important contributors to the intake of the ΣPFAS4 included in the assessment. When VKM previously calculated UB and LB exposure of ΣPFAS4 (VKM 2022), the measured levels were below LOQ in the majority of samples for these food groups. VKM still estimated that potatoes/fruits/vegetables contributed about 17 to 32 % of the total estimated intake, with an uncertainty related to the large number of samples below the LOQ. Here we estimated that use of sewage sludge could increase the ∑PFAS4 levels by 1.4 – 2.4 ng/L in milk over a period of 90 years. Similarly, the concentrations in meat are estimated to increase by 2.4 – 2.8 ng/kg. This would have a significant impact on the intake of these compounds and could increase the intakes by 10 %. The increased intakes would lead to further exceedance of the TWI. All increase of dietary exposure to ΣPFAS4 is undesirable, and the estimated significant increase of levels in cereals, potatoes, vegetables, milk and meat with sewage sludge as fertiliser would add to the existing risks to human health.

In conclusion, the use of sewage sludge as fertiliser will probably contribute to an increased dietary intake of PFAS, which is undesirable, since the current exposure from food is already estimated to exceed the TWI.

8.6.1.2 Dioxins and PCBs

Dietary PCB-exposure includes both dioxin-like PCBs (DL-PCBs) and NDL-PCBs. The compounds are highly lipophilic and bind strongly to soil and particles. Their uptake into plants is therefore limited and depended on the soil characteristics (**Chapter 7.3**). Even though the prediction model indicated that PCB (including NDL-PCB) concentrations in soil would increase with repeated sewage sludge applications (**Chapter 8.5.6.1**), the corresponding increase in plants is modest. PCBs in food do not cause acute health effects but accumulate in the body over time, which may cause adverse effects.

Dioxins and the DL-PCBS,
Dioxins and the DL-PCBS, act by the same molecular mode of action, are assessed as a group, using toxic equivalent factors to adjust for the different potencies of the dioxin and PCB congeners. EFSA established a TWI of 2 pg TEQ/kg b.w./week for DL-PCBs and dioxins, comprising 29 congeners, based on decreased sperm concentration in men after prenatal and childhood exposure to dioxins and dioxin-like PCBs (EFSA 2018). Using Norwegian data for contaminant occurrence and food consumption, VKM estimated the exposure as ranging from 2.3 (mean LB) to 24.2 (P95 UB) pg TEQ/kg b.w./week, meaning that both the mean and P95 exposures were above the TWI for all consumer age groups (VKM 2022). Meat and dairy products were the main contributors to the exposure.

Dioxins and DL PCBs were only measured in 2 samples of sewage sludge but are assessed due to the known importance of these contaminants. The total occurrence of the compounds is expressed as Toxic Equivalents (TEQ) where the occurrence of the different congeners is corrected for differences in potency and summarized. The mean of all groups of the dioxin-related compounds is 1.6 ng TEQ/kg. We assume these compounds behave similar to ∑PCB6 since these compounds have many similar chemical properties such as stability and lipophilicity. By assuming that the relation between dioxins and DL PCBs in plants are similar to the relation in soil we estimate TEQs in plants to be 0.00014 pg TEQ/kg in cereals, 0.00253 pg TEQ/kg in potatoes and 0.00463 pg TEQ/kg in carrots. If dioxins and DL-PCBs behave as NDL-PCBs, these concentrations will increase by about 8-fold during the 90 years of repeated applications. These concentrations are expected to increase the dietary intake with up to 10 %, in addition to increased transfer to meat and milk, but this transfer has not been quantified.

Overall, the modelling indicate that the sewage sludge application may increase the intake of dioxins and dioxin-like PCB by an additional 10–20 %, which is undesirable since the TWI is already exceeded.

NDL PCBs
The NDL-PCBs, including the PCB6 frequently analysed, act via other mechanisms than dioxins and DL-PCBs and cannot be assessed in the same model. EFSA has not established any HBGV for NDL-like PCBs. A main confounder with both experimental and epidemiological studies is the potential interference of the more potent DL-PCBs and possibly dioxins in the studies. Instead, EFSA developed a Margin of Body Burden approach in the risk assessment of NDL-PCBs and based on that derived an overall NOAEL of 30–40 µg/kg b.w./day (EFSA 2005). EFSA also concluded that PCB6 constituted about 50 % of the total PCB and could be used as indicators for PCB exposure. In 2008, VKM had concluded that the TWI for dioxins and DL-PCBs would generally also protect against adverse effects that may arise from dietary exposure to total PCB, including NDL-PCBs, given the composition and levels of dioxins, DL-PCBs and NDL-PCBs in Norwegian food at the time (VKM 2008).

There is, however, guidance on maximum levels for different food categories for both DL-PCBs and NDL-PCBs (∑PCB6), e.g., respectively, 4.0 pg/g fat and 40 ng/g fat in bovine meat, 6.5 pg/g and 125 ng/g in wild-caught freshwater fish, and 4.0 pg/g and 40 ng/g in milk (EU 2023).

In the current assessment, the NDL-PCB sum ∑PCB6 is estimated to be in the ng/kg range in cereals, potato and vegetables. While food items of plant origin are underrepresented in the exposure estimate on NDL-PCBs by EFSA, levels of 0.035 to 0.036 µg/kg in meat and 0.001-0.1 µg/L in milk were considered (EFSA 2012). EFSA estimated the mean and high intake of NDL-PCBs in humans in the range of, respectively, 4.3 to 25.7 and 7.8 to 53.7 ng/kg b.w./day.

Overall, sewage sludge will probably be a minor contributor to dietary intake of PCBs but the additional intake of ∑PCB6 coming from plants grown on soil treated with sewage sludge as fertiliser, directly or particularly through milk and meat, is of concern, especially for high consumers of milk, for whom the estimated extra intake is predicted to be about 1 ng/kg b.w./day.

8.6.1.3 Polyaromatic hydrocarbons

For PAHs, EFSA concluded that ∑PAH4 or ∑PAH8 are suitable indicators for both occurrence and toxicity of PAHs in food (EFSA 2008). In the risk assessment EFSA used a MOE approach based on carcinogenicity studies with a BMDL of 0.34 µg/kg b.w./day for ∑PAH4 (benzo(α)pyrene (BaP), chrysene, benz(α)anthracene and benzo(α)fluoranthene) or a BMDL 0.49 µg/kg b.w./day for ∑PAH8 (∑PAH4 and benzo(κ)fluoranthene, Benzo[ghi]perylene, Dibenz[a,h]anthracene and Indeno[1,2,3-cd]pyrene (IP)). The median dietary exposure across European countries was calculated both for mean and high dietary consumers as, respectively, 19.5 ng/kg b.w./day and 34.5 ng/kg b.w./day for ∑PAH4, and 28.8 ng/kg b.w./day) and 51.3 ng/kg b.w./day for ∑PAH8. EFSA concluded that the MOE for average consumers was of low concern but indicated potential concern for high consumers. Cereals and vegetables contributed significantly to the estimated intake. Mean concentrations (UB) for 16 PAH congeners in samples across 13 food categories analysed in 17 European countries ranged from 0.15 µg/kg (DBaiP) to 0.81 µg/kg BaP and up to 3.27 µg/kg (chrysene) and the mean ∑PAH4 concentrations in cereals (LB) were 1.54 – 2.03 µg/kg and in vegetables 1.43 – 1,71 µg/kg (EFSA 2008). Maximum allowed levels of ∑PAH4 in different food products range from 1 µg/kg in baby food to 50 µg/kg in dried herbs, spices and plant powders (EU 2023). In Norway, a limit of 30 µg/kg in mussels has been established, which was evaluated by VKM (VKM 2011). PAHs are metabolised and excreted in animals and humans after uptake, and the carry-over into milk and meat is very low so that plant products are the main source of dietary intake.

The ∑PAH4 concentrations in food used in the EFSA assessment were higher than the predicted addition in plant-derived products resulting from the use of sewage sludge as fertiliser. The added level was calculated as up to 0. 36 µg/kg for ∑PAH4 in cereals, which is a 30 % increase to the concentrations used by EFSA in their estimation. As cereals was one of the major contributors to the total intake, this impact will be of significance for the total exposure and of concern as the MOE is already low for the high intake.

8.6.1.4 Chlorinated paraffins

Short chain (SCCPs), middle chain (MCCPs) and long chain chlorinated paraffins (LCCPs) are all found in the sewage sludge and a fraction is absorbed to plants. The predicted concentrations in after a single application of sewage sludge is cereals 0.07 µg/kg in both cereals, potatoes and vegetables of the SCCPs. The concentrations of the MCCPS are 0.35 µg/kg in all three plants while it is 0.19 µg/kg for the LCCPs. As the chlorinated paraffins accumulate in soil over time, the concentrations are expected to increase about 8-fold in 90 years.

The toxicity of the chlorinated paraffins may vary with the degree of chlorination in addition to the chain length (EFSA 2020). EFSA evaluated the chlorinated paraffins and identified a BMDL10 of 2.3 mg/kg bw/day as a reference point and for MCCPs a BMDL of 36 mg/kg bw/day was used. For the LCCPs, EFSA identified a NOAEL for 100 mg/kg bw/day for the lower chlorinated (43% chlorination) LCCPs and 900 mg/kg bw/day for higher chlorinated LCCPs. For all 3 groups EFSA used a MOE approach and concluded that a MOE above 100+ would be

regarded as no health concern. Only data from fish were available to EFSA for the estimation of exposure. The mean upper bound intake of SCCBs from fish was estimated in the range 1.9 – 35 ng/kg bw/day and the 95 percentiles in the range 5.0 – 87 ng/kg bw/day. For the MCCPS the estimated mean upper bound intakes were in the range 3.2 – 59 ng/kg bw/day and the 95 percentile intakes ranged from 8.5 – 148 ng/kg bw/day.

EFSA had no data from other food groups so comparison with our predicted concentrations is not possible. The prediction models indicate that consumption of food from sludge-treated soil could increase the intake in a less than 1 µg/day which would be of low significance compared to the BMDL taking the MOE of 1000 into account. The predicted food concentrations of MCPPS are higher than for the SCCPs, but also the HBGV is higher, and the intake will be of no concern also for these compounds.

8.6.1.5 Brominated flame retardants

There is a large number of brominated flame retardants present in sewage sludge. A main group are the polybrominated diphenyl ethers (PBDEs). EFSA concluded to use a Total Margin of Exposure (MOET) approach in their evaluation (EFSA 2024). This approach is used to evaluate combined health risks of exposure to multiple chemicals and assumes dose addition for contaminants affecting the same body organ. EFSA concluded that the estimated intake of PBDEs (mean 0-6 ng/kg b.w./day) raises a health concern. The contribution to the intake from plant-derived food was not included in the estimations and assumed to be very low. The predicted increase in PBDE concentrations in cereals and vegetables of 0.009 ng/kg in cereals, 1.1 ng/kg in potatoes and 1.8 ng/kg in root vegetables could potentially make a significant additional contribution to the dietary intake of PBDEs. In addition, the use of sewage sludge as fertiliser is predicted to increase the carry-over into meat (0.7 µg/kg) and milk (0.2 µg/L). This would also lead to an increased exposure with an additional 10 %. This increase is undesirable as EFSA concluded that the MOET is already low and of concern.

The concentration of hexabromocyclododecane (HBCDD) is predicted to increase in plants following sewage sludge application. There are 3 different stereoisomers of HBCDD, and they are all present in sludge. In the evaluation of HBCDD, EFSA estimated a human LOAEL of 2.35 µg/kg b.w./day and stated that an MOE of 24 or higher would indicate low concern (EFSA 2021), The dietary intakes were estimated to be in the range of 0.07 – 3.6 µg/ kg b.w./day and the MOE were in the range from 34,000 to 650. EFSA therefore concluded that this was not of any health concern. Sewage sludge is predicted to increase the concentrations in potatoes by 7 µg/kg, in carrots by 1 µg/kg feed and in cereals by 0.06 µg/kg. The added concentrations following use of sewage sludge in meat and milk is predicted to be minimal. The application of sewage sludge is not expected to have a significant impact on exposure for HBCDD.

EFSA has also established a TDI for tetrabromobisphenol A of 0.7 mg/kg b.w./day and mean exposures were determined in the range from below 0.01 ng/kg b.w . to 30 ng/g b.w./day for different age groups using lower vs. upper bound calculations. The estimated 95-percentiles were in the range of below 0.01 ng/kg b.w./day to 85 ng/kg b.w./day (EFSA 2024). EFSA concluded that the current exposure was well below the TDI, stating with 90 to 95 % certainty that the current exposure was not a cause for concern. All HBCDD analysis in this assessment in cereals, potatoes and vegetables were below the LOQ. However, the application of sewage sludge as fertiliser is predicted to increase the concentrations in cereals by 4 µg/kg), potatoes by 63 µg/kg and carrots by 108 µg/kg. In addition, a carry-over into meat of 2 µg/kg and milk

of 0.2 µg/L was predicted. This increase would have a significant impact on the total HBCDD intake and consequently reduce the safety margin between the TDI and the estimated intake.

8.6.1.6 Siloxanes

Siloxanes are among the contaminants detected at the highest concentrations in sludge and predicted to reach the highest concentrations in plants. The siloxane with the highest predicted concentrations in edible parts of plants is octadecamethyloctasiloxane (L8) with 0.221 µg/kg in cereals, 2.14 µg/kg in potatoes and 3.02 µg/kg in carrots. In addition, the compound is predicted to reach high concentrations in meat (5.22 mg/kg) and milk 0.5 mg/L). Hexadecametylheptasiloxane (L7) is modelled to reach 0.15 µg/kg in cereals, 1.51 µg/kg in potatos and 1.74 in vegetables. Furthermore, the model predicted concentrations of 1.9 mg/kg in meat and 0.18 mg/l in milk. Tetradecamethylsiloxane (L6) is predicted to reach concentrations of 0.12 µg/kg in cereals and 2 µg/kg in potatoes and vegetables. The predicted concentrations are, however, well below the proposed MRLs for siloxanes, and, also below the levels found in experiments studying the migration from food contact materials into model food (DTU 2017).

Also, a range of other siloxanes are predicted to enter plants and be transferred to meat and milk, but in lower concentrations. Danish Technical University (DTU) has proposed action limits for 12 mg/kg food for the sum of cyclic siloxanes (D-3 – D8) for adults and 2 mg/kg food for children (DTU 2017). In addition, a general limit of 60 mg/kg for the sum of cyclic and linear siloxanes (D-3-D8 and L3-L13) has been suggested.

Siloxanes are also leaching from food contact materials into food products, but the levels will depend largely on a range of factors such as food category, temperature, type of food contact material, etc. The intake of siloxanes from food is not likely to exceed the proposed action limits for food. The predicted increase of siloxanes in food products as a result of sewage sludge applications is 1000-fold lower than the proposed action limits. However, the models indicate a high carry-over into animal-derived food products with the concentration of ocadecamethyloctasiloxane (L8) predicted to reach 5 mg/kg in meat and 5 mg/L in milk in the 100-year period. Even though this still is below the proposed action limits for adults, it is an undesirable increase in contaminant concentrations in staple food.

8.6.1.7 Phosphate plasticisers and flame retardants

Several of the compounds in this group had a very low plant uptake, and plants are therefore unlikely to have any impact on their dietary intake. All other compounds in this group have very low concentrations in relation to their HBGV and are therefore considered to constitute a low risk. The transfer into meat and milk is predicted to lead to low additional exposure and still well below the relevant HBGV.

8.6.1.8 Other flame retardants

The plant uptake of these compounds is very low, and the additional dietary intake following sewage sludge application is not expected to constitute any risk.

8.6.1.9 Phthalates

Most phthalates have a low plant uptake, and sewage sludge is therefore unlikely to have a major impact on the total dietary intake of most of these compounds. The most abundant

phthalate in sludge is DEHP, which is also expected to have the highest predicted increase in plants. DEHP plant concentrations may increase by 0.047 µg/kg in cereals, 0.62 µg/kg in potatoes and 3.6 µg/kg in carrots. In addition, the model predicts an increase of 0.35 µg/kg in meat and 0.035 µg/L in milk. EFSA has defined a group TDI for phthalates of 50 µg/kg b.w./day for DEHP equivalents of 4 phthalates (DBP, BBP, DEHP and DINP), meaning that the other phthalates need to be adjusted for differences in potencies (EFSA 2019). EFSA estimated dietary intakes in the rage of 0.9. 11-7 µg/kg b.w./day, which constitute up to 23% of the TDI. The predicted additional exposure to phthalates from sewage sludge applications would be very low compared to the TDI and are therefore considered to be of minor importance.

8.6.1.10 Bisphenols

Use of sewage sludge is predicted to increase the concentration of bisphenol congeners in cereals, potatoes and carrots. 2,2'-Bisphenol F is expected to reach the highest concentrations in plants, reaching concentrations of 12 µg/kg in cereals, 10 µg/kg in potatoes and 70 µg/kg in carrots, while the other bisphenols are predicted to reach 10-fold lower levels. The carry-over to milk and meat is predicted to be very low for all bisphenol congeners, resulting in negligible predicted concentrations (< 1.0 E-9 µg/kg or µg/L).

Bisphenol disturbs the immune system at low concentrations. EFSA has set a TDI of 0.2 ng/kg b.w./day based on effects on the immune system. In addition, bisphenol A is a known endocrine disruptor with oestrogenic and anti-androgenic effects (EFSA 2023). By comparison with a previous intake estimate from 2015 (EFSA 2015), EFSA concluded that the intake of bisphenol A exceeded the TDI by 2 to 3 orders of magnitude (EFSA 2023). The model-predicted increase in concentrations in plants, milk or meat is, however, very low compared to other sources, but any increase in intake is undesirable.

In addition to bisphenol A, also other bisphenol congeners have the potential to elicit oestrogenic effects, but according to the model used here, the predicted concentrations in food are low after the application of sewage sludge and not considered to constitute an increase of the existing risk.

8.6.1.11 Rubber-related compounds

Of the rubber-related compounds found in sewage sludge, 1,3-Diphenylguanidine (DPG) is predicted to reach the highest concentrations in food plants, reaching concentrations of 3 µg/kg in cereals, 0.6 µg/kg in potatoes and 5 µg/kg in carrots. The second highest plant concentrations were predicted for 2-mercaptobenzothiazole, reaching 0.6 µg/kg in cereals, 1 µg/kg in potatoes and 5 µg/kg in carrots.

No TDI was identified for DPG, but a NOAEL of 17 mg/kg b.w./day has been reported (Breider et al., 2025), and ECHA has derived a DNEL (Derived No Effect Level) of 17 µg/kg b.w./day (ECHA CHEM, 2010). The Swiss study indicated a dietary intake well below this level (Breider et al., 2025). The levels predicted for food after the application of sewage sludge were well below the concentrations measured in the Swiss study.

Other rubber-related compounds are predicted to have low concentrations in food as compared to the HBGV and not considered to be of any risk.

The transfer into meat and milk is predicted to be low for all rubber-related compounds included in this assessment and thus not of any risk.

8.6.1.12 Corrosion inhibitors

The corrosion inhibitor benzotriazole was modelled to reach 0.15 µg/kg in cereals, but only less than 0.00001 µg/kg in potatoes and carrots. The oral toxicity of the compound is poorly characterised, but Health Canada (Health Canada, 2025) has identified a NOAEL of 30 mg/kg b.w./day for systemic toxicity from a study in rats on the basis of kidney effects in adult females at higher doses, while the NOAEL for reproductive and developmental effects was 300 mg/kg b.w. per day. For tolyltriazole, the NOAEL for systemic toxicity in rats was 150 mg/kg b.w. per day based on haematological and clinical biochemical effects at higher doses (Health Canada, 2025).

For 5-methylbenzotriazole, the model predicted concentrations of 0.9, 18 and 5.6 µg/kg in cereals, potatoes and carrots, respectively. A TDI or similar threshold has not been set by EFSA, but Danish authorities have suggested a TDI of 0.0067 mg/kg b.w./day (Danish Ministry of the Environment, 2013). The carry-over into meat and milk is predicted to be negligible (below 0.0000000001 µg/kg or µg/L). These compounds are not likely to constitute any risk for the population following sewage sludge applications.

8.6.1.13 UV chemicals

The chemical with the highest predicted concentrations in food plants are 2-(2H-benzotriazole-2-yl)-4-methyl-phenol, octocrylene, UV-329 and UV 360.

For 2-(2H-benzotriazole-2-yl)-4-methyl-phenol, ECHA has derived a DNEL of 0.28 mg/kg b.w./day (ECHA CHEM, 2015), while EPA considers the compound as inert and thus without the need for defining a TDI (EPA, 2015). Based on the predicted concentrations in plants from the application of sewage sludge (cereals: 0.065 µg/kg; potatoes: 0.197 µg/kg; vegetables: 0.111 µg/kg), it is unlikely that the potential increase in crop plants will constitute a risk for human consumers.

Octocrylene is regulated as a food contact material with an SML of 0.05 µg/kg food. A TDI has not been set, but ECHA CHEM, 2010 has established a DNEL of 0.8 mg/kg b.w./day. The predicted food concentrations after sewage sludge applications are below the SML for cereals (0.007 µg/kg), but exceed the SML in potatoes and vegetables (0.489 µg/kg and 1.580 µg/kg, respectively), indicating an undesirable increase of dietary intake, but not likely to exceed the DNEL unless combined with other sources.

The other UV chemicals are predicted to have a low plant uptake and thus low concentrations in food plants.

8.6.1.14 Pigments and dyes

The pigments and dyes evaluated in this assessment have generally a low plant uptake and do not accumulate in soil. Their toxicity is low, and the estimated carry-over into meat and milk is negligible for all compounds. The compounds are considered not of relevance for human toxicity.

8.6.1.15 Solvents

The predicted concentrations of solvents in plants after applications of sewage sludge are all very low, and the predicted concentrations in meat and milk are negligible so that the solvents are considered not of relevance for human toxicity.

8.6.1.16 Antioxidants

The predicted concentrations of antioxidants in the edible part og the plants are generally low (< 0.01 µg/kg after applications of sewage sludge except for N-1,3-dimethylbutyl-N'-phenyl-p-phenylendiamine (6PPD), which reaches 0.39 µg/kg in potatoes. There is little information about the toxicity of antioxidants, but they are generally considered to have a low toxicity. The transfer into meat and milk is low, and antioxidants in sludge are therefore not considered to constitute any risk for consumers of food.

8.6.1.17 Surfactants

A few substances within this group are taken up into plants, particularly into cereals, while others are not. Bis(2-ethylhexyl)phosphate is predicted to reach the highest concentration with 5.45 µg/kg in cereals, while the concentrations in potatoes and carrots are predicted to reach 0.05 and 0.008 µg/kg, respectively. ECHA has established a DNEL of 0.25 mg/kg b.w./day for bis(2-ethylhexyl)phosphate (**ECHA CHEM, 2013).** This indicates that this compound will not constitute any risk to consumers following sludge applications. The transfer into milk (0.00003 mg/L) and meat (0.00003 mg/kg) is also predicted to be limited and not likely to be of any concern.

Sodium 4-Dodecylbenzenesulphonate is estimated to reach 2.095 µg/kg in cereals, 0.495 µg/kg in potatoes and 0.107 µg/kg in carrots). The transfer into meat and milk is predicted to be low (< 0.0000001 mg/kg or mg/L). The toxicological information about this compound is limited but a NOAEL of 75 mg/kg b.w./day was reported from a study in rats receiving sodium 4-dodecylbenzenesulphonate for 22 weeks in their diet (American College of Toxicology, 1993), indicating a low risk.

8.6.1.18 Alkylphenols and derivatives

4-Nonylphenol diethoxylate and 4-n-Nonylphenol are frequently detected in sewage sludge, but the plant uptake is expected to be low. The predicted concentrations in plants for 4-Nonylphenol diethoxylate are up to 0.029 µg/kg in cereals, 0.068 µg/kg in potatoes and 0.161 µg/kg in carrots, while the concentrations of nonylphenol are lower. The transfer into meat and milk is negligible.

Nonylphenols and their ethoxylate derivates have shown to elicit xenoestrogenic effects, mimicking oestrogen, and they are irritating at high concentrations (Chokwe et al. 2017). Oral toxicity studies (90-days) have been performed for 4-nonylphenol ethoxylates in rats and dogs (referred by Nielsen et al. 1999). NOAELs ranging between 40 and 160 mg/kg b.w. per day for rats and a NOEL of 40 mg/kg b.w. per day for dogs have been determined. For 4-nonylphenol, a LOAEL of 15 mg/kg b.w. per day in developmental/reproductive studies in rat has been identified.

4-Nonylphenol diethoxylate is biotransformed into 4-nonylphenol. The Danish Environmental Protection Directorate has proposed a TDI of 5 µg/kg b.w./day for 4-nonylphenol and 13 µg/kg b.w./day for 4-nonylphenol diethoxylate based on observed effects related to reproduction and kidney alterations (Miljøstyrelsen, 2000). It is unlikely that the additional intake from food produced after sewage sludge application will significantly affect the current dietary exposure.

8.6.1.19 Antimicrobial biocides

These compounds are generally poorly absorbed into plants. Furthermore, the predicted transfer into meat and milk is negligible so that a risk has not been identified.

8.6.1.20 Fragrances

A large number of fragrances have been detected in Norwegian sewage sludge samples. The plant uptake from these compounds is expected to be low, and risks from dietary intake of fragrances after the application of sewage sludge to agricultural soils are considered as low.

8.6.1.21 Cosmetic biocides

The plant uptake of triclosan and triclorcarban is estimated to be limited. The predicted concentrations of triclosan are 0.0024 µg/kg in cereals, 0.078 µg/kg in potatoes and 0.238 µg/kg in vegetables. The carry-over into meat and milk is low (0.022 µg/kg in meat and 0.002 µg/l in milk). Health Canada has proposed an ADI for triclosan of 0.08 mg/kg b.w./day (Health Canada 2024). The risk associated with triclosan in food from sludge-amended soil is therefore considered as low.

The predicted concentrations of triclorcarban in food are comparably lower, and the compound is probably less toxic with a NOAEL of 23 mg/kg b.w./day and an estimated MOE of 200,000 for exposure from food and environment (Health Canada 2023)

The other biocides considered in this risk assessment are predicted to occur in food in low concentrations and to be well below the relevant HBGV.

8.6.2 Hazards from drugs

8.6.2.1 Predicted bioaccumulation in plants of prioritised drugs

The hazards for health risks in humans from the exposure to drugs in food after using sewage sludge as agricultural fertiliser were characterised in accordance with the parameters presented in **Table 8.2-1.** Among the 82 drugs with the highest risk score (**Tables 8.2-2** and **8.2-3**), 45 substances were predicted to accumulate in plant parts (seeds, leaves, root, tuber) immediately after the first application of sewage sludge (Y1) or after repeated applications over 100 years (Y100) (**Table 8.6.2-1**). Corresponding data were not available for metoprolol, citalopram and buprenorphine.

Table 8.6.2-1. **Drugs with high risk scores that are predicted to accumulate (bold accumulation shown) in plant parts after the first application (Y1) or after repeated applications over 100 years (Y100). Drugs marked in bold are considered of substantial risk.**

ATC	Drug	CAS No.	Y1	Y100
A	**Loperamide**	53179-11-6	< 1	**2.1**
C	**Hydrochlorothiazide**	58-93-5	**1.8** (leaves)	1
C	Bisoprolol	66722-44-9	< 1	**1.3**
C	Propanolol	525-66-6	< 1	**1.8**
C	Carvedilol	72956-09-3	< 1	**3.4**
C	Valsartan	137862-53-4	< 1	**2.8**
C	**Eprosartan**	133040-01-4	< 1	**5.8**
C	**Telmisartan**	144701-48-4	< 1	**7.6**
C	**Amiodarone**	1951-25-3	< 1	**7.7**

C	Fenofibrate	49562-28-9	< 1	**2.1**
C	**Lercanidipine**	100427-26-7	< 1	**7.7**
D	Ketoconazole	65277-42-1	< 1	**3.1**
D	Clotrimazole	2 3593-75-1	< 1	**7.1**
G	Progesterone	57-83-0	< 1	**1.6**
G	**Levonorgestrel**	797-63-7	< 1	**1.2**
G	**Desogestrel**	54024-22-5	< 1	**9.2**
J	**Doxycycline**	564-25-0	**4.9** (leaves)	1
J	**Tetracycline**	60-54-8	< 1	**7.3**
J	**Oxytetracycline**	79-57-2	< 1	**7.3**
J	**Ciprofloxacin**	85721-33-1	< 1	**7.7**
J	**Roxithromycin**	80214-83-1	< 1	**1.8**
J	**Clarithromycin**	81103-11-9	< 1	**2**
J	Azithromycin	83905-01-5	< 1	**3.1**
J	**Erythromycin**	114-07-8	< 1	**3.2**
J	Sulfamethazine	57-68-1	**1.4** (leaves)	1
L	Paclitaxel	33069-62-4	< 1	**1.1**
L	**Tamoxifen**	10540-29-1	< 1	**2.3**
N	Codeine	76-57-3	< 1	**1.9**
N	Lamotrigine	84057-84-1	**1.1** (leaves)	1
N	**Carbamazepine**	298-46-4	**1.5** (leaves)	1
N	**Oxcarbazepine**	28721-07-5	**1.2** (leaves)	1
N	Clonazepam	1622-61-3	**1.2** (leaves)	1
N	**Oxazepam**	604-75-1	**3.1** (leaves)	1
N	Sertraline	79617-96-2	< 1	**2.2**
N	Norsertraline	87857-41-8	< 1	**2.1**
N	Fluoxetine	54910-89-3	< 1	**2**
N	**Amitriptyline**	50-48-6	< 1	**9.7**
N	**Maprotiline**	10262-69-8	< 1	**7.8**
N	Memantine	19982-08-2	< 1	**1.1**
N	Donepezil	120014-06-4	< 1	**2**
P	Mebendazole	31431-39-7	**1.2** (leaves)	1
P	Fenbendazole	43210-67-9	**2** (leaves)	1
R	**Fexofenadine**	83799-24-0	< 1	**6.4**
R	**Chlorhexidine**	55-56-1	< 1	**1.8**
V	**Ethylenediamine-tetraacetic acid**	60-00-4	**1.9** (leaves)	1

The table shows that risks arise either directly after the sewage application through transfer into leafy plants, or after repeated applications during the 100-year period, which appears to be the main hazard. In the following. drugs of particular interest are described in more detail. However, a considerable number have already been mentioned in **Chapter 8.5.2.27**. Those, for which substantial risks from dietary exposure, either in Y1 or Y100, are expected are underlined.

ATC A - Alimentary tract and metabolism

Loperamide, a long-acting anti-diarrheal drug, is predicted to accumulate 2-fold in plants after repeated sewage sludge applications. The predicted ADIp is with 1.3 µg/kg b.w./d low so that additional intake from plant-derived food is undesirable.

ATC C - Cardiovascular system

Hydrochlorothiazide, a diuretic and antihypertensive drug, is not predicted to accumulate in plants over time, but is present in leaves at elevated levels after each application of sewage

sludge. The predicted ADIp of 2.5 µg/kg b.w./d is rather low. Large amounts of leafy vegetables should thus not be consumed in the first year after a sludge application. The other drugs identified in ATC C are all predicted to accumulate in plants over time (Y100).

Bisoprolol, propranolol and carvedilol, beta-1 adrenergic blockers, are expected to accumulate between 1.3- to 3.5-fold in plants over 100 years. The predicted ADIp are, respectively 1.4, 32 and 300 µg/kg b.w./d, which is in reversed order to the accumulation hazard, mitigating potential risks.

Valsartan, eprosartan and telmisartan, angiotensin-receptor blockers, are expected to accumulate, respectively, 2.8- 5.8- and 7.6-fold in plants over 100 years, which for eprosartan and telmisartan would mean a substantial increase in plants after repeated sewage sludge applications. The predicted ADIp are, respectively 40, 45 and 0.3 µg/kg b.w./d, which suggests a substantial risk from dietary exposure with telmisartan.

Amiodarone, a class III antiarrhythmic used to regulate heart rhythm, is expected to accumulate 7.7-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 30 µg/kg b.w./d is considered as of intermediate hazard (**Table 8.2-1**) so that considerable risk from intake of plants is mainly expected for high consumers. However, the accumulation potential is considerable, implicating a risk for undesirable additional dietary intake.

Fenofibrate, a fibric acid derivative acting as peroxisome proliferator receptor alpha activator and used to lower cholesterol, is expected to accumulate about 2-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 100 µg/kg b.w./d is relatively high so that the risk is expected to be rather low.

Lercanidipine, a calcium channel blocker used for the management of hypertension, is expected to accumulate 7.7-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 10 µg/kg b.w./d is low so that additional dietary exposure is undesirable.

ATC D Dermatologicals
Ketoconazole and clotrimazole, broad-spectrum imidazole antifungal drugs, are expected to accumulate, respectively, 3.1- and 7.1-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of, respectively, 29 and 500 µg/kg b.w./d are considered as of intermediate and low, so that immediate risks from dietary exposure are considered as relatively low. However, the increasing development og anti-fungal resistance in Europe is of concern and threatens the treatment of systemic fungal infections. Thus, the accumulation of imidazole derivates in food and the environment is undesirable.

ATC G Sex hormones
Progesterone, a natural hormone used to help maintain pregnancy or normalise the menstrual cycle, is not predicted to accumulate in plants over time, but is present in leaves at elevated levels after each application of sewage sludge. The established ADI of 30 µg/kg b.w./d is considered as of intermediate hazard; however, consumption of high amounts of leafy vegetables in the first year after a sewage sludge application should be avoided.

Levonogestrel and desogestrel, synthetic progestins used as contraceptives, are expected to accumulate, respectively, 1.2- and 9.2-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of, respectively, 0.003 and 0.005 µg/kg b.w./d are very low

so that any additional intake is undesirable. Especially the accumulation of desogestrel, which was prescribed more than 120,000 times in Norway in 2021, is of concern.

ATC J *Antiinfectives, systemic*
Doxycycline, a second-generation tetracycline antibiotic used to treat a wide variety of bacterial infections, is not predicted to accumulate in plants over time, but is present in leaves at elevated levels after each application of sewage sludge. The established ADI of 3 µg/kg b.w./d is rather low. Large amounts of leafy vegetables should thus not be consumed in the first year after a sludge application.

Tetracycline and Oxytetracycline, tetracycline antibiotics used to treat a variety of bacterial infections, are expected to accumulate 7.3-fold in plants after repeated sewage sludge applications over 100 years. Both have an established ADI of 30 µg/kg b.w./d, considered as intermediate, so that immediate risks from dietary exposure is considered as relatively low. However, the increasing development of anti-bacterial resistance in Europe is of concern and threatens the treatment of bacterial infections. Thus, the accumulation of tetracyclines in food and the environment is undesirable.

Ciprofloxacin, a second-generation fluoroquinolone antibiotic, is expected to accumulate 7.7-fold in plants after repeated sewage sludge applications over 100 years. The established ADI, ranging from 0.15 to 0.6 µg/kg b.w./d in different countries, are very low so that any additional dietary exposure is undesirable. Moreover, the development of anti-bacterial resistance is of concern.

Roxithromycin, clarithromycin, azithromycin and erythromycin, macrolide antibiotics used to treat a variety of bacterial infections, are expected to accumulate, respectively, 1.8-, 2-, 3.1- and 3.2-fold in plants after repeated sewage sludge applications over 100 years. The established ADI of, respectively, 0.4, 0.2, 12 and 0.7 µg/kg b.w./d are very low, except for azithromycin, so that any additional dietary exposure is undesirable. Moreover, the development of anti-bacterial resistance is of concern.

Sulfamethazine, a sulfonamide antibiotic, is not predicted to accumulate in plants over time, but is present in leaves at elevated levels after each application of sewage sludge. The established ADI of 50 µg/kg b.w./d is in the intermediate range. Large amounts of leafy vegetables should not be consumed in the first year after a sludge application.

ATC L Antineoplastics
Paclitaxel, a taxoid chemotherapeutic agent, is expected to slightly accumulate (1.1-fold) in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 0.05 µg/kg b.w./d is very low so that any additional intake is undesirable.

Tamoxifen, a non-steroidal antioestrogen used to treat breast cancer, is expected to accumulate 2.3-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 0.05 µg/kg b.w./d is very low so that any additional intake is undesirable.

ATC N Nervous System
Codeine, an opioid analgesic used to treat moderate to severe pain, is expected to accumulate 1.9-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 2 µg/kg b.w./d is low so that any additional intake is undesirable.

Lamotrigine, a phenyltriazine anticonvulsant, is not predicted to accumulate in plants over time, but is present in leaves at slightly elevated levels after each application of sewage sludge.

The predicted ADIp of 3 µg/kg b.w./d is low so that any additional intake is undesirable. Large amounts of leafy vegetables should thus not be consumed in the first year after a sludge application.

Carbamazepine and oxcarbazepine, anticonvulsants used to treat various types of seizures, are not predicted to accumulate in plants over time, but are present in leaves at elevated levels after each application of sewage sludge. The established ADI of 15.9 µg/kg b.w./d for carbamazepine and predicted ADIp of 10 µg/kg b.w./d are considered as of, respectively, intermediate and high hazard. The consumption of high amounts of leafy vegetables in the first year after a sewage sludge application should be avoided.

Clonazepam and oxazepam, benzodiazepines with slow onset used to treat anxiety disorders, are not predicted to accumulate in plants over time, but are present in leaves at elevated levels after each application of sewage sludge. The predicted ADIp of, respectively, 13 and 0.2 µg/kg b.w./d are considered as of intermediate and high hazard. Any additional intake is undesirable so that large amounts of leafy vegetables should not be consumed in the first year after a sludge application. Oxazepam was prescribed more than 130,000 times in Norway in 2021.

Sertraline and norsertraline, selective serotonin reuptake inhibitor used to treat depression, anxiety and other psychiatric disorders, are expected to accumulate, respectively, 2.2- and 2.1-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of, respectively, 20 and 300 µg/kg b.w./d are considered as of intermediate and low hazard so that potential risks from dietary exposure are expected to be rather low. However, sertraline has been detected in all analysed sewage sludge samples with a median concentration of 365 µg/kg dw. Norsertraline is the active metabolite.

Fluoxetine, a selective serotonin reuptake inhibitor used to treat major depressive disorder, is expected to accumulate 2-fold in plants after repeated sewage sludge applications over 100 years. The established ADI of 2.9 µg/kg b.w./d is low, and any additional intake is undesirable. The drug was prescribed less than 15,000 times in 2021 in Norway.

Amitriptyline, a tricyclic antidepressant used to treat symptoms of depression and anxiety, is expected to accumulate by as much as 9.7-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 20 µg/kg b.w./d is considered as of intermediate hazard, but the high increase in plants is of concern. The drug is prescribed at considerable numbers in Norway and has been detected in all analysed sewage sludge samples with a median concentration of 240 µg/kg dw.

Maprotiline, a tetracyclic antidepressant used to treat depression, bipolar disorder and anxiety, is expected to accumulate 7.8-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 4 µg/kg b.w./d is low so that any additional intake is undesirable. Prescription data for 2021 were unavailable but the drug was found with high frequency in sewage sludge samples at a median concentration of 81 µg/kg dw.

Memantine, an N-methyl-D-aspartate (NMDA) receptor antagonist used to treat Alzheimer's disease, is expected to only slightly accumulate (1.1-fold) in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 10 µg/kg b.w./d is considered as low so that any additional intake is undesirable. The drug was little prescribed in 2021, which could increase with the increasing prevalence of Alzheimer's in an aging population.

Donepezil, an acetylcholinesterase inhibitor used to treat symptoms like confusion, agitation, and memory loss associated with Alzheimer's Disease, is expected to accumulate 2-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 10 µg/kg b.w./d is considered as low so that any additional intake is undesirable. The drug was little prescribed in 2021, which could increase with the increasing prevalence of Alzheimer's in an aging population.

ATC P Antiparasitics
Mebendazole and fenbendazole, benzimidazole, anthelmintics used to treat worm infections, are not predicted to accumulate in plants over time, but are present in leaves at elevated levels after each application of sewage sludge. The established ADI of, respectively, 2.5 and 7 µg/kg b.w./d are low, so that any additional intake is undesirable and large amounts of leafy vegetables should not be consumed in the first year after a sludge application. As anthelmintics, the drugs are mostly used as veterinary medicines and are known to transfer into meat, milk and eggs. However, they are also used in anti-cancer therapy.

ATC R Respiratory System
Fexofenadine, a second-generation antihistamine used in the treatment of various allergic symptoms, is expected to accumulate 6.4-fold in plants after repeated sewage sludge applications over 100 years. The predicted ADIp of 30 µg/kg b.w./d is considered as of intermediate hazard, but additional dietary uptake is undesirable. The drug was detected in almost all analysed sewage sludge samples with a median concentration of 1690 µg/kg dw. Prescriptions in 2021 in Norway accounted to about 60,000.

Chlorhexidine, a broad-spectrum antimicrobial biguanide used as a topical antiseptic and in dental practice, is expected to accumulate 1.8-fold in plants after repeated sewage sludge applications over 100 years. The established ADI of 5 µg/kg b.w./d is considered as low so that additional dietary uptake is undesirable. The drug is available without prescription so that consumption data in Norway are unclear. It was detected in almost all analysed sewage sludge samples with a median concentration of 1600 µg/kg dw.

ATC v Various
Ethylenediamine-tetraacetic acid (EDTA), a chelating agent used to treat heavy metal intoxication, is not predicted to accumulate in plants over time, but is present in leaves at elevated levels after each application of sewage sludge. Apart from medicinal use, EDTA has also a number of applications as a chemical. The established ADI of 1 µg/kg b.w./d is considered as low so that additional dietary uptake is undesirable and large amounts of leafy vegetables should not be consumed in the first year after a sludge application. Only two sewage sludge samples were analysed for EDTA; however, they contained a median concentration of 1100 µg/kg dw.

8.6.2.2 Comparison of prioritised drugs with the previous risk assessment

In this hazard characterisation of drugs in sewage sludge used as fertiliser, substances were included that were prioritised according to the selection criteria stated in **Chapter 6.6** and evaluation parameters given in **Chapter 8.2**. The drug selection was mainly based on measured occurrence data from wastewater treatment facilities in Norway, which was the major difference to the tiered selection approach used in VKM's previous assessment of risks from the use of sewage sludge in agriculture (VKM 2009).

In 2009, analytical data for drugs in sewage sludge were not available so that maximum $PEC_{slugde\ (max)}$ were calculated based on annual sales and the yearly sludge production for all 1414 drug substances on the Norwegian market in 2006 excluding ATC groups B, D, S and V, reducing the number of drugs to 595. A cut-off $PEC_{slugde\ (max)}$ of 587 µg/kg, estimated to correspond to < 100 µg/kg in soil was introduced (**Chapter 1.1.1**). Very potent anticancer and antibacterial drugs, and hormones were excluded from the cut-off so that in total 209 drugs remained. In the next tier, PEC_{slugde} was refined by considering drug lipophilicity (K_d). After using the same cut-off level, 142 drugs remained. Subsequently, PEC_{slugde} was further refined by considering drug biotransformation after uptake in humans by factoring in the fraction metabolised. Applying the same cut-off level decreased to 59 µg/kg for anticancer and antibacterial drugs, and hormones) reduced the total number of drugs to 22. Finally, under consideration of biodegradation in wastewater treatment facilities, the final number of drugs that had to be assessed was 14.

The 14 identified drugs belonged to ATC classes that also were relevant in the present risk assessment. In ATC A, ranitidine and mesalazine were evaluated. Ranitidine is used to treat acid reflux, but prescriptions have been decreasing since 2017, reaching zero in 2021. The drug did not fulfil any of the three selection criteria in this assessment and was therefore not evaluated. In contrast, mesalazine, used to moderate active ulcerative colitis, was considered (**Appendix II**) but excluded from the hazard characterisation because of extensive biotransformation and low prescription numbers. In ATC B, the anti-thrombotic agent dipyridamole was considered in 2009. Since the prescription numbers of this drug have decreased to below 10,000 in 2021, and it did not fulfil any of the selection criteria, it was not evaluated in the present assessment. In ATC C, metoprolol, losartan and atorvastatin were evaluated in 2009. Their hazards were also characterised in this risk assessment and considered as moderate to high with regard to their pharmacological and toxic properties. However, since they were not expected to accumulate in plants, risks connected to the dietary exposure from food produced after the application of sewage sludge to agricultural soils were assumed to be low. In ATC J, the antibiotics tetracycline, and ciprofloxacin were considered as the most relevant in 2009. These drugs are also among those expected to cause considerable risks in the present assessment. In ATC M, the muscle relaxant carisoprodol was considered in 2009. Prescriptions for this drug are currently close to zero and it is under action of market withdrawal because of substantial abuse due to potent sedative properties. The drug did not fulfil any of the selection criteria in the present risk assessment and was therefore excluded. In ATC N, the anticonvulsants gabapentin and levetiracetam, and the antipsychotic chlorprothixene were considered in 2009. Whereas gabapentin is detected frequently in sewage sludge in Norge and connected hazards were consequently characterised in the present risk assessment, the drug is not expected to accumulate in plants and thus not considered to be of relevant risk with regard to the dietary exposure of humans. Levetiracetam and chlorprothixene did not fulfil any of the selection criteria and were thus not evaluated. In ATC R, the anti-histaminic fexofenadine was considered in 2009. The drug has also been characterised as of concern in the present risk assessment due to its considerable potency, high levels in sewage sludge and expected accumulation in plants.

In summary, some of the drugs prioritised in the 2009 assessment after a selection process based on predicted sludge concentrations have been confirmed in the present assessment, which is supported by measured drug levels. However, the relevance of 50 % of the drugs was confirmed, while the others were excluded, mostly because their current prescription numbers are low to zero.

9 Risk Characterisation

9.1 Environmental risk

The risk of adverse effects on soil- and aquatic living organisms has been assessed based on the predicted concentrations in soil and surface water (PEC_{soil} and PEC_{sw}) and predicted no-effect concentrations (PNEC) in the corresponding media. The risk characterisation ratio (RCR) was calculated as RCR = PEC/PNEC, where RCR > 1 indicates potential risk.

A gradation of RCR into categories such as low, significant or high risk, previously applied in the assessment of heavy metals and arsenic (As) in fertilisers (VKM, 2022), was not applied in the present evaluation. Due to considerable uncertainties in the hazard characterisation, arising from the limited number of experimentally derived PNEC values and environmental fate parameters (DT_{50} and K_{oc}), a conservative approach was adopted in selecting input parameters. in addition, several scenarios of sewage sludge and sewage sludge-based product applications were intentionally designed to be conservative.

The PNEC-values used for soil-living organisms were derived from aquatic organisms ($PNEC_{aq}$). When experimental data were lacking, PNECs were estimated using quantitative structure–activity relationships (QSARs). This approach was applied to almost half (26 of 56) of the $PNEC_{aq}$ values associated with RCR > 1 (denoted $PNEC_{aq,qsar}$). However, QSAR-based estimates introduce additional uncertainties (see **Chapters 3.3** and **Chapter 10**).

Because the toxicity assessment is based on effects in aquatic organisms rather than soil-living organisms - which may differ in sensitivity – results should be interpreted with caution. When a potential risk to soil-living organisms from contaminants in sewage sludge was identified, efforts were made to locate experimental $PNEC_{soil}$ values derived from soil organism data.

Risks to soil-living organisms (RCR > 1) were characterised for the period immediately following sewage sludge application (within 30 days), evaluated at year 91 or 100 (representing 10 applications at 10-year intervals or annual applications, respectively). This is referred to as long-term risk ($RCR_{soil,peak,100yr}$).

The $RCR_{soil,peak,91}$ values for compounds with RCR > 1 are presented in **Figures 9.1.1-1 to 9.1.1-4**. These figures either compare $RCR_{soil,peak}$ values across contaminants after nine applications under different scenarios or illustrate the temporal development of $RCR_{soil,peak}$ from the first to the ninth application for selected organic contaminants.

To further examine predicted concentrations in soil (PEC_{soil}), the time profiles of five representative contaminants were analysed: UV-329 (maximum $RCR_{soil,peak}$ 108), EHDPP (16), Isocyclemone E (3.0), PFOS (2.7), and carbamazepine (2.1). PEC_{soil} values were plotted over time frames of 1 year, 1–10 years, and up to 100 years (**Figure 9.1.3-1**). These contaminants were selected based on their differing physicochemical properties and high detection frequency in sewage sludge (>0.9), with measured concentrations above the limit of quantification in 17 to 143 samples.

The modelling results highlight the influence of different sewage sludge application scenarios on contaminant accumulation in soil, showing considerable variation in predicted concentrations. Furthermore, degradation processes and transfer between environmental

compartments (e.g. from soil to water, or water to biota) affect the persistence of contaminants in soil and, consequently, the associated risk to soil-living organisms.

9.1.1 Soil-living organisms

9.1.1.1 Today's practice application of sewage sludge according to P-limitation in the Fertiliser use regulation (ToR2a)

$RCR_{soil/peak/100yr}$ after the 10th application of repeated sewage sludge applications (10 applications, 10-year intervals).

The scenario ToR2a considers 10 applications of sewage sludge to agricultural soil over a period of 91 years (11.2 tonnes/ha/10 yr), with applications every tenth year. 56 contaminants with estimated concentrations in soil directly after the tenth application of $RCR_{soil/peak/100yr}$ > 1 are exceeding PNEC set for toxic effects to soil-living organisms and therefore considered to be of risk. **Figure 9.1.1-1** shows the $RCR_{soil/peak/100yr}$ as means of the eight Norwegian regions considered in this assessment, and the minimum and maximum values (information about scenarios in **Table 5.1-1**).

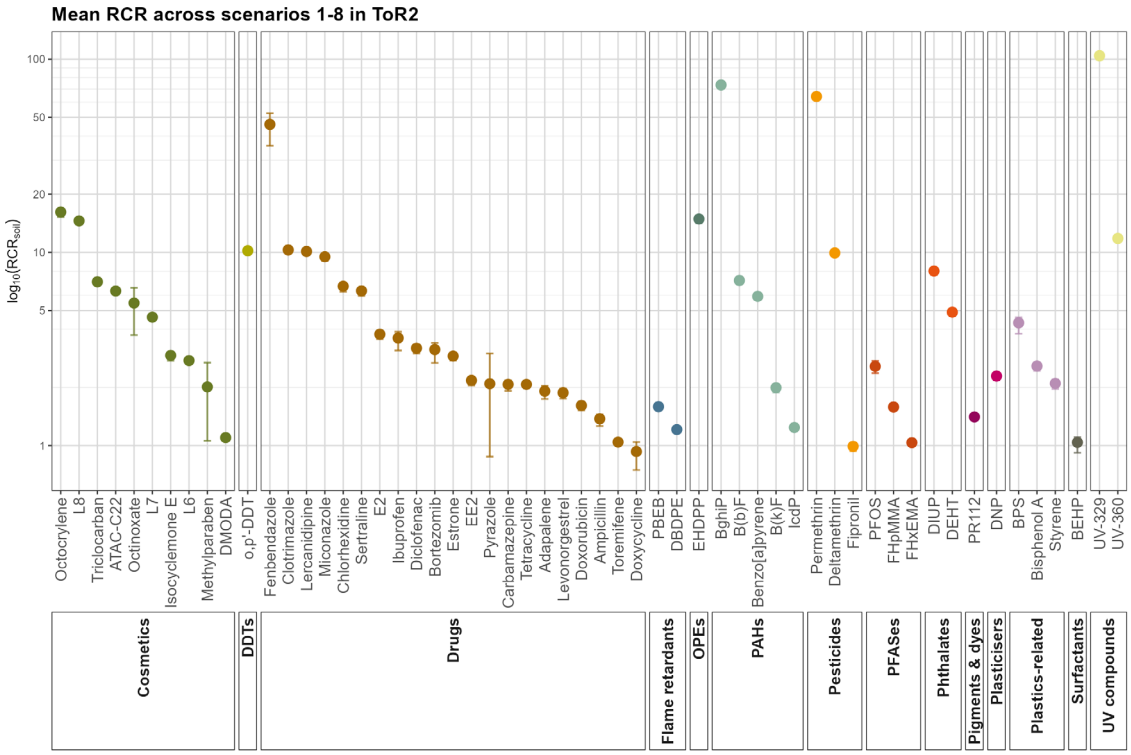


Figure 9.1.1-1. All contaminants predicted to have $RCR_{soil/peak/91}$ > 1 after 10 sewage sludge applications over 91 years according to the ToR2a scenarios.

Note: Only contaminants that had $RCR_{soil/peak/91}$ > 1 in at least one scenario are shown. Points indicate the mean $RCR_{soil/peak/91}$ value. The minimum and maximum $RCR_{soil/peak/91}$ across the different scenarios are marked by whiskers. The contaminants are ordered by chemical group and shown in the order highest to lowest value. A log10-scale is used for better graphic design.

PNECs derived from QSAR data have much higher uncertainty (**Chapter 3.3**), and results calculated for these compounds should be interpreted with caution. When applying more stringent quality criteria for the quality of the assessment (e.g only include PNECs derived

experimentally, number of detections in sludge, detection frequency), the RCR for the contaminants in (**Figure 9.1.1-2)** are more certain.

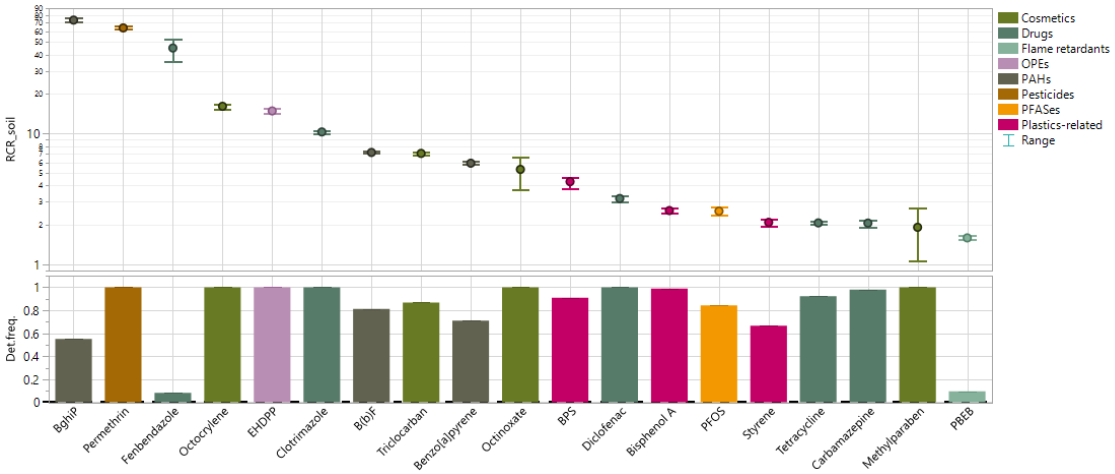


Figure 9.1.1-2. Contaminants satisfying data-quality criteria with $RCR_{soil/peak/91}$ > 1 after 10 sewage sludge applications over 91 years according to the ToR2a scenarios.
Note: The compounds satisfying the data-quality criteria are more certain to have RCR above one than those in Figure 9.1.1-1. The axis for RCR is on a log10 scale. The bar plots in the lower panel show detection frequencies in sludge.

A few of the contaminants had relatively low detection frequencies, i.e. fenbendazole and PBEB. However, most of the compounds in **Figure 9.1.1-2** were quantified with high frequency in the sludge samples. Of the 19 compounds, five are drugs, four cosmetics, three plastics-related, three PAHs, and one pesticide, flame retardant, OPE and PFAS. The BghiP (PAH), permethrin (pesticide) and octocrylene (cosmetics) had the highest predicted risk with a maximum $RCR_{soil/peak/100yr}$ of 76, 66, 52, 16 and 15, respectively (depending on the location and crop).

Information about degradation rate in soil (DT50soil), mobility (Koc) used in the modelling and about sewage sludge (number of samples/WWTPs samples are from, the frequency of data>LOD is summarised in **Table 9.1.1**. All the organic contaminants with quality criteria have been measured above detection limit in Norwegian sewage sludge, and with a few exceptions, a high detection frequency.

Table 9.1.1 Properties of compounds with identified risk to soil living organisms.

Group	Name	Max RCR	N detections in sludge	Detection frequency	Water solubility (mg/L)	logKoc (L/kg)	DT50 soil (d)
Cosmetics	Methylparaben	2.7	39	1	2600	1.6	16
Cosmetics	Octinoxate	6.6	157	1	6.1	3	16
Cosmetics	Octocrylene	17	112	1	0.58	4.1	1,582
Cosmetics	Triclocarban	7.2	53	0.87	9.9	4.7	15,819
Drugs	Carbamazepine	2.2	143	0.98	120	2.5	158
Drugs	Clotrimazole	10	7	1	0.16	4.6	15,819
Drugs	Diclofenac	3.3	141	1	1.8	2.8	158
Drugs	Fenbendazole	52	12	0.083	0.01	1.6	158
Drugs	Tetracycline	2.1	13	0.92	420	4.8	15,819
Flame retardants	PBEB	1.6	124	0.097	0.0003	4.9	15,819
OPEs	EHDPP	16	124	1	1.9	3.4	158

PAHs	**B(b)F**	**7.4**	**256**	**0.81**	**0.0021**	**5.6**	**158,188**
PAHs	**Benzo[a]pyrene**	**6.1**	**300**	**0.71**	**0.002**	**5.6**	**158,188**
PAHs	**BghiP**	**76**	**301**	**0.55**	**0.00023**	**4.6**	**15,819**
Pesticides	**Permethrin**	**66**	**7**	**1**	**0.083**	**4.8**	**15,819**
PFASes	**PFOS**	**2.7**	**198**	**0.84**	**410**	**2.9**	**527,292**
Plastics-related	Bisphenol A	2.7	251	0.99	170	3	158
Plastics-related	BPS	4.6	120	0.91	690	2.7	158
Plastics-related	Styrene	2.2	6	0.67	220	3	158

Note: The group, name, number of detections in sludge, detection frequency, water solubility, logKoc and the half-life in soil are shown. The compounds with the most "risk years" (combination of RCR>1 and long DT50) are marked in bold.

Based on this information, the conclusion for risk towards soil living organisms after application is that the compounds with long half-life and risk may be a suggested way to prioritise among the compounds. In this case, the PAHs (B(b)F, Benzo(a)pyrene and BghiP), the pesticide permethrin and PFOS will have many "risk years" (understood as a combination of risk and DT50). A compound like methylparaben on the other hand, are estimated to be below RCR only a month after application. Therefore, the half-life of the contaminants is very important to consider.

$RCR_{soil/peak}$ immediately after a sewage sludge application over the 100-year period

The estimated $RCR_{soil,peak}$ changed over the 100-year period due to repeated sludge applications and biodegradation processes. **Figure 9.1.1-3** illustrates changes over time for contaminants exceeding $RCR_{soil,peak}$ >1 in scenario 6, grass production in Melhus, with application of dewatered sewage sludge (11.2 tonnes/ha/10 years). Persistent compounds such as PAHs, flame retardants, DDTs and PFAS accumulate over time, with each additional application of sludge. Other groups and individual contaminants showed no accumulation over time and are, therefore, visible as a stable line, such as e.g. OPEs, phthalates, plasticisers, plastics-related compounds and surfactants. clotrimazole, and tetracycline had an increased RCR from 1 application vs. 9 applications (7-10 times increased risk), octocrylene and PFOS had a smaller increase in risk over time (2 and 1.4), while the other contaminants had fairly stable risk over time.

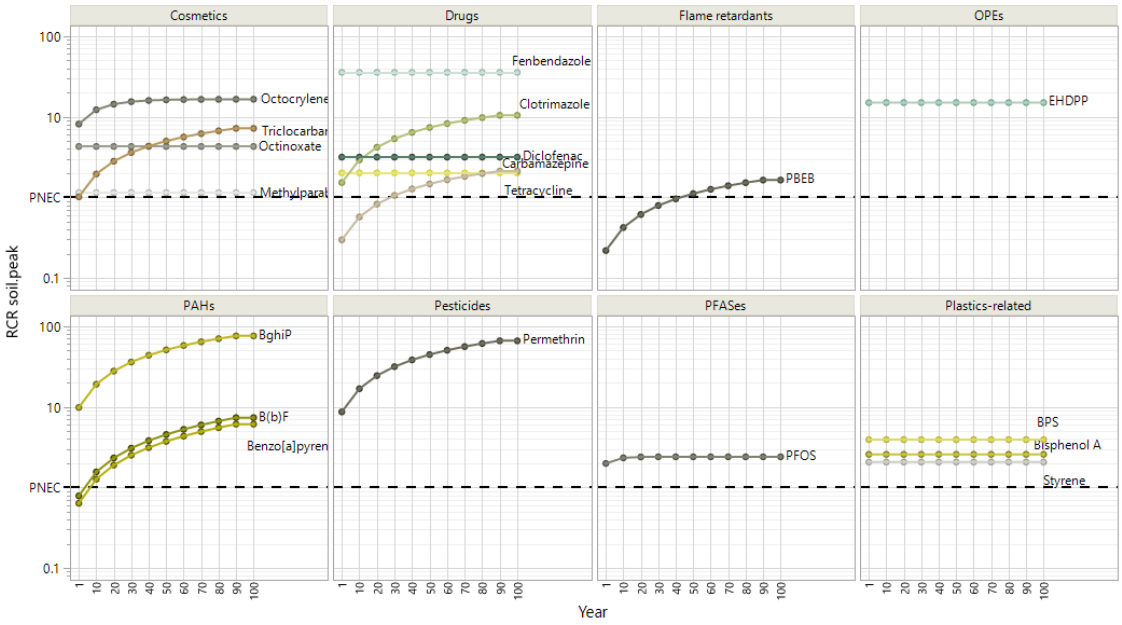


Figure 9.1.1-3. Development of $RCR_{soil,peak}$ over 100 years after repeated sludge applications according to scenario 6, grass production in Melhus (11.2 tonnes/ha/10 yrs).
Note: Contaminants are shown on a loc10 scale with different colours and are grouped with regard to their chemical group affiliations. Contaminants with RCR >1 and reliable data are included. PNEC is indicated at RCR=1. The lines connecting the $RCR_{soil,peak}$ points of each contaminant have been added for illustration purposes only. Please refer to **Figure 9.1.3-1** for a realistic presentation of the time trends.

Some contaminants are considered on a group basis, for example, sum ΣPBDE6, sum ΣDDT (4 congeners) and sum ΣPCB6 and sumΣ PCB7. The concentrations over time are shown in **Figure 9.1.1-4** for grass production in Melhus using three application practices.

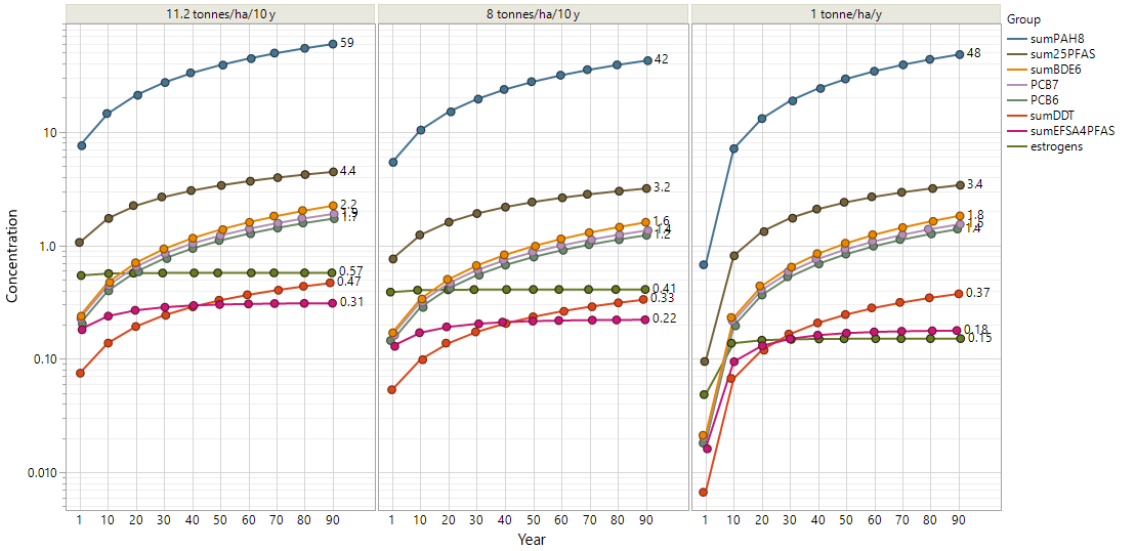


Figure 9.1.1-4 The long-term development of $RCR_{soil,peak}$ for contaminant groups, for grass production in Melhus and three application practices
Note: The three application practices are today's practice (11.2 tonnes/10 years, left panel), reduced application (8 tonnes/10 years, middle panel), and yearly applications (1 tonne/year, right panel). The contaminant groups are (i) environmental concern: SPAH8, SPFAS25, SBDE6, SPCB7; human health concern: SPCB6 and EFSA4PFAS; estrogens: SDDT (4 isomers). Concentrations are shown in log10 scale. The numbers signify final year concentrations. The lines connect the RCRsoil,peak points. Please refer to **Figure 9.1.3-1** for a realistic presentation of concentration time series.

Figure 9.1.1.4 shows that most of the most relevant contaminant groups accumulate in soil over time after repeated sewage sludge applications. Persistent chemicals such as PAHs, PCBs, DDTs and PBDEs accumulate to a greater extent in soil than oestrogens, which $RCR_{soil,peak}$ curves flatten after several application cycles. PAHs, PCBs DDTs and PBDEs have a high affinity to lipids and organic matter in the soil and high molecular stability. They will therefore persist in soil for a prolonged time period. PFAS have slightly different physiochemical properties than the POPs (Persistent Organic Pollutants) because they are surface-active, which means that they are both lipid-soluble and water-soluble. SEFSA4PFAS accumulate more slowly than, for example, SDDTs (also 4 congeners). Although the $RCR_{soil,peak}$ after the first sewage sludge application was lower for SDDTs than for SEFSA4PFAS, this order was predicted to change after 3 to 4 applications. The impact of different application rates is further discussed in the next chapter.

9.1.1.2 Impact of alternative application rates of dewatered sewage sludge (8 tonnes/ha/10 years and 1 tonne/ha/year)

$RCR_{soil/peak/91}$ after the 10th application of repeated sewage sludge applications (10 application, 10-year intervals or after yearly applications

Since risk were shown with application 11.2 tonnes/ha/10yeas, application of 8 tonnes/ha/years and 1 tonne/ha/yr were evaluated.

Figure 9.1.2-1 shows contaminants with $RCR_{soil/peak/91}$ >1 after sewage sludge applications according to today's practice (11 tonnes/ha/10 yrs), with a reduced amount (8 tonnes/ha/10 yrs) and yearly applications (1 tonne/ha/year). When decreasing the amount applied from 11.2 tonnes to 8 tonnes every 10 years, the RCR are decreasing accordingly (a reduced risk of 0.71 (8 tonnes divided by 11.2 tonnes=0.71)). Since ToR2a and TOR2d1 only differ in the amounts of sewage sludge applied, the decrease in environmental risk can be expressed by this factor. None of the 19 compounds that had passed quality criteria was estimated to be reduced below RCR <1 (**Figure 9.1.2-1**).

Changing to annual application of 1 tonne each year, seven compounds were estimated to have a reduced RCR<1; octinoxate, BPS, diclofenac, bisphenol A, methylparaben, styrene and carbamazepine (these are marked with a triangle in **Figure 9.1.2-1**. The reduction comes in compounds with low half-life and sufficiently low RCR. However, for persistent compounds, the risk by yearly application of 1 tonne increases the risk for these versus applying 8 tonne/10 years. The reason is that the amount of sludge applied will be higher (10 tonnes after 10 applications) compared to the scenario of 8 tonnes /10 year. Persistent compounds will not degrade substantially during these years, and therefore, the amounts applied will be higher, and thereby the RCR. Depending on the contaminant properties, annual application result in higher risk for some contaminants and lower long-term RCRs than for ToR2d1 (**Figure 9.1.2-1**, lower panel). See also Table 9.1.2.1 for $RCR_{peak.soil.91}$.

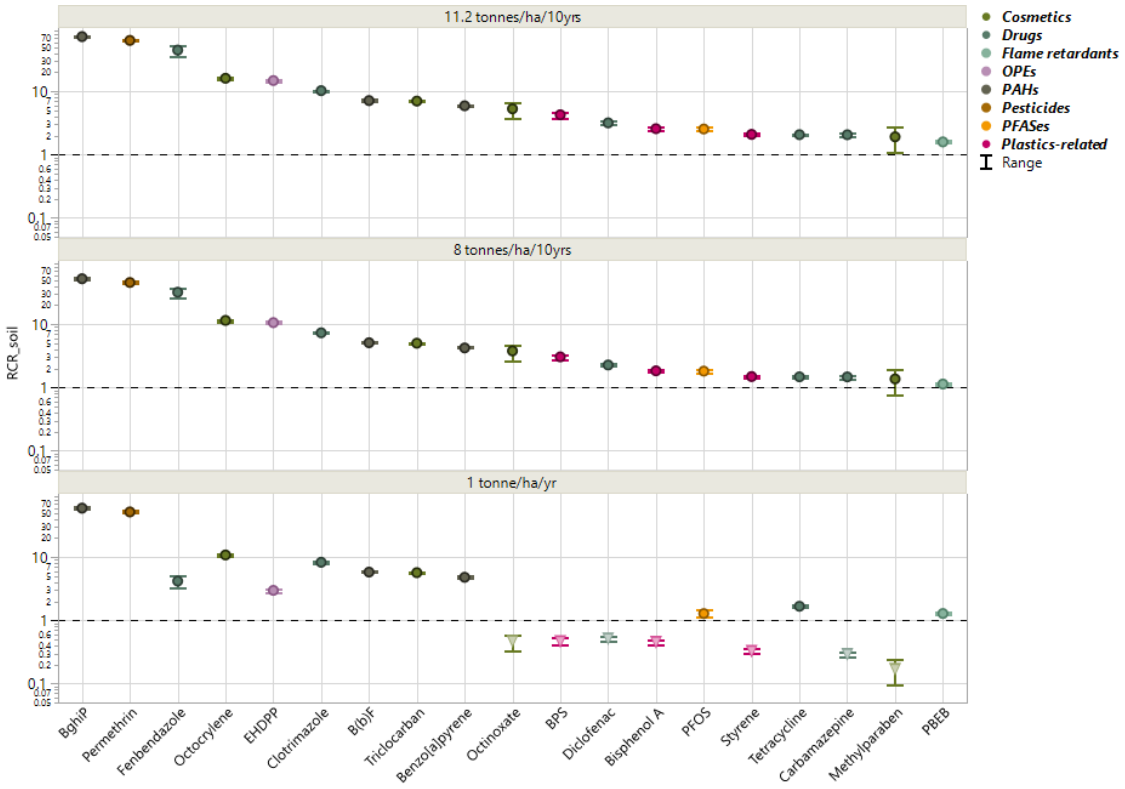


Figure 9.1.2.1. Contaminants with $RCR_{soil/peak/91}$ > 1 after application of sewage sludge in accordance with different application practices

Note: The three application practices are: ToR2a (11.2 tonnes every 10th year, top panel), TOR2d1 (8 tonnes every 10th year, middle panel), ToR2d2 (1 tonne every year, lower panel). The risk is on a log10 scale. The range for all locations/rotations is shown as whiskers to the mean value, which is represented by a dot. Contaminants, for which reducing application amounts from 11.2 tonnes/10 yrs resulted in $RCR_{soil/peak/91}$ decreasing to below 1 are marked with a triangle and lighter colors.

Table 9.1.2.1 Minimum/maximum $RCR_{peak,soil,91}$ for the contaminants with identified risk for the three applications.

Group	Name	11.2 tonnes/ha/10 y		8 tonnes/ ha/10 y		1 tonne/ha/y		Ratio (1 tonne/ha/y vs 8 tonnes/ha/10 y)	
		Min RCR	Max RCR	Min RCR	Max RCR	Min RCR	Max RCR	Min	Max
Cosmetics	Methylparaben	1.1	2.7	0.76	1.9	0.095	0.24	0.13	0.13
	Octinoxate	3.7	6.6	2.7	4.7	0.33	0.59	0.13	0.13
	Octocrylene	15	17	11	12	10	11	0.93	0.95
	Triclocarban	6.8	7.2	4.9	5.1	5.5	5.8	1.1	1.1
Drugs	Carbamazepine	1.9	2.2	1.4	1.6	0.26	0.32	0.19	0.21
	Clotrimazole	9.9	10	7.1	7.5	8	8.5	1.1	1.1
	Diclofenac	3	3.3	2.1	2.4	0.47	0.56	0.22	0.24
	Fenbendazole	36	52	25	37	3.3	5	0.13	0.13
	Tetracycline	2	2.1	1.4	1.5	1.6	1.7	1.1	1.1
Flame retardants	PBEB	1.5	1.6	1.1	1.2	1.2	1.3	1.1	1.1
OPEs	EHDPP	14	16	10	11	2.7	3.2	0.27	0.29
PAHs	B(b)F	7	7.4	5	5.3	5.7	6	1.1	1.1
	Benzo[a]pyrene	5.8	6.1	4.2	4.4	4.7	5	1.1	1.1
	BghiP	71	76	51	54	58	62	1.1	1.1
Pesticides	Permethrin	62	66	44	47	50	54	1.1	1.1

PFASes	PFOS	2.4	2.7	1.7	2	1.1	1.5	0.64	0.77
Plastics-related	Bisphenol A	2.4	2.7	1.7	1.9	0.42	0.48	0.24	0.26
	BPS	3.8	4.6	2.7	3.3	0.4	0.53	0.15	0.16
	Styrene	2	2.2	1.4	1.6	0.3	0.35	0.21	0.23

Note: The RCR ratios (RCR 1 tonne/ha/year divided by RCR 8 tonnes/ha/10 years) are shown in the last two columns. A ratio above 1 means that the RCR is higher when applying 1 tonne yearly compared to applying 8 tonnes over 10 years. The amount applied are higher after 9 yearly applications.

The information in Table 9.1.2.1 shows that reducing the application will reduce the risk. Employing yearly application will reduce the risk for all compounds, but how much is depending on the properties of the contaminants.

Comparison of risk application of dewatered sewage sludge – todays application practice with reduced application rates (ToR2) and regional differences

Comparison PECsoil over time for chemicals with RCR_{soil}>1

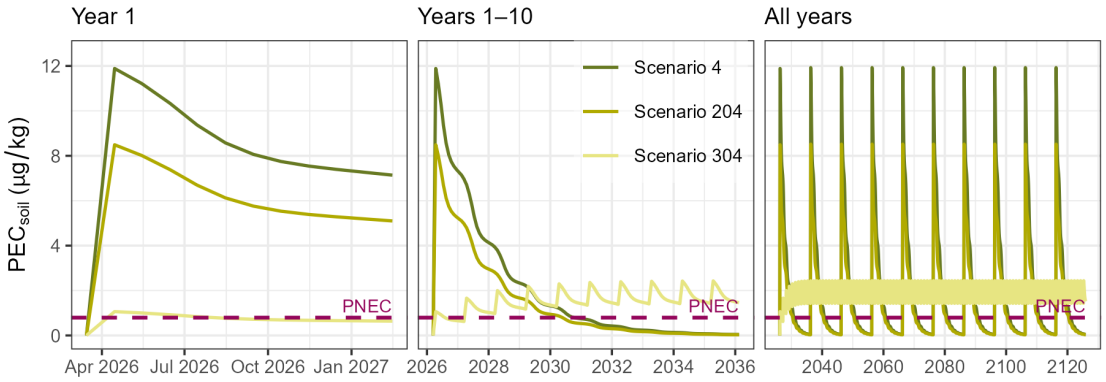
Today's practice of application of dewatered sewage sludge is regulated by amount of P which can be spread in agricultural soil in Norway (given the concentration of heavy metals, DEHP, Sum PFOS and PFOA and PCNB7, is below the maximum limit values). limitation given in the Norwegian Fertilising Use Regulation, which in DM is approximately 11.2 tonnes/ha/10years. Since risk (RCR_{soil}>1) were identified with application of todays' practise of dewatered sewage sludge, application of 8 tonnes/ha/10 years and to 1 tonne/ha/year was evaluated.

Reducing the amount of sewage sludge from 11.2 and 8 to 1 tonne/ha reduce the $RCR_{soil/peak}$ and number of chemicals with $RCR_{soil/peak}$>1 (**Figure 9.1.2-1**). In addition, the change in frequency of application also influence the predicted soil concentrations over time.

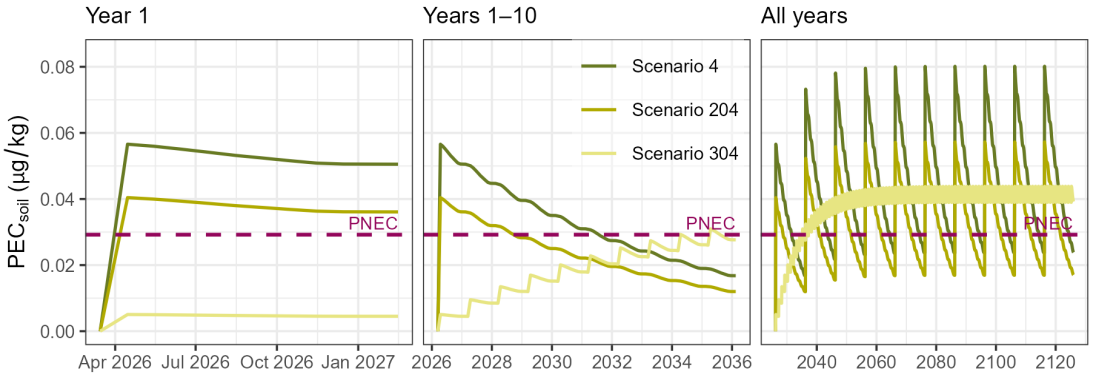
For instance, in **Figure 7.1.-1** presenting PEC_{soil} over time for one year, 1-10 years and all years, PFOS, EHDPP, Isocyclemone and UV-329 all accumulate overreach $PNEC_{soil}$ over 100 years, but during the first 10 years, the pattern are different and while these chemicals PEC_{soil} reach the PNEC level for annual application (1 tonne/ha), the peak PEC_{soil} after application are reduced below the $PNEC_{soil}$. For Carbamazepine the PEC_{soil} pattern is different, only reaching the $PNEC_{soil}$ during the peaks immediately after application. Again, the reason for these differences is primary due to mobility (Koc) but also degradation rates in soil (DT50).

An overview of chemicals which indicated RCR_{soil}>1 in the different scenarios include in evaluation of todays' practice (11.2 tonnes/ha/10years) and reduced amount and frequency (8 tonnes/ha/10years and 1 tonne/ha/year, respectively) is shown in **Table 9.1.2.1**. For each of the chemicals which indicated risk toward soil living organisms (RCR_{soil} >1) for todays' practice are given a comment. In the **Table 9.1.1.3-1**, $PNEC_{soil}$ derived from $PNEC_{aqua}$ and used in the risk assessment together with other $PNEC_{soil}$ found after a search for experimental based values, are included. Information about some of the chemicals which particular high interest are shown in **Table 9.1.1.3-1**.

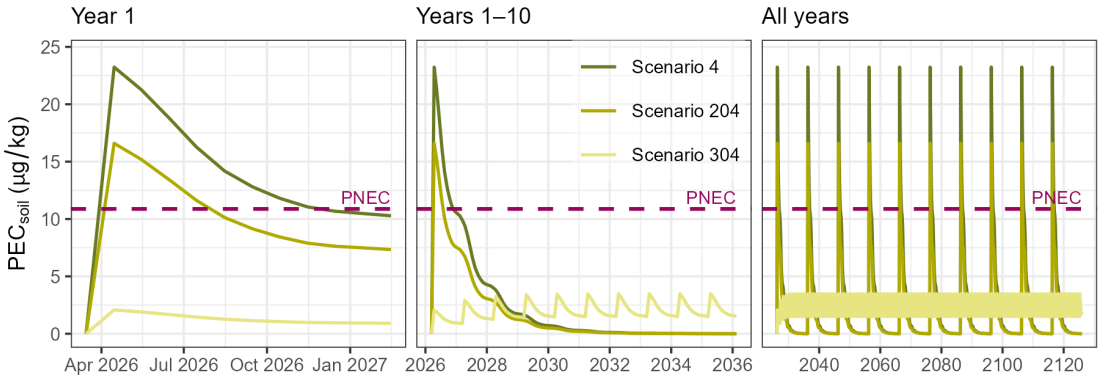
EHDPP (1241-94-7)



PFOS (1763-23-1)



Carbamazepine (298-46-4)



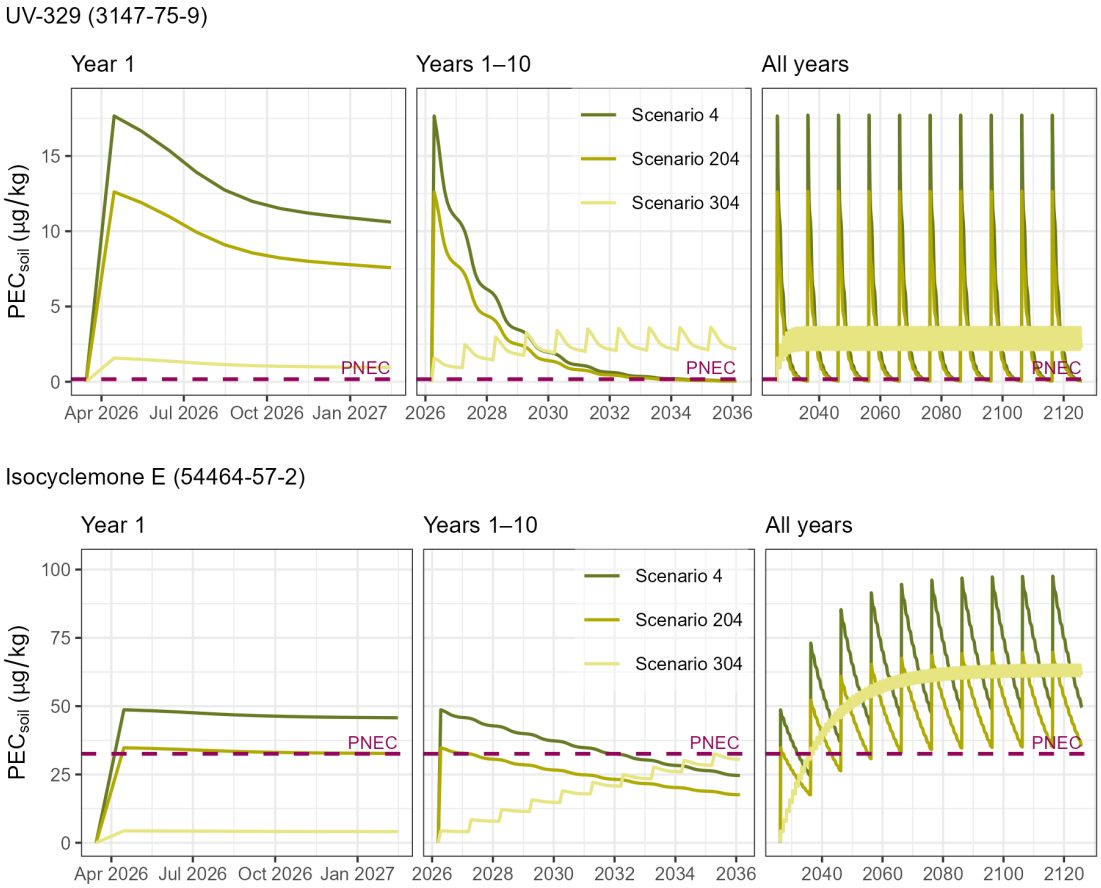


Figure 9.1.1.3-1. PEC$_{soil}$ and PNEC for 5 representative contaminants in potato production fields in Stange.
Note: Scenarios 4 and 204 call for application of 11.2 or 8 tonnes/ha/10 years of dewatered sewage sludge, respectively. Scenario 304 calls for application of 1 tonne/ha/year. The scenarios are further described in ToR2a (Scenario 4), ToR2d1 (Scenario 204) and ToR2d2 (Scenario 304). The dashed horizontal line is PNEC$_{soil}$. Each chemical is identified by its short name and CAS number.

Evaluation of PNEC$_{soil}$ data used to predict RCR$_{soil}$ > 1

The risk characterisation is based on PNEC$_{soil}$ values derived from aquatic toxicity data (PNEC$_{aqua}$) using standard extrapolation approaches. This approach is a useful tool for screening for toxicity > 1000 chemicals, and what is common in when not experimental PNEC$_{soil}$ is available (e.g. Almashaqbeh et al., 2026; Homem et al., 2017).

When the assessment resulted in RCR$_{soil/peak}$>1 which indicates potential concern for soil living organisms for many chemicals, it is important to recognise that the underlying PNEC$_{soil}$ values are associated with considerable uncertainty, as they rely on indirect estimates rather than soil-specific toxicity data.

The majority of the PNEC$_{soil}$ values applied in the initial assessment were derived from QSAR-based aquatic toxicity estimates (572 of 852 chemicals) and subsequently converted to soil thresholds using partitioning coefficients (Kd) and default soil parameters (**Chapter 3.3**). This approach involves multiple layers of extrapolation and may not adequately reflect toxicity, exposure, or sensitivity in the terrestrial compartment.

To improve the scientific robustness of the assessment and to better support the interpretation of potential risks to soil-living organisms, additional efforts were therefore made to identify $PNEC_{soil}$ values derived from experimental soil data.

Table 9.1.3-1. **Overview of applied $PNEC_{soil}$ (derived from PNECaq.) in the present assessment together with other $PNEC_{soil}$ values (Pedersen et al, 2019; Heimstad et al. 2025 (MILBY program).**

Name	Groups	RCRsoil / peak/ 100yr	DT50	Koc	# samples	# plants w/ data	Freq. all plants	MEDIAN sludge conc Q90	PNEC soil	PNEC soil/ exp[1]	PNEC soil[2]
UV-329	UV comp.	104.6	158	787	17	3	0.88	3075	0.17		10000
Chlorhexidine	Drugs	6.3	1582	20614	11	3	0.91	1600	2.47		84
Ibuprofen	Drugs	3.7	158	139	13	1	0.00	500	0.03	1690	
Octocrylene	Cosmetics	15.3	1582	13866	112	13	1.00	7400	5.63		1250
EHDPP	OPEs	15.0	158	2491	124	14	1.00	2070	0.79		302
Benzo[a]pyrene	PAHs	5.8	158188	391858	300	17	0.71	120	1.18	53	
Diclofenac	Drugs	3.2	158	589	141	16	1.00	300	0.53	66	
Bisphenol A	Plastics-related	2.6	158	1080	251	17	0.99	2105	4.60	3700	
PFOS	PFASes	2.4	527292	821	198	17	0.84	9.5	0.03	200	373
Tetracycline	Drugs	2.0	15819	59969	13	1	0.92	4540	95.22	6000	

9.1.1.3 Comparative environmental risk assessment of sewage sludge derived fertilising products in Norwegian agricultural systems (ToR3)

Evaluation of a less strict regulation and a shorter time between the application of sewage sludge before cultivation of vegetables according to EU Sewage Sludge Directive (86/278/EEC) compared to Norwegian Fertiliser Use Regulations (FOR-2025-01-29-115), is only relevant for concentrations of contaminants in plants (PEC_{plants}) and potential increased exposure toward farm animals and humans.

Evaluation of surface spreading of liquid fraction of digested sewage sludge grassland was requested in ToR3. The model used in the risk assessment is based on concentrations in a certain soil volume, i.*e.* it cannot perform calculations on a 2-dimensional unit like soil surface. Due to this limitation, only shallow subsurface injection (0.05 - 0.10 m) was evaluated.

An overview of scenarios which have been evaluated for environmental risk is given in **Table 9.1.4-1**. It includes application of liquid digestate and different sewage-sludge based products, pellets, biochar and struvite. Initially 104 different scenarios with a variety of combinations of use of sewage sludge-based products for different crops, different regions, and in addition, surface application with use of different application methods.

Given a general high uncertainty, for instance related to tolerance level (selection of PNEC), parameters used in modelling for exposure concentrations in soil and surface water for predicting fate of the different organic contaminants which primarily are based on predicted values, is in itself a challenge for performing a risk assessment for application of sewage sludge in agriculture.

Including evaluation of different sewage sludge-products and different application methods as asked for in Terms of References (ToR3), increase the uncertainties so much that a risk assessment is difficult. It is solved by presenting the uncertainty related to each of the products evaluated, presenting the data and the sources used, and by highlighting the uncertainty.

Particularly high uncertainty is associated with the application of the liquid fraction of digested sewage sludge and pellets, as the estimates are based on measured concentrations in dewatered sewage sludge. For pellets, contaminant concentrations are likely reduced due to the addition of binding agents and nutrients during the pelleting process. However, this dilution is expected to be modest and likely falls within the range of the general uncertainty already described.

For liquid fraction of digested sewage sludge, a prediction of the concentration is based on Koc values, which for most compounds are based on predicted values. The Norwegian Fertilising Use Regulations does not allow use of liquid digestate from sewage sludge to be applied in agriculture.

The concentration in the digestate will vary highly, depending on the amount of the co-substrate and maybe also on the co-substrate. The same situation is maybe the case for concentration of contaminants in pellets, where also sewage sludge might be mixed with other co-substrates before production of pellets.

In this evaluation, reduction or changes of the concentration of contaminants compared to dewatered sewage sludge is not accounted for even if it is known the concentrations are far less realistic and representative than for what have been applied for evaluation for dewatered sewage sludge, which in itself is a realistic worst-case approach using median of 90 percentile concentration, and using lowest LOD (Upper Bound values).

Evaluation of different scenarios:

1. ***Application of liquid fraction of sewage sludge digestate to grassland in all regions surface spreading, modelled with use of 0.05 m as standard, compared with 0.10 m soil depth (deep injection)***

2. ***Application of liquid fraction of sewage sludge digestate to cultivation of cereals, potato and vegetables in all regions, mixed into 0.15 m soil depth.***

3. ***Application of pellets to cultivation of cereals, potato and vegetables in all regions, mixed into 0.15 m soil depth.***

4. ***Application of biochar for cultivation of cereals, potato and vegetables in all regions, mixed into 0.15 m soil depth.***

Again, given all the uncertainty makes an evaluation of risk difficult. Biochar is applied primary as soil improver. The contaminants present in sewage sludge will during the pyrolysis decrease, and the residue left in the biochar are dependent on the process parameters in the pyrolysis process and the inherent physico-chemical properties of the chemical. In addition, during pyrolysis, compounds like PAHs, PCB and dioxins will be formed, which also is dependent on process parameters during pyrolysis process. Concentration of catalytic metals in sludge, Fe and Cu, will also influence.

In the present risk assessment, model-predicted levels of organic contaminants in biochar have been derived from the same data set of measured concentrations of contaminants used for risk evaluation of dewatered sewage sludge (described in Annex I, Chapter 4.3.1 appendix).

Model-predicted residue concentration of organic contaminants in biochar at 300-800°C were performed (see Chapter 6.5). As a conservative approach, used throughout the risk assessment, application of biochar processed at 400°C. It was also analysis of a long list of organic contaminants, including pharmaceuticals, of biochar produced from Norwegian sewage sludge at 400°C, which make a comparison of the model-predicted and measured analysis possible.

Since biochar during the pyrolysis change their physical properties, it gains sorption properties and make the contaminants less bioavailable, unless an organism ingest the biochar particle. The reduction in extractable amount of PFAS in biochar (non-extractable residue, NER) has been evaluated and is well known. This is also the case for other contaminants.

However, the exact fate of such strongly bound contaminants in biochar, is unclear – do they degrade more slowly or is it assumed they never will be bioavailable as solved compound? This makes an evaluation of the long-term risk potential, $RCR_{soil,peak,90\ yrs}$, even more unsure than for the other sewage sludge-based products.

The model-prediction for formation of PCB and PAH and the predicted concentration at different temperatures during pyrolysis (300-800 °C) are shown in **Table 9.1.4-1**

Table 9.1.4-1. Model-predictions for formation of PCBs and PAHs during pyrolyses at temperatures of 300-800°C

T (°C)	PCBs formed	PAHs formed
	ng/kg biochar	µg/kg biochar
300	1 142	1 782
400	3 828	2 832
500	2 796	11 588
600	676	10 690
700	43	2 007

800	0.97	1 528

Note: For more information, see Chapter A-4.3.1 in the Appendix.

5. Application of struvite as fertiliser

Struvite is produced by chemical precipitation in wastewater (during the wastewater treatment or in reject water) and a commercial fertiliser product. It is a more slow-release mineral fertiliser than other mineral fertilisers and is also allowed used in organic farming in Norway.

Content of heavy metals as a result of co-precipitation or sorb to the product have has higher focus than organic contaminants and is excepted to contain organic matter in low amount. However, via literature search a few publications with relevance were found; particularly relevant was the paper by Bloem et al., (2024) analysed for antibiotics in struvite from different commercially P-recovery technologies in WWTPs in Germany and Netherland. Mean and maximum values for four of eight antibiotics included in their study - enrofloxacin, norfloxacin, ofloxacin and ciprofloxacin – were included in the risk assessment. These antibiotics were measured above detection limit in all samples (n= 9 and n=13).

In Norwegian sewage sludge, one of these four antibiotics, ciprofloxacin was measured and detected above the detection limit in 10 of 13 samples (all samples from one WWTP). The other three antibiotics were not detected above detection limits in Norwegian sewage sludge. Concentrations in struvite (Bloem et al., 2024) and in Norwegian sewage sludge are shown in **Table 9.1.4-2**.

Application of struvite mixed in upper 0.05 m of soil in grassland or mixed in with 0.15 m soil depth in cultivation of e.g. cereals, potatoes, vegetables or other crops, the predicted risk over 90 years given as $RCR_{soil,peak,90\ yrs}$, are all below > 0.02.

Table 9.1.4-2. Mean and maximum of measured concentrations of the four antibiotics, enrofloxacin, norfloxacin, ofloxacin, and ciprofloxacin, in commercially produced struvite and sewage sludge.

		Bloem et al., 2024		Norwegian sewage sludge	Liquid digestate (Koc derivated)
		Mean	Max		
CAS No	Name	µg/kg dw			µg/L
93106-60-6	Enrofloxacin	1.22	26.2	250	0.03
70458-96-7	Norfloxacin	6.8	59.9	500	3.30
82419-36-1	Ofloxacin	12.84	131	253	0.03
85721-33-1	Ciprofloxacin	16.06	251	998	1.36

Note: The data for struvite is from Bloem et al. (2024), while Norwegian sewage sludge concentrations are the ones used in the present risk assessment. The values are detected only for ciprofloxacin.

9.1.1.4 Risk when using sewage sludge new ways (ToR3)

A few more contaminants were identified as having risk in ToR3 scenarios compared to ToR2. Originally, 78 compounds were identified as having an RCR > 1 at least one scenario **(Figure 9.2.2.4.1).**

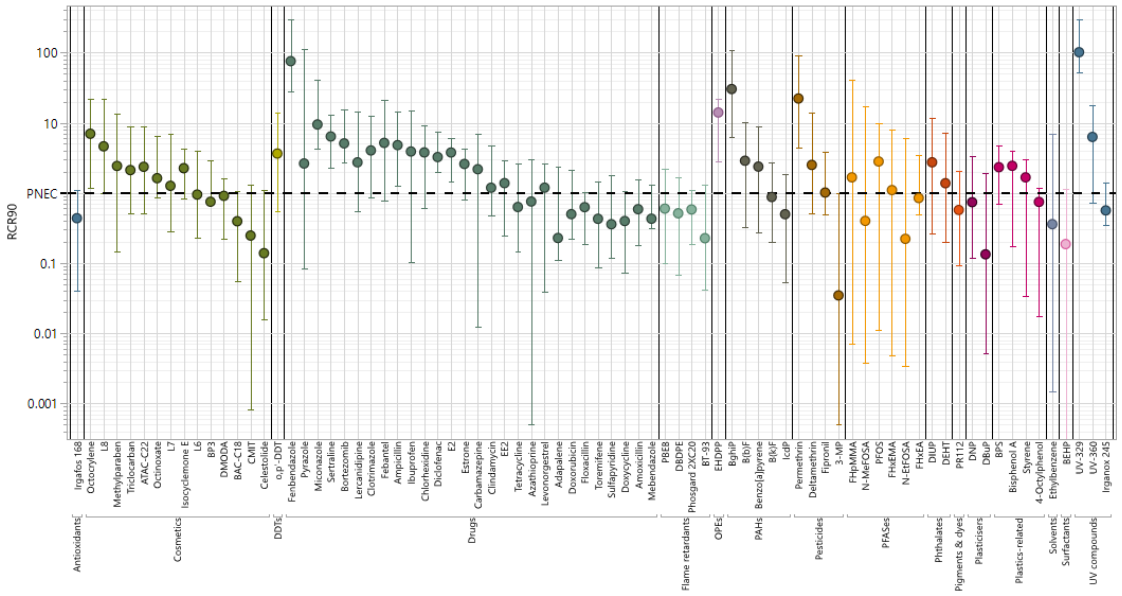


Figure 9.2.2.4.1 $RCR_{soil/peak/100}$ for 78 compounds showing RCR>1 in one or more scenarios in ToR3. *Note:* The RCRs are shown in decreasing order by the group and mean for each contaminant. The mean is shown by a circle, with whiskers indicating the range of RCRs. The axis is on a log10 scale.

After a quality check as described previously, the list was reduced to 23 compounds as shown in **Figure 9.2.2.4.2** and **Table 9.2.2.4**. These are mostly the same compounds as identified in Tor2. Notably, four compounds in the table have quite low detection frequencies: fenbenazole, PBEB, 4-octylphenol and ehtylnenzene. These three compounds are therefore more uncertain since the detection frequencies were all below 10 %, and thereby below the quality criteria.

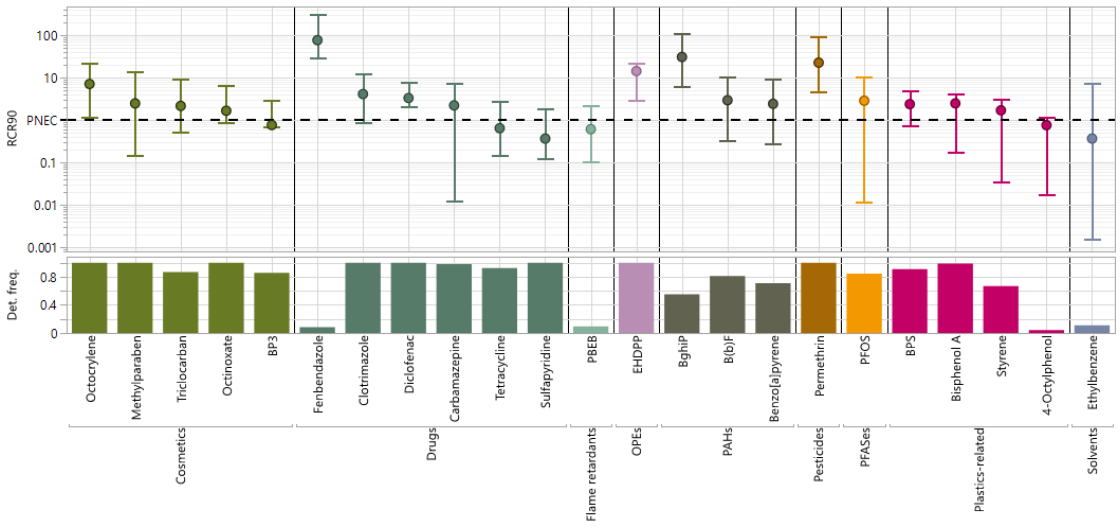


Figure 9.2.2.4.2 $RCR_{soil,peak,91}$ for contaminants satisfying data-quality criteria and with RCR > 1 in one or more scenarios in ToR3.
Note: RCR is in the upper panel, with the axis on a log10 scale. In the lower panel, the detection frequencies are shown.

The same compounds as identified previously with high risk combined with long half-lives (marked in bold in Table 9.2.2.4.1) were identified as posing the most "risk-years".

Group	Name	Max RCR90	N detections in sludge	Detection frequency	Water solubility (mg/L)	logKoc(L/kg)	DT50
Cosmetics	Octocrylene	20	112	1	0.58	4.1	1,582
Cosmetics	Methylparaben	14	39	1	2600	1.6	16
Cosmetics	Triclocarban	8.9	53	0.868	9.9	4.7	15,819
Cosmetics	Octinoxate	6.6	157	1	6.1	3	16
Cosmetics	BP3	2.9	112	0.857	49	2.6	158
Drugs	Fenbendazole	300	12	0.0833	0.01	1.6	158
Drugs	Clotrimazole	12	7	1	0.16	4.6	15,819
Drugs	Diclofenac	7.5	141	1	1.8	2.8	158
Drugs	Carbamazepine	7	143	0.979	120	2.5	158
Drugs	Tetracycline	2.6	13	0.923	420	4.8	15,819
Drugs	Sulfapyridine	1.8	129	1	310	2	158
Flame retardants	PBEB	2.2	124	0.0968	0.0003	4.9	15,819
OPEs	EHDPP	22	124	1	1.9	3.4	158
PAHs	**BghiP**	**110**	**301**	**0.551**	**0.00023**	**4.6**	**15,819**
PAHs	**B(b)F**	**10**	**256**	**0.813**	**0.0021**	**5.6**	**158,188**
PAHs	**Benzo[a]pyrene**	**8.8**	**300**	**0.71**	**0.002**	**5.6**	**158,188**
Pesticides	**Permethrin**	**91**	**7**	**1**	**0.083**	**4.8**	**15,819**
PFASes	**PFOS**	**9.8**	**198**	**0.843**	**410**	**2.9**	**527,292**
Plastics-related	BPS	4.7	120	0.908	690	2.7	158
Plastics-related	Bisphenol A	4	251	0.988	170	3	158
Plastics-related	Styrene	3	6	0.667	220	3	158
Plastics-related	4-Octylphenol	1.2	157	0.0446	18	3.2	158
Solvents	Ethylbenzene	7	73	0.11	170	1.1	158

Table 9.2.2.4.1 Properties of compounds with risk to soil living organisms.
Note: DT50 is the half-life in soil. The compounds with the most "risk years" (combination of RCR>1 and long DT50) are marked in bold.

9.1.2 Aquatic organisms

9.1.2.1 Today's practice application of sewage sludge according to P-limitation in Norwegian fertiliser use regulations (ToR2a)

RCR_{SW} predicted for surface water receiving runoff from soils, where sludge has been applied after today's practice (11.2 tonnes/ha/10 yrs), are shown for three drugs in **Figure 9.2.1-1** after the 1st and 10th application. A 1/10 dilution of the effluent is assumed, which is a conservative estimate. Probably, a 1/10 dilution is only appropriate for the first couple of meters into a nearby stream, whereafter the dilution increases considerably, which should be considered when interpreting the results.

Levonorgestrel, a synthetic sex hormone used for contraception (**Table 8.2-3**), was found to be the contaminant with the highest risk to nearby surface water, both after 1 and 10 sludge applications. The drug has been identified as a contaminant with a high risk to aquatic organisms in a study on estimated drug concentrations based on drug prescriptions in Norway (Welch et al. 2023). In 2021, it was prescribed about 150,000 (**Appendix II on Drugs** to this risk assessment). However, the detection frequency of levonorgestrel in sewage sludge samples from Norwegian water treatment facilities has so far been 0, indicating that the compound has not actually been measured in sewage sludge at concentrations above the LOQ (25 µg/kg dw) (**Figure 9.2.1.1**). However, the hormone is very potent (LOEC < 0.8 ng/L in fish) so that the currently used analytical methods may not be sensitive enough to measure low levels that can elicit effects in aquatic organisms.

Fenbendazole, an anthelmintic used to treat worm infections in domestic animals, has been detected with a detection frequency of 0.1 in Norwegian sewage sludge samples. The predicted RCR_{SW} after 1 and 10 sludge applications are above 1, but lower than for levonorgestrel. The drug is among those considered to have the highest overall risk (**Table 8.2-2**). Furthermore, environmental contaminations with azole compounds are undesirable because of the risk of anti-fungal resistance development.

Doxorubicin, an anti-cancer drug, has been detected with a detection frequency of 0.2 in Norwegian sewage sludge samples. The predicted RCR_{SW} after 1 and 10 sludge applications are above 1. The drug is extremely potent (ADIp 0.05 µg/kg/d in humans) and among those considered to have the highest overall risk (**Table 8.2-2**). Effects on aquatic organisms could thus also occur at low concentrations.

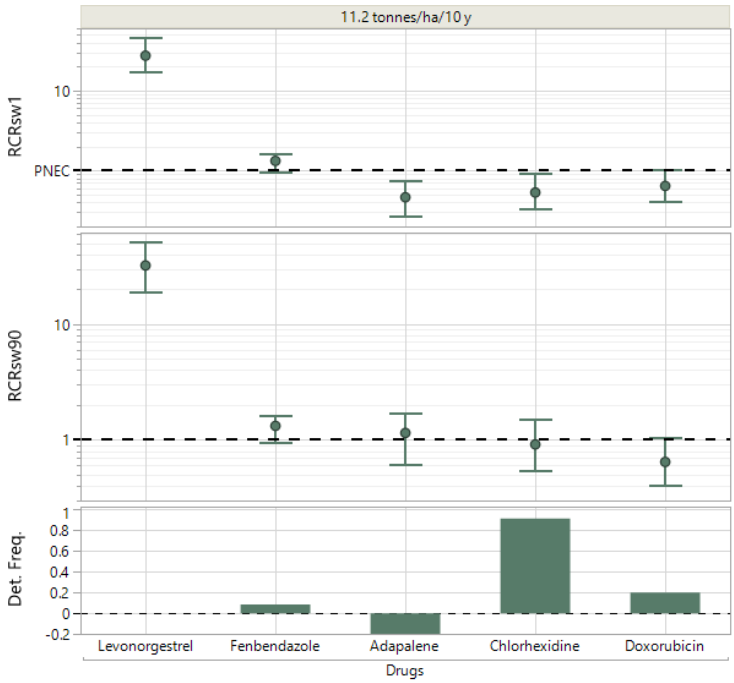


Figure 9.2.1-1. Short-term and long-term RCR_{sw}.
Note: Upper panel: RCR after the 1st application. Middle panel: RCR after the 10th application of sewage sludge. Application according to ToR 2A, 11.2 tonnes/ha/10 yrs. RCRs are indicated in log10 scale. Means are marked by dots, and min to max—by ranges, showing variation between different locations/crop rotations. Only contaminants with RCR_{SW} >1 are shown, in decreasing order of RCR after 10 applications. The bottom panel shows the detection frequencies. Negative frequencies indicate that the compound has not been analysed for (model-based value is used).

After 10 sludge applications, two additional drugs, adapalene and chlorhexidine, reached RCR_{SW} >1 (**Figure 9.2.1.1**). Chlorhexidine, an antimicrobial used as a topical antiseptic (e.g. as mouthwash) has been detected with high frequency (> 0.5) in Norwegian sewage sludge samples. The drug is among those considered to have the highest overall risk (**Table 8.2-2**). It has been detected in the Alna River at concentrations of up to 2 ng/L in a recent study (Ruus et al. 2025). Adapalene, a topical retinoid to treat acne, has not been analysed in Norwegian sewage sludge samples so far. Its overall risk has been evaluated to not be critical (**Appendix II on Drugs** to this risk assessment), but the persistence in soil is predicted to be high with the potential to accumulate (2.7-fold after 10 sludge applications). It could be therefore advantageous to include this drug into monitoring programmes for sewage sludge.

9.1.2.2 Impact of alternative application rates of dewatered sewage sludge (8 tonnes/ha/10 years and 1 tonne/ha/year (ToR2d1, ToR2d2)) on RCR in surface water

Risk to quatic organisms in the different ToR applications and scenarios are shown in figure 9.1.1.6.1. The 5 compounds showing risk are commented previously. It can be seen that the risk is reduced when applying 8 tonnes/ha/10 y compared to 11.2 tonnes/ha/10 y. The risk is not reduced when applying yearly for adapalene, but for the other compouds the RCR is reduced by more. When applying more stringent quality criteria, fenbendazole was the only contaminant that satisfied experimental PNEC and being detected in sludge. However,

fenbenazole had as previously mentioned a detection frequency of < 10%, and was only quantified in 12 samples.

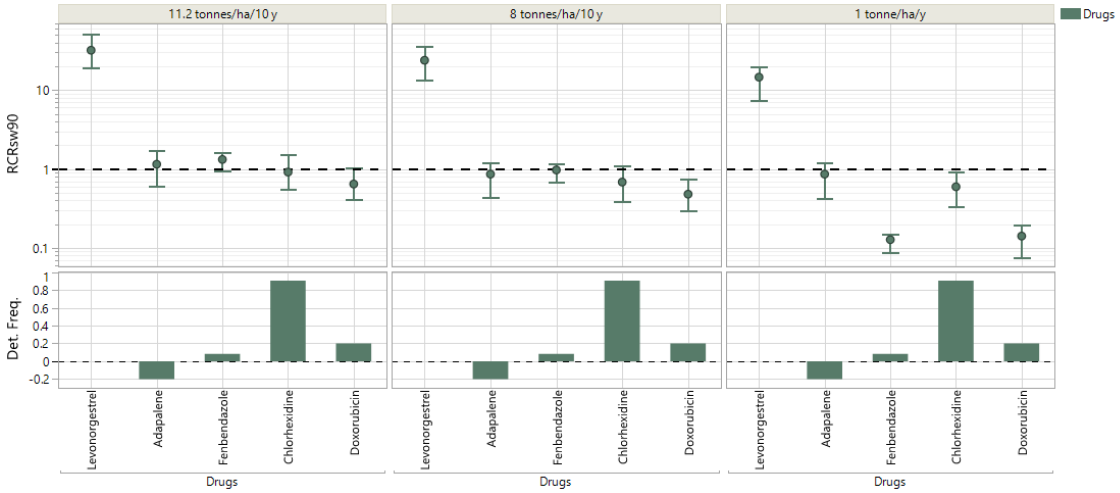


Figure 9.1.1.6.1 $RCR_{sw,91}$ for contaminants exceeding PNEC in one or more scenarios.
Note: RCRs are shown in the upper panels. The mean risk is indicated with a circle while whiskers indicate the range. The scale is on log10-values. In the lower panels, the detection frequencies are shown with bar plots. Missing bars indicate no measurements above LOQ. Negative values indicate that the drug concentrations were estimated based on consumption.

9.1.2.3 Comparative environmental risk assessment of sewage sludge derived fertilising products in Norwegian agricultural systems (ToR3)

Risk to aquatic organisms

Potential risk to aquatic organisms was identified for 79 contaminants (see Figure 9.1.2.3-1).

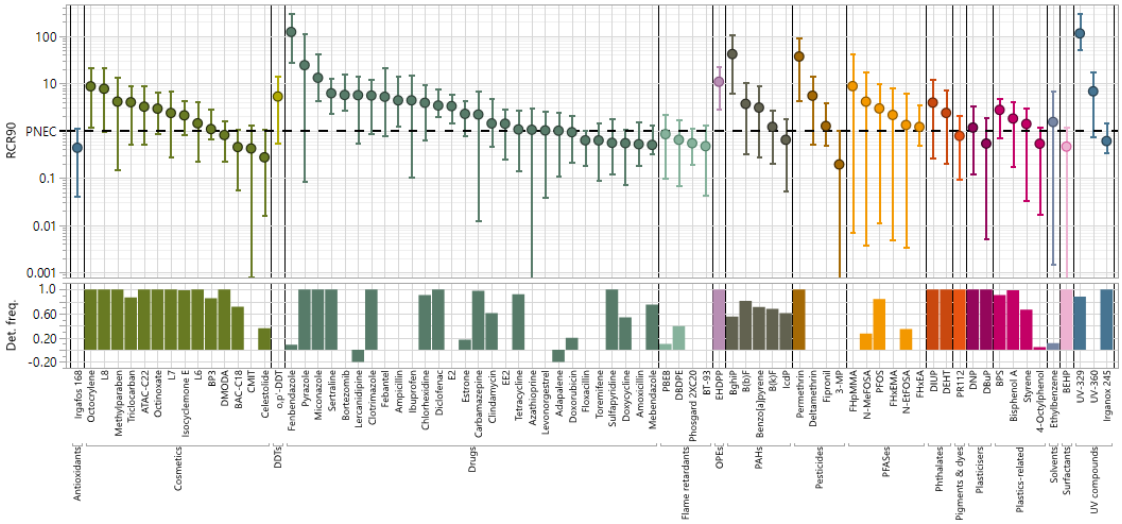


Figure 9.1.2.3-1 $RCR_{sw,91}$ for contaminants exceeding PNEC in one or more scenarios (ToR3).
Note: In the upper panel, the mean risk is indicated with a circle while whiskers indicate the range. The scale is on log10-values. In the lower panel, the detection frequencies are shown with bar plots. Missing bars indicate no measurements above LOQ. Negative values indicate that the drug concentrations were estimated based on consumption.

When using only experimentally derived PNECs, potential risk to aquatic organisms, $RCR_{sw,91}$ was identified for 17 contaminants (Figure 9.1.2.3-2). Some of the contaminants were not detected in sludge and were therefore based on UB values. Two of the drugs were not analysed for in sludge, so concentrations and thereby risk are based on consumption data.

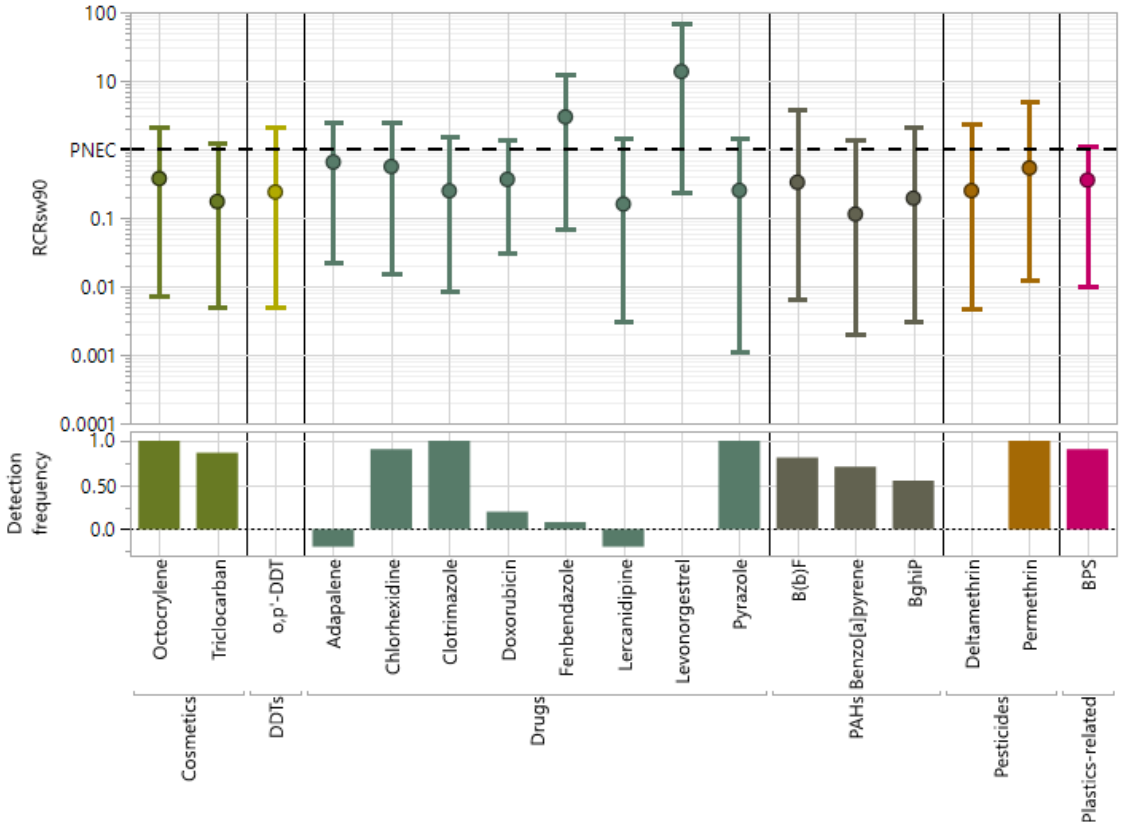


Figure 9.1.2.3-2 $RCR_{sw,91}$ for contaminants exceeding experimental PNEC in one or more scenarios.
Note: RCRs are shown in the upper panel. The mean risk is indicated with a circle while whiskers indicate the range. The scale is on log10-values. In the lower panel, the detection frequencies are shown with bar plots. Missing bars indicate no measurements above LOQ. Negative values indicate that the drug concentrations were estimated based on consumption.

After a quality evaluation of detection in sludge, 9 compounds are listed in Table 9.1.2.3-1, and also shown in Figure 9.1.2.3-3. The compounds showing the highest risk combined with long half-life, were PAHs (B(b)F and benzo(a)pyrene).

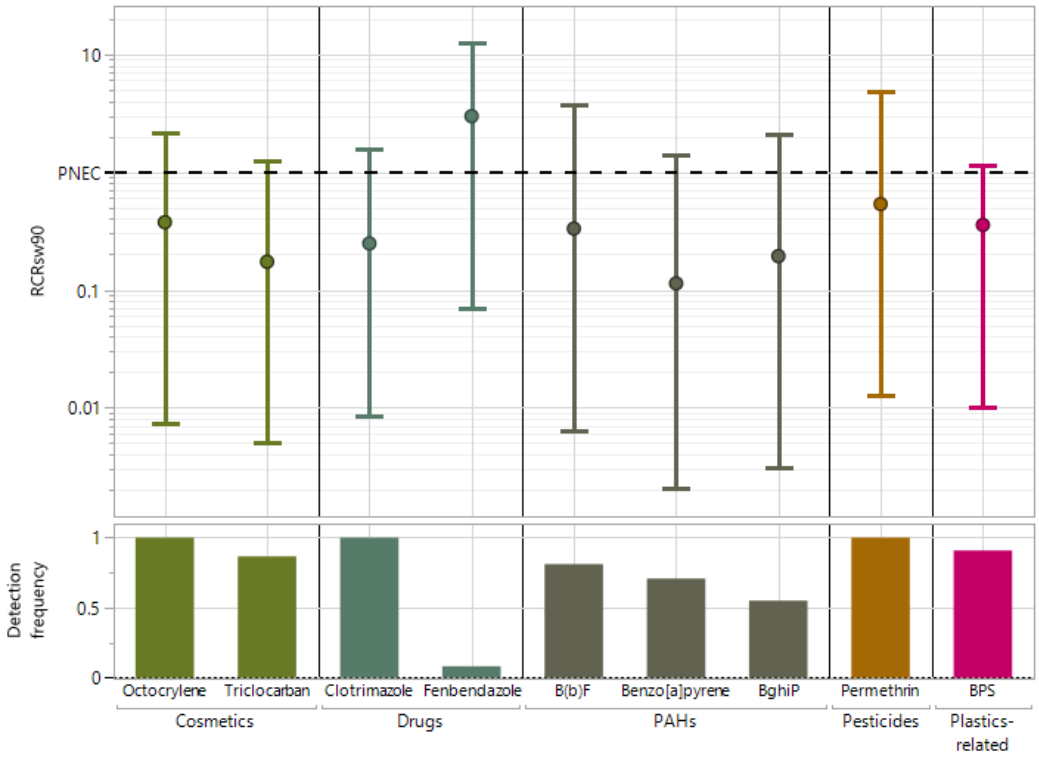


Figure 9.1.2.3-3 $RCR_{sw,90}$ for compounds satisfying data-quality criteria and with an RCR > 1.
Note: RCRs are shown in the upper panel for all ToR3 scenarios. Mean RCR is indicated with a dot, while the range is indicated with whiskers, The detection frequency is shown as the barplot in the lower panel.

Table 9.1.1.7-1 Properties of compounds with risk to aquatic living organisms.

Group	Name	Max	N	Detection	Water	logKoc	DT50
metics	Octocrylene	2.2	112	1	0.58	4.1	1,582
Cosmetics	Triclocarban	1.2	53	0.87	9.9	4.7	15,820
Drugs	Clotrimazole	1.6	7	1	0.16	4.6	15,820
Drugs	Fenbendazole	12	12	0.083	0.01	1.6	158
PAHs	B(b)F	3.7	256	0.81	0.0021	5.6	158,200
PAHs	Benzo[a]pyrene	1.4	300	0.71	0.002	5.6	158,200
PAHs	BghiP	2.1	301	0.55	0.00023	4.6	15,820
Pesticides	Permethrin	4.9	7	1	0.083	4.8	15,820
Plastics-related	BPS	1.1	120	0.91	690	2.7	158

Note: DT50 is the half-life.

9.2 Secondary poisoning of wildlife

The accumulation of contaminants from water to small freshwater fish was calculated by multiplying the concentrations in surface water (PEC_{sw}) with the respective BCF. The resulting concentrations (PEC_{fish}) are typical for small fish of trophic level (TL) 2 in the food chain in a nearby river. They are shown in **Table 9.3.1** for all locations and scenarios in ToR2.

Table 9.3-1. PEC_{fish} of contaminants groups and PFOS in small fish.

Summary group	Location	Scenario	PEC_{fish} (TL2 fish) after 1st appl. (µg/kg ww)	PEC_{fish} (TL2 fish) after 9th appl. (µg/kg ww)	EQS biota (µg/kg ww)
ΣPCB7	Ås	Cereals	0.10	**0.75**	0.6
		Grass	0.11	**0.80**	
	Melhus	Cereals	0.05	0.35	
		Grass	0.13	**0.96**	
	Stange	Cereals	0.07	0.53	
		Potato	0.07	0.53	
		Vegetables	0.07	0.53	
		Grass	0.10	**0.74**	
ΣBDE6	Ås	Cereals	**0.034**	**0.32**	0.0085
		Grass	**0.037**	**0.35**	
	Melhus	Cereals	**0.016**	**0.15**	
		Grass	**0.043**	**0.41**	
	Stange	Cereals	**0.024**	**0.23**	
		Potato	**0.024**	**0.23**	
		Vegetables	**0.024**	**0.23**	
		Grass	**0.033**	**0.31**	
ΣDDT	Ås	Cereals	0.045	0.23	610
		Grass	0.049	0.25	
	Melhus	Cereals	0.021	0.11	
		Grass	0.058	0.3	
	Stange	Cereals	0.031	0.16	
		Potato	0.031	0.16	
		Vegetables	0.031	0.16	
		Grass	0.043	0.23	
PFOS	Ås	Cereals	1.7	2.1	9.1
		Grass	3.5	4.4	
	Melhus	Cereals	1.6	1.9	
		Grass	4.2	5.1	
	Stange	Cereals	2.3	3.2	
		Potato	2.3	3.2	
		Vegetables	2.3	3.2	
		Grass	3.1	4.4	

Note: PEC_{fish} is estimated for small fish in rivers in the vicinity of agricultural areas treated with sewage sludge according to ToR2a (11.2 tonnes/ha/10 yrs) after 1 and 9 applications. PEC_{fish} exceeding the EQS are indicated with bold font and blue color. For further details on EQS biota, see **Chapter 4.3**.

The data in **Table 9.3-1** illustrate that the PEC_{fish} of all contaminants included increase over time at all locations and with all crop scenarios. PFOS showed a lower increase than ΣPCB7, ΣBDE6 and ΣDDT. Furthermore, the PEC_{fish} determined for ΣPCB7 exceeded the EQS level in some locations after 9 applications according to today's practice (11.2 tonnes/ha/10y sewage sludge). ΣBDE6 exceeded the EQS level in all scenarios. It is expected to exceed EQS in biota in many areas and considered as a ubiquitous contaminant. In contrast, ΣDDT was substantially below the EQS level.

When comparing the concentrations estimated in fish to those measured in fish from supposedly pristine areas (see Chapter 4.3), for example the concentration of PFOS in small trout/salmon were <0.1 -1 × EQS (i.e. 0.9-9 µg/kg ww since the EQS is 9.1 µg/kg. The levels estimated for small fish are therefore higher than the lowest levels observed in pristine areas,

but lower than the highest levels observed. After 10 applications, the estimated levels in fish can be as high as 4-5 µg/kg ww. This may therefore increase the contaminant load of PFOS in nearby rivers to a level that is half of the current EQS.

PFOS is not estimated to exceed today's EQS of 9.1 µg/kg ww in biota. However, the EQS for PFOS set by the EU has recently been exchanged by a group-EQS for ΣPFAS25 measured in PFOA-equivalents, as specified in the EQS directive 2026/805. The new EQS is with 0.0077 µg/kg ww substantially lower. VKM has estimated ΣPFAS25 in PFOA-equivalents for TL2 fish as shown in **Table 9.3-2**.

Table 9.3-2. ΣPFAS25 in PFOA-equivalents according to the EQS directive 2026/805.

Summary group	Location	Scenario	PEC_{fish} (TL2 fish) after 1st appl. (µg/kg ww)	PEC_{fish} (TL2 fish) after 9th appl. (µg/kg ww)	EQS biota (µg/kg ww)
ΣPFAS25	Ås	Cereals	**8.9**	**13**	0.077
		Grass	**9.4**	**14**	
	Melhus	Cereals	**4.1**	**6.0**	
		Grass	**11**	**16**	
	Stange	Cereals	**6.1**	**11**	
		Potato	**6.1**	**11**	
		Vegetables	**6.1**	**11**	
		Grass	**8.3**	**15**	

Note: Numbers indicated in blue and bold are exceeding the EQS.

The new EQS for ΣPFAS25 is much stricter than the previous EQS for PFOS, which was based on a superseded TDI for PFOS (EQS dossier, 2011). When employing the new EQS for ΣPFAS25, the PEC_{fish} are exceeding the EQS by more than 140 times in the worst scenario after the first sewage sludge application. Since many PFAS are biomagnifying, the situation after repeated applications is even worse, indicating a high risk for secondary poisonings of wildlife.

PFOS and long-chain PFCAs biomagnify in the terrestrial food web, increasing the risks for higher trophic level predators. The EQS biota for PFOS in prey has been set to 33 ng/g ww, intending to hinder secondary poisoning in predators. Analysed soil samples did not exceed the PNEC for soil organisms (373 ng/g dw), but analyses of earthworm showed that the 33 ng/g ww threshold was exceed in 18 of the samples. In Fieldfare eggs, the PFOS threshold was exceeded in 35 % of the samples (**Chapter 8.4**). However, in Red Fox and Brown rat, the PFOS concentrations in liver were generally below the thresholds for direct toxicity, but indicated exposure via the food web.

Overall, there is a clear risk of secondary poisoning with PFOS in wildlife (e.g., red fox) and birds of prey (e.g., sparrowhawk) feeding on contaminated earthworms and birds, especially in urban and industrial hotspots. Moreover, there is a potential risk of secondary poisoning with PCB, especially in top predators (birds of prey). For other contaminant groups such as chlorinated paraffins, phthalates, OPEs, siloxanes, UV compounds and bisphenols, the risks for secondary poisoning are considered as low on the basis of the current contaminant levels in sewage sludge. It is also worth noting that secondary poisoning of wildlife has been found to be highest in urban areas, but that sewage sludge will be applied in agricultural areas, and thus

the immediate impact on wildlife might be less concerning, although an increase of long-time exposure is undesirable.

9.3 Characterisation of health risks for farm animals from sewage sludge applications

Chemical contaminants analysed in minimum 10 samples of sewage sludge from minimum two sewage plants and detected in minimum 10 % of the samples were included in assessment of contaminants in the rations for various categories of farm animals. These contaminants constitute 232 contaminants with data both for plants and soil, and in addition, some contaminants with concentrations only for soil as these contaminants were not considered to be taken up in plants in significant amounts.

Five groups of farm animals have been selected for assessment (**Table 3.6-2**), with focus on high-lactating cows (dairy cows). The dairy cows are very relevant to consider for the assessment of health effect concerning use of sewage sludge because they constitute a major part of animal husbandry, they get varied diet consisting of forage/grass and compound feed and they use to graze on cultural pastures that are in spotlight for potential fertilising with sewage sludge. In addition, adult sheep with lambs, growing pigs, laying hens and adult lactating goats are also considered. Together these animal groups represent a variation concerning the composition of total rations regarding forage, compound feed, and intake of soil, as well as range in total intake related to the animals' body weights.

The scenarios considered, include the exposure of animals to the various contaminants through soil and plants (grass and cereals (compound feed)) which are grown in that soil after application of 11.2 tonnes (dry weight; dw) of dewatered sewage sludge/ha/10 years or after application of 1.3 tonnes dw of liquid fraction of sewage sludge digestate. The total rations (µg/kg dry matter; dm) were calculated based on the contribution of contaminants from compound feed, grass/forage, soil and liquid digestate in the animals' total ration (**Table 3.6-2**).

The risk characterisation of the various contaminants for farm animal health is based on estimation of their intake and toxicity characterisation of the various contaminant residues (hazards). For estimation of intake of the various contaminants in total rations, a separation was done between intake when the animals are grazing on pasture and when they are fed in a housed system (indoor feeding). The estimated intake and evaluation of hazards are presented in chapter 8.5.6. The hazard evaluation is largely based on available toxicological data for the contaminants (technical chemicals, pollutants, cosmetics and drugs) for human risk characterisation (TDIs/ADIs) and relevant toxicological studies in rodents (NOAELs, LOAELs, BMDLs), because there are only exceptionally available toxicity data and knowledge on tolerable levels of the contaminants in the target farm animal species. It is important to point out that TDIs and ADIs are maximal human intake doses considered to be tolerated/accepted every day over years. However, the exposure in animals through use of sewage sludge will fluctuate, and the exposure levels estimated are considered in the upper layer of the fluctuation.

9.3.1 Risks related to application of 11.2 tonnes (dw) of dewatered sewage sludge/ha/10 years

From the comprehensive list of individual contaminants (or chemical or functional groups) that have been evaluated, only a few individual contaminants are considered of concern for farm animals. However, very few of the contaminants assessed have been toxicologically studied in farm animals and relevant tolerable levels are almost lacking. Thus, the calculated concentrations of individual contaminants in the daily rations for farm animals are compared with ADIs/TDIs set for humans, and with NOAELs or BMDLs in rodents. For most of the contaminants, the farm animal exposure levels are far below such levels – with some exceptions that are described below. The total level of contaminants in total animal ration from use of sewage sludge is a rather small number: The sum of 232 contaminants considered adds up to less than 0.3 mg/kg for farm animals.

Of particular concern are bisphenols. Bisphenol A shows an estimated intake in total ration for high lactating grazing cows at 0.85 µg/kg DM, and somewhat lower in the ration for non-grazing cows. For bisphenol A, the contribution from soil amounts to 42 % in total ration for the grazing dairy cows. Bisphenol compounds have very different plant uptakes. The corresponding intake of sum of bisphenols quantified in sewage sludge for the high lactating grazing cows is 1.6 µg/kg DM total ration, and estimated daily dose is 64 ng/kg b.w. per day. Most toxicological knowledge comes from bisphenol A. The rationale for sum up the bisphenols is that some other compounds in the bisphenol group are considered to possess similar or even higher toxicity potential than bisphenol A. Compared with the BMDL of bisphenol A for critical immune effects in mice at 8.2 ng/kg b.w., the estimated dose for cows is 8 times above. Considering the human TDI of 0.2 ng/kg b.w. per day the dose for cows is 300 times above. Bisphenol A and most other detected bisphenols do not accumulate in soil and are a chemical group on priority list to be phased out. Thus, the levels of these contaminants are not expected to increase over time. The background level of bisphenols in soil in Norway and animal exposure from other sources are not known.

Doxorubicin, used to treat various cancers, **is of concern**. It has an estimated intake level of 2.6 µg/kg DM total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is small (19 %) resulting in an intake level of 2.2 µg/kg total ration in non-grazing cows. No significant accumulation in soil is expected from repeated sludge applications. The level in cows total ration, equivalent to 0.09 µg/kg b.w. per day, is above a predicted ADIp of 0.05 µg/kg b.w. per day in humans.

Levonorgestrel, a synthetic progestin used to prevent pregnancy and as an emergency contraceptive, **may be of concern**. It has an estimated intake level of 0.035 µg/kg DM total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is small (13 %). No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a sludge application (0.0014 µg/kg b.w. per day) is expected to be only slightly below the predicted ADIp of 0.003 µg/kg b.w. per day in humans.

Estrone, a natural oestrogen used to treat perimenopausal and postmenopausal symptoms **may be of concern**. Its oestrogenic potency is one third that of oestradiol. Estrone has an estimated intake level of 0.025 µg/kg DM total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil amounts to 34 %. No significant accumulation in soil is expected from repeated sludge applications. The daily dose after a

sludge application (0.001 µg/kg b.w. per day for grazing dairy cows) is expected to be below the ADI of 0.007 µg/kg b.w. per day in humans, but with a small safety margin.

Carbamazepine, an anticonvulsant and analgesic drug used, **may possibly be of concern**. Carbamazepine is one of the chemicals with highest estimated level in gras/forage. It has an estimated intake level of 9.4 µg/kg total ration in grazing dairy cows after one application of sewage sludge. The contribution from soil is low so that for non-grazing cows, the intake level is only slightly lower. The estimated half-life in soil is about 6 months and no significant accumulation in soil is expected from repeated sludge applications. The estimated daily dose of 0.4 µg/kg b.w. per day for dairy cows after a sludge application is expected to be below the ADI of 15.9 µg/kg b.w. per day in humans but the safety margin is rather small.

Furthermore, also **phthalates may possibly be of concern**. The compound of quantitively most importance in animal rations, DEHP (bis-2-ethylhexyl-phthalate), is estimated at 9.6 µg/kg total ration for high lactating grazing cows. Intake of soil is considered the major contribution, and the contaminant is estimated to accumulate to double levels after 10 sludge applications (100 years). The exposure is compared with the proposed group-TDI for phthalates in humans, expressed as DEHP equivalents at 50 µg/kg b.w. per day. With DEHP being predicted to have the highest intake levels in animals after sewage sludge applications, the human TDI can also be considered as relevant for farm animals. For dairy cows, this TDI would correspond to an intake level of 1.3 mg/kg DM total ration. With an estimated intake of close to 20 µg/kg total ration DM for high lactating grazing cows after 100 years the margin is <100 x for DEHP alone, and there are several other contributing phthalates at lower levels with similar effects as DEHP.

Thus, rather few individual contaminants are considered to imply health risk for farm animals from use of sewage sludge as described. However, **effect risks of combined exposure** from the comprehensive conglomerate of various contaminants, such as the many contaminants that may act as endocrine disruptors or those influencing metabolism of endogenous and exogenous compounds, cannot be excluded. The probability for subtle or more pronounced health effects from interactive operating contaminants **may be considerable**. Studies that have described developmental and reproductive effects in sheep grazing on pastures after application of sewage sludge substantiate such risks (See chapter 8.5.3).

Concerning microbial resistance, the concentrations of residues of antibiotics and biocides available for farm animal exposure from use of sewage sludge on soil to be used as pasture or forage/feed production, seen isolated, are probably too low to imply a risk to influence on microbial resistance in farm animals. However, microbial resistance may more likely develop where the concentrations of antibiotic and biocide residues are higher, such as where fresh sewage sludge is in contact with soil. Environmental spreading of resistant microorganisms and resistance genes may then occur, also to farm animals. The pollution and spreading of such chemical residues with sewage sludge most probably play a role in the large evolution of microbial resistance (Larsson & Flach, 2022).

For other drugs than those mentioned to be of risk concern for animal health, the animal exposures are far below the established or predicted ADIs for individual substances, which imply that health risks are unlikely from individual substances. The uncertainty of risk lies in possible interaction effects. The same applies to the occurrence of following groups of chemicals which are not considered to imply health risks individually for farm animals via sewage sludge:

For brominated flame retardants (BFRs) and perfluorinated compounds (PFCs) the ratio between available NOAELs and exposure in farm animals is approximately 1000 and not considered of concern.

For other groups: PCBs, dioxins, DDTs, chlorinated paraffins, PAHs, phosphates, technical UV-chemicals, antioxidants, surfactants, siloxanes and fragrances this ratio is more than 1000.

For HCB, other flame retardants (than BFRs, PFCs and phosphates), other plasticisers, rubber-related compounds, corrosion inhibitors, pigments/dyes, solvents, other detected technical chemicals, cosmetic UV-filters and cosmetic biocides this ratio is far more than 1000.

For phenolic disinfectants and technical biocides ratios are also considered to be large enough not to imply a farm animal health risk, but toxicity data are sparse.

9.3.2 Risks related to application of 1.3 ton (dw) of liquid digestate/ha/year

When applying liquid fraction of sewage sludge, the animal exposure for bisphenol A (and some other bisphenols) increases by a factor 2 and the exposure for carbamazepine increases by a factor 5. For bisphenol A the increase is due to higher exposure through forage and digested sludge, while the increase for carbamazepine primarily is a result of increased uptake in grass (forage).

For doxorubin, levonorgestrel and DEHP the use of digested sewage sludge does not seem to increase the potential risk to farm animals compared to dewatered sewage sludge.

9.4 Characterisation of health risks in humans

Contaminants from all chemical groups (**Chapter 6.1.3**) were included in the assessment of risks in humans from the consumption of food produced in areas treated with sewage sludge, when they had been measured in Norwegian sewage sludge at concentrations above their respective LOQ. It is, however, important to consider that the LOQ for several contaminants are rather high and that more sensitive analytical methods are required to allow effective monitoring of sewage sludge. In addition to contaminants with concentrations above LOQ, additional criteria for the selection of highly potent drugs such as a predicted ecotoxicological potential (RCR-Q90) > 1 or more than 25 000 prescriptions in Norway in 2021, were employed (**Chapter 6.7**).

Hazards to humans from contaminants in sewage sludge were identified applying the methodologies described in **Chapter 3.7**. A complete intake estimation in humans from food for all contaminants in sewage sludge based on food consumption data, dietary habits and occurrence in all food categories was not feasible within the framework of the present risk assessment nor required in the ToR. Both toxicity data and occurrence data in most types of food are lacking for a large number of the assessed contaminants.

Therefore, the risk assessment was based on the predicted transfer from soil into plants (**Chapter 3.4.4**) after a sludge application and the accumulation potential in crops over the 100-year period with 10 applications, using today's application practice (12.2 tonnes/ha/10 yrs). In a conservative approach, the highest predicted contaminant concentrations in crops were applied.

Hazards connected to the dietary exposure of contaminants with identified contaminants were characterised by comparison of predicted concentrations in crops to existing or predicted (based on existing toxicity data) TDI or ADI for humans (HBGV), under consideration of the respective contaminant's accumulation potential (**Chapter 8.6**).

Generally, it is considered as undesirable that the current load of organic contaminants in agricultural soils increases through applications of sewage sludge as fertiliser, especially with regard to the already elevated levels of e.g. PFAS and PCBs, and the possibility of mixed toxicity effects. However, using today's application practice of sewage sludge is considered to currently be of relatively low risk for the food safety of the general population for many contaminants that have been detected in the sludge.

There are, however, some important exemptions concerning highly potent drugs (ATC C cardiovascular drugs, ATC J antibiotics, ATC L anti-cancer drugs, ATC N antidepressants, ATP antiparasitics, ATC R respiratory system), group sums of persistent organic contaminants (POPs, e.g. ΣPFAS4, ∑PCB6) and contaminants occurring at high levels in sewage sludge (e.g., siloxanes, UV chemicals) (**Chapter 8.6**). The contaminants and contaminant groups considered to constitute the main risk to food safety are summarised in **Table 9.4-1**.

The present dietary intakes of these contaminants or groups of chemicals are already of concern as assessed in previous risk assessments, and the use of sewage sludge as fertiliser is predicted to increase the intakes even more. The only substances, for which the estimated dietary intake does not already exceed the HBGV, are siloxanes and the UV filter octocrylene. For these, the predictions do still not indicate that the intake would reach toxic levels from sewage sludge applications, but additional exposure from improper use or leaching from food contact materials could increase the risk considerably.

Table 9.4-1**. Contaminants and contaminant groups**

Compounds	Assessment	Comment
SPFAS4	Any increase in human dietary intake is undesirable since the current intake is already above the TWI.	Nationally and internationally prioritised to reduce usage and occurrence. Thus, levels in sludge are expected to decrease in the future.
NDL-PCBs (∑PCB6)	The current dietary intake is already of concern, sewage sludge is predicted increase exposure, which is undesirable even though the addition from sewage sludge is expected to be low.	Prioritised to reduce usage and occurrence. Restrictions on use and discharge are already established. Thus, levels in sludge are expected to decrease in the future.
Dioxins and dioxin-like PCBs	The current dietary intake is already of concern, and sewage sludge is predicted to add 10 to 20 %, which is undesirable.	Prioritised to reduce usage and occurrence. Restrictions on use and discharge are already established. Thus, levels in sludge are expected to decrease in the future.
SPAH	The predicted increase in food through sewage sludge applications is of concern as it will add significantly to the existing exposure, and the MOE is already low for consumers with high intake.	Prioritised to reduce usage and emissions into the environment Thus, levels in sludge could be lower in the future.
SPBDE	The predicted increase in food through sewage sludge applications is of concern as it will add significantly to the exposure, and the MOE is already low for consumers with high intake. Particularly the transfer into animal-derived food is of concern.	Prioritised to reduce usage and occurrence. Restrictions on use and discharge are already established. Thus, levels in sludge are expected to decrease in the future.
Siloxanes	A significant increase of siloxanes in meat and milk from the use of sewage sludge as agricultural fertiliser is predicted.	On national and international priority lists to reduce usage and occurrence. Thus, levels in sludge are expected to decrease in the future.

Compounds	Assessment	Comment
	The estimated intake is still below the HBGV, but of considerable extent, which appear to be undesirable since toxicity data and mixed effect data are limited.	
Bisphenol A	The current dietary intake of BPA (immunotoxic, oestrogenic and antiandrogenic) exceeds the TDI by 2- to 3-fold. Even the predicted low additional increase in the dietary exposure from sewage sludge applications is undesirable.	On national and international priority lists to reduce usage and occurrence. Thus, levels in sludge are expected to decrease in the future.
Octocrylene	The UV filter is predicted to reach in some crops levels above the SML after of sewage sludge applications, which is undesirable.	The total exposure depends particularly on migration from food contact materials.
Drugs	Drugs that would have a dietary intake from crops after sewage sludge applications (either immediately after the application or through accumulation after repeated applications) of particular concern with regard to established ADI or predicted ADIp in humans include: loperamide, hydrochlorothiazide, eprosartan, telmisartan, amiodarone, lercanidipine, levonorgestrel, desogestrel, doxycycline, tetracycline, oxytetracycline, ciprofloxacin, roxithromycin, clarithromycin, erythromycin, tamoxifen, carbamazepine, oxcarbazepine, oxazepam, amitriptyline, maprotiline, fexofenadine, chlorhexidine, ethylenediamine-tetraacetic acid. For some drugs that are frequently prescribed in Norway (> 150,000 in 2021) (e.g. pantoprazole, esomeprazole, prednisolone, levothyroxine sodium, phenoxymethylpenicillin, zopiclone, melatonin, fluticasone furoate, ethylmorphine and desloratadine) analytical data are not available, and future monitoring is recommended. Atorvastatin (>400,000 prescriptions) is found with high frequency in Norwegian sewage sludge but not predicted to relevantly accumulate in crops. It could, however, be relevant for uptake into fish. The same could apply to mirtazapine, venlafaxine, citalopram, sertraline, diclofenac, paclitaxel, doxorubicin and tebuconazole, which are not accumulated to relevant levels in plants but have a high environmental RCR.	

9.5 Toxicity of mixtures

Humans, animals and the environment are exposed to large numbers of xenobiotic substances, either naturally occurring or man-made compounds. These substances are present in food, the environment and workplaces. Many substances are present in today's urban wastewater from diverse sources, for example drugs and industrially-used chemicals substances, just to mention a few.

While assessments of risks to the environment, animals and (mostly) humans have been performed for substances that have been identified as especially important because of a high occurrence, high potency or toxicity, or high dietary intake, and thresholds intended to protect environmental biota, farm animals and humans (e.g. Health-Based Guidance Value (HBGV) such as TDI or ADI) have been established by competent national and international authorities, comparable assessments of substance mixtures are lacking.

Simultaneous exposure to multiple substances is a challenge for risk evaluation. It has to consider the substance-specific, toxicological mode-of-actions (MoA), effect concentrations (potencies), potential interactions at molecular targets, species differences in target organisms. Together, substances may lead to additive or even synergistic (i.e. more than additive), but also inhibitory effects as compared to the toxicity of the individual contaminants.

In environmental risk assessment of chemical mixtures, two different methods have usually been used to assess mixture risks: **Concentration/dose addition (CA)** and **Independent action (IA)** (referred to by EFSA as response addition) (Backhaus & Faust, 2012). In the article it is

stated that mixture toxicities that are higher than predicted by CA, are rare findings, and that therefore CA can be used as a precautionary first tier irrespectively of the modes of action of the mixture components.

CA is also the approach suggested by EFSA for a substance-based approach (EFSA Scientific Committee et al., 2019). The approach consists of summing the risk quotients (RCR) for ecological risk characterisation and hazard index (HI) for human/animal risk. The RCR is defined as the PEC (predicted environmental concentration) divided by the PNEC (predicted no-effect concentration). The resulting mathematical expression for ecological risk assessment is:

$$\sum_{i=1}^{n} \frac{PEC_i}{PNEC_i}$$

Where
PEC_i is the concentration of the i^{th} component in an n-component mixture
$PNEC_i$ is the predicted no-effect concentration of compound i.

This approach is normally used for compounds binding to the same receptor, i.e., for those having a similar mode of action (MoA). There are several examples of substances that share molecular mechanisms, for example several dioxins and planar PCBs. In a regulatory concept, dioxins have a tolerable daily intake based on a sum of several congeners.

EFSA has published a guidance document for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals (EFSA Scientific Committee et al., 2021). EFSA proposes a framework to apply hazard-driven criteria for grouping chemicals into assessment groups using mechanistic information on toxicity as the gold standard while also considering toxic potency and toxicokinetic features. In practice, the lowest uncertainty in grouping can be achieved when knowledge on an adverse outcome pathway (AOP) is available, followed by knowledge on a MoA for the chemicals under evaluation. Grouping using target organ/system toxicology is linked to higher uncertainty. Structural similarity may also be used as criteria for grouping chemicals into assessment groups, and in addition software tools such as OECD QSAR Toolbox. Toxicokinetic data can also be useful for grouping, particularly when metabolism information is available for a class of compounds and toxicologically relevant metabolites are shared. The guidance also gives recommendations for prioritization methods.

Several well-known groups of similar acting compounds have derived toxicological information about toxic equivalence factors (TEF) or relative potency factors (RPF). In ecological risk assessment the concept analogous to RPF is toxic units (TU). Dioxins are the most common example of the TEF approach, and TEFs are internationally established (DeVito et al., 2024; Van den Berg et al., 2006).

According to (EFSA Scientific Committee et al., 2021) applying response addition requires *evidence* of independent action between individual chemical substances or assessment group. Response addition is more commonly used in ecological risk assessments but requires availability of the dose-response data for each individual chemical substance. Risk is then no longer expressed as a PEC/PNEC ratio, but as the population fraction showing an effect (e.g. mortality). *Response addition (IA) is rarely used in the human and animal health area* and is therefore not further described here.

In addition to the interactions in hazard assessment, it is important to consider that chemical interactions, toxicokinetic and toxicodynamic interactions can take place. Synergy is of greater concern for decision-making in the food and feed area than antagonism. In a regulatory concept, risk assessors therefore often apply an extra uncertainty factor, or apply uncertainty factor for indications of interactions.

For prioritization of the specific chemicals that are drivers of toxicity or risk in an assessment group, the method of maximum cumulative ratio (MCR) can be used. The MCR is the ratio of the combined toxicity to the highest toxicity from a single component within the assessment group.

In this report, we have not assessed the potential interactions between different compounds unless included in the available hazard assessments. For example, group TDIs and MOEs are used for the exposures to compounds within groups such as PAHs, PDBEs and dioxin and dioxin-like PCBs. Furthermore, experiments with animals exposed to relevant mixtures through the use as fertilisers on pastures considered in the assessment of risk to grazing animals but without characterization of types of interactions of chemicals in the sludge.

Microbial resistance

The knowledge of spreading microbial resistance via antibiotic and biocide residues from sewage sludge in agriculture is very low. However, microbial resistance may most likely develop where the concentrations of antibiotic and biocide residues from sewage sludge are relatively high, such as where fresh sewage sludge is in contact with soil. There is reasonable to assume that environmental spreading of resistant microorganisms and resistance genes may then occur in the food chain to farm animals and humans. The pollution and spreading of such chemical residues with sewage sludge most probably play a role in the large evolution of microbial resistance (Larsson & Flach, 2022).

10 Uncertainties and sensitivity

Risk describes the likelihood of adverse effects occurring as a result of exposure. In this assessment, risk is evaluated through a quantitative comparison of estimated exposure levels and relevant tolerance thresholds for multiple receptors, ranging from soil organisms to farm animals and humans. The exposure of organic contaminants to the receptors in this assessment is modelled both through common application practice of sewage sludge and new ways of application of sewage sludge and sewage sludge-based products (pellets, biochar, struvite, and liquid fraction of sewage sludge digestate).

The resulting risk estimates are quantitative but subject to considerable uncertainty. Outcomes depend on model assumptions, data availability and the representativeness of selected input values. The model applied in this assessment integrates state-of-the-art process descriptions to predict concentrations of organic contaminants in soils, surface waters, crops, and the food chain up to 100 years into the future, but its complexity necessitates the use of numerous input parameters and assumptions. The long-term nature of predictions magnifies uncertainty at longer horizons, where environmental and management conditions may change in unknown ways. There may also be unknown sources of risk, since while the sludge used as fertiliser on pastures has been analysed for a range of contaminants, there may still be other harmful compounds in sludge that have not been tested for. Furthermore, some analysed contaminants are lacking toxicological data as well as information on ADME for farm animals.

Modelled processes cannot fully replicate natural systems. Certain processes, are known limitations and may influence predicted concentrations. Model relevance has therefore been evaluated where possible by comparison with measured present-day concentrations in surface waters, showing reasonable agreement for current conditions.

Key sources of uncertainty include concentration of organic chemicals in sewage sludge and sewage sludge-based products (both measured, MEC, and predicted, PEC), degradation rates in soil (DT50soil), partition coefficients (Koc and Kd) and transfer factors for uptake in different crops and organisms (e.g., BCF_{plant}) and weather characteristics (e.g., precipitation rates).

Compared to the previous risk assessment that focused on heavy metals and elements, there are no systematic data on measured background concentrations of organic contaminants in agricultural soil in Norway, and thus, in this risk assessment, background concentrations in soil are set to zero.

A sensitivity analysis was conducted for selected parameters to illustrate how variability in key inputs affects the model outputs. Decision-makers should therefore interpret the risk estimates as indicative rather than predictive and consider the identified uncertainties when using the results to inform management and/or regulatory decisions.

In the remainder of this chapter, different identified data- and modelling-related sources of uncertainty are discussed in more detail.

10.1 Merging occurrence data from different sources

The data used in this risk assessment originate from multiple sources. The bulk of occurrence data comes from the Vannmiljø database, where compound names are given in Norwegian and some entries are supplemented with more detailed descriptions. CAS numbers are the

only internationally recognised identifiers included in the dataset; however, they are incomplete and contain a number of deprecated and/or incorrect entries. Data from previously published reports used in this risk assessment similarly either lacked chemical information beyond compound names or included only a limited number of CAS numbers. Given that the number of chemicals under consideration exceeds 1,000, comprehensive manual curation is not feasible. Nevertheless, considerable effort was made to verify and complete the CAS number records.

CAS numbers are known to be insufficient as unique chemical identifiers. The same CAS number may appear in different datasets referring to different chemicals, while the same chemical may be listed under different CAS numbers across databases. This is known as the many-to-many matching problem. For example, for *Ethylbenzene*, both CAS numbers 100-41-4 and 68908-88-3 map to PubChem CID 7500, whereas CAS number 122-40-7 (originally identified in the data as *alpha-Amylcinnamaldehyde*) matches at least three PubChem CIDs: 1623625, 1712058, and 31209. It is well established that chemical databases may contain easily confused entries, particularly when non-systematic identifiers are used rather than, for example, InChI keys (see, for example, Akhondi et al. (2012 and 2015))

A number of sewage sludge analyses were reported as sums or mixtures of chemicals. These mixtures may or may not have valid assigned CAS numbers, but they typically lack data on individual chemical properties.

Consequently, although great care was taken when constructing the occurrence database, residual errors cannot be ruled out. However, any such errors are unlikely to introduce systematic bias in a particular direction.

10.2 Chemical properties

The occurrence data has been merged with chemical property data. Given the large number of chemicals considered, many do not have complete property coverage in available databases. In many cases, a hybrid approach was therefore adopted, combining experimental and modelled values from major databases (e.g. Comptox and NORMAN), together with additional estimates modelled by the authors. Where uncertainty remained, conservative values were selected.

10.3 Estimating chemical occurrence distributions

10.3.1 Measured sewage sludge concentrations

The overall majority of the sewage sludge data used in the risk assessment were derived from the 5-yearly monitoring campaigns at up to 19 Norwegian sludge treatment facilities collecting monthly composite samples over five months from October to February in each campaign. As many of these facilities receive sewage sludge that are generated at mechanical or chemical wastewater treatment plants (WWTPs) where the sludge retention time is very short (from minutes to a few hours) compared to regular biological treatment plants (with treatments that take days to weeks or even longer), concentration peaks in the influent to the WWTPs may be reflected in the sludge leaving the treatment plant. However, the month-long timeframe for the composite samples indicates that any concentration peaks in the sludge leaving the sludge treatment facility will be properly averaged out.

The median value of the 90th percentile of the upper bound concentration value ($MEC_{sludge,90,UB}$) for each treatment facility was used in the risk assessment, representing a high, but realistic, concentration in the sewage sludge that could be applied to farmland. **Table 10.3.1-1** lists all compounds with sufficient physicochemical property-data to assess the risk to soil-living organisms and that have an RCR_{soil}>1. The number of samples, number of facilities the samples came from and the ratio of the samples that exceeded LOQ (or LOD) are shown in the same table together with an assessment of the confidence level of the concentration estimates:

- *High*: Samples from at least five facilities with at least 50 % detection frequency.
- *Moderate*: At least 10 samples from at least two facilities with at least 10 % detection frequency.
- *Low*: Not qualifying the criteria for moderate confidence but with detection frequency >0.
- *Very low*: No samples with detected values.

Table 10.3.1-1 also shows the average of the median upper bound value at each plant ($\overline{MEC}_{sludge,med,UB}$) (±standard deviation) together with the $MEC_{sludge,90,UB}$ value. It is worth noting that the three compounds with the biggest difference between the $\overline{MEC}_{sludge,med,UB}$ value and the $MEC_{sludge,90,UB}$ value among the high-confidence concentration estimates are the two with the highest RCR_{soil} values (BghiP and octocrylene) and PFOS, with 5.6x, 5.3x and 7.6x difference between $\overline{MEC}_{sludge,med,UB}$ and $MEC_{sludge,90,UB}$, respectively.

Table 10.3.1-1. Descriptive statistics of data on sewage sludge concentrations.

CAS	Name	RCR_{soil}	N_{sample}	N_{plant}	Ratio>LOQ	Conf.	$\overline{MEC}_{sludge,med,UB}$ (µg/kg dw)	$MEC_{sludge,90,UB}$ (µg/kg dw)
191-24-2	BghiP	76	301	17	0.55	High	39±23	220
6197-30-4	Octocrylene	16.7	112	13	1.00	High	1,900±1 400	10,100
1241-94-7	EHDPP	15.5	124	14	1.00	High	620±680	2,500
205-99-2	B(b)F	7.4	256	17	0.81	High	69±39	185
101-20-2	Triclocarban	7.2	53	15	0.87	High	157±116	230
5466-77-3	Octinoxate	6.6	157	16	1.00	High	430±410	1,300
79617-96-2	Sertraline	6.5	138	16	1.00	High	220±130	350
50-32-8	Benzo[a]pyrene	6.1	300	17	0.71	High	54±31	150
80-09-1	BPS	4.6	120	13	0.91	High	270±500	490
15307-86-5	Diclofenac	3.3	141	16	1.00	High	124±73	400
54464-57-2	Isocyclemone E	3.0	82	15	0.99	High	6,000±2,700	8,800
1763-23-1	PFOS	2.7	198	17	0.84	High	10±15	74
80-05-7	Bisphenol A	2.7	251	17	0.99	High	1,000±800	2,500
99-76-3	Methylparaben	2.7	39	8	1.00	High	2,900±1,300	3,900
298-46-4	Carbamazepine	2.2	143	16	0.98	High	2,100±2,400	4,900
207-08-9	B(k)F	2.1	256	17	0.68	High	37±24	155
193-39-5	IcdP	1.28	295	17	0.61	High	47±24	220
3147-75-9	UV-329	108	17	3	0.88	Mod.	1,300±1,200	2,200
96507-80-1	DIUP	8.3	12	2	1.00	Mod.	3,100±1,800	3,700
55-56-1	Chlorhexidine	6.9	11	3	0.91	Mod.	860±730	1,100
23214-92-8	Doxorubicin	1.69	10	2	0.20	Mod.	2,100±2,900	2,900

CAS	Name	RCR_{soil}	N_{sample}	N_{plant}	Ratio>LOQ	Conf.	$\overline{MEC}_{sludge,med,UB}$ (µg/kg dw)	$MEC_{sludge,90,UB}$ (µg/kg dw)
6535-46-2	PR112	1.47	10	2	1.00	Mod.	17±18	36
84852-53-9	DBDPE	1.24	97	16	0.39	Mod.	34±30	120
298-07-7	BEHP	1.11	11	2	1.00	Mod.	1,200±100	3,100
52645-53-1	Permethrin	66	7	3	1.00	Low	210±160	470
43210-67-9	Fenbendazole	52	12	1	0.08	Low	7.5	57
556-69-4	L8	15.1	4	1	1.00	Low	10,800	65,000
103597-45-1	UV-360	12.3	10	2	0.00	Low	125	125
789-02-6	o,p'-DDT	10.5	87	15	0.00	Low	3.0	3.0
23593-75-1	Clotrimazole	10.5	7	1	1.00	Low	220	250
52918-63-5	Deltamethrin	10.3	6	3	0.00	Low	1.0	1.0
22916-47-8	Miconazole	9.9	8	1	1.00	Low	87	390
17301-53-0	ATAC-C22	6.6	1	1	1.00	Low	3,200	3,200
6422-86-2	DEHT	5.1	6	2	1.00	Low	1,400±1500	1,900
541-01-5	L7	4.8	4	1	1.00	Low	7,000	44,000
53-16-7	Estrone	3.0	12	1	0.17	Low	13.0	50
288-13-1	Pyrazole	3.0	6	3	1.00	Low	430±230	500
107-52-8	L6	2.9	4	1	1.00	Low	4,300	28,000
84-76-4	DNP	2.4	1	1	1.00	Low	420	420
100-42-5	Styrene	2.2	6	3	0.67	Low	24±12	36
60-54-8	Tetracycline	2.1	13	1	0.92	Low	119	4,500
85-22-3	PBEB	1.64	124	16	0.10	Low	4.3	7.9
124-28-7	DMODA	1.15	6	3	1.00	Low	163±129	193
564-25-0	Doxycycline	1.04	13	1	0.54	Low	38	420
Compounds with RCR>1 and sufficient property-data but not detected in any sludge samples								
120068-37-3	Fipronil	1.04	4	1	0.00	Very low	1.0	1.0
50-28-2	E2	3.9	13	1	0.00	Low	10.0	50
15687-27-1	Ibuprofen	3.9	13	1	0.00	Very low	75	500
179324-69-7	Bortezomib	3.4	2	1	0.00	Very low	1,200	1,200
57-63-6	EE2	2.2	11	1	0.00	Very low	10.0	50
797-63-7	Levonorgestrel	1.97	8	1	0.00	Very low	25	250
3934-23-4	FHpMMA	1.64	6	2	0.00	Very low	20	20
69-53-4	Ampicillin	1.45	8	1	0.00	Very low	5.0	50
89778-26-7	Toremifene	1.08	8	1	0.00	Very low	5.0	50
2144-53-8	FHxEMA	1.07	6	2	0.00	Very low	20	20

Note: $\overline{MEC}_{sludge,med,UB}$ column shows the average (with standard deviation) of the median upper bound values for each facility. $MEC_{sludge,90,UB}$ column shows the median of 90th percentile values at each facility. The table includes compounds with RCR_{soil}>1. 'Conf.' is the assessed confidence level in the concentration estimates. It is based on the number of samples (N_{sample}), the number of facilities from which the samples were collected (N_{plant}) and the ratio of the samples that were above LOQ (or LOD). See the text of this subsection for precise definitions of the confidence levels.

10.3.2 Handling of censored test results

Test results for sewage sludge are frequently reported below the limit of quantification (LOQ). Such results are commonly handled using an upper-bound (UB) approach, by setting the result equal to the LOQ. However, for the bulk of the occurrence data (Vannmiljø), the reporting limit is not specified and may correspond either to the LOQ or to the limit of detection (LOD). The typical relationship between these is $LOQ = LOD * 3.3$. For external reports, limits were usually reported as LOD, whereas for the NRA data they were reported as LOQ (see Section 6.1.1 for further details on the different data sources). All censored results were treated as if the reporting limit corresponded to the LOQ. This assumption leads to an underestimation of UB for an unknown fraction of censored observations. In addition, for compounds with no detected values, the UB value was set to the minimum LOQ/LOD since 2010. The combined effects of these assumptions can be illustrated using a subset of chemicals with only a single detected value in our dataset. As expected, it is the compounds with the fewest detections that are most sensitive to how censored results are treated. Note that, for the purposes of the table below, results from different WWTPs are pooled, whereas in the risk assessment each WWTP is treated separately. Accordingly, the table is intended solely to illustrate the impact of these assumptions.

We take a sub-sample of chemicals that had just one detected value and, within each chemical group, the highest number of tests. For these chemicals, we first compute the actual 90th percentile of the upper bound assuming that all unidentified limits correspond to LOQ, $UB_{.90}^{min,orig}$, and assuming that all unidentified limits correspond to LOD, $UB_{.90}^{max,orig}$. We then remove the detected values and compute counterfactual UB counterparts, $UB_{.90}^{min}$ and $UB_{.90}^{max}$. These two values capture the effect of removing that one detected value. We then compute the upper bound based on the lowest limit after 2009 (the lowest of all times if no testing was done since 2009), UB^{2010+}. The results are in the table below.

Adopting the minimum limit as the upper bound estimate, UB^{2010+}, has a dramatic effect on some compounds: for example, *DEP*, where the estimate goes from 100 down to 0.5. For other compounds, this assumption makes no difference, for example, *DDT*. Taking extreme values such as the maximum or minimum exposes the analysis to errors in the database, where there is always some likelihood that a small share of test results is entered using the wrong units. In this case, using UB^{2010+} as the main occurrence estimate results in a risk of gross underestimation.

Making the assumption that all unidentified limits are LOQs has an important effect here, also when considering the full set of results, including the detected value, $UB_{.90}^{min,orig}$ v $UB_{.90}^{max,orig}$. Interestingly, while for many compounds $UB_{.90}^{min,orig} > UB_{.90}^{min}$ and $UB_{.90}^{max,orig} > UB_{.90}^{max}$, as expected, for some the inequalities are either reversed or are actually equalities. This suggests a pattern in which test quality is often poor, and the only detected value is actually below the test limits for a number of other tests of the compound. See, for example, *Dichlorophen* and *Musk Moskene*.

Table 10.3.2-1. Effects of UB-related assumptions.

Group	Name	Test #	$UB_{.90}^{max,orig}$	$UB_{.90}^{max}$	$UB_{.90}^{min,orig}$	$UB_{.90}^{min}$	UB^{2010+}
Antimicrobial biocides	Me-TCS	140	16.50	16.50	5.00	5.00	5.00
Antioxidants	BDIIB	10	11.07	3.30	9.00	1.00	1.00

Bisphenols & derivatives	Bisphenol C	4	66.00	66.00	20.00	20.00	1.60
Cosmetics	3-Benzylidene camphor	6	99.00	99.00	55.00	30.00	30.00
DDTs	DDT	93	9.90	9.90	3.00	3.00	3.00
Drugs	Iodixanol	2	9.33	3.30	9.10	1.00	1.00
Flame retardants	TBA	31	0.20	0.20	0.06	0.06	0.02
Fragrances	Musk Moskene	166	66.00	66.00	20.00	20.00	1.00
Organotins	DPhT	40	13.20	13.20	4.00	4.00	0.50
PFASes	6:2 FTUCA	2	0.54	0.13	0.53	0.04	0.04
Phthalates	DEP	128	330.00	330.00	100.00	100.00	0.50
Pigments & dyes	Ac-SMX (N1)	39	23.83	23.86	7.22	7.23	1.40
Siloxanes	L3	6	66.00	66.00	20.00	20.00	20.00
Solvents	Dichlorophen	7	22.11	22.44	6.70	6.80	4.60

One should not rely on detection frequency as a measure of the potential for exposure to a chemical or for prioritizing between chemicals. This is particularly true when comparisons are made across different compounds and without any control for test quality (tests with high LOQs v. tests with low LOQs). Indeed, 260 compounds have tests with censored limits above the minimum detected value. In fact, 94 compounds have tests with censoring above the maximum detected level. Note that these numbers do not take into account that some censoring may be done at LOD rather than LOQ. An abundance of poor-quality tests for some chemicals is not a reason to conclude that exposure risks are modest. For example, *Phantolide*, with 159 tests in the data, appears at first glance to have a 16.98% detection rate, whereas if one excludes non-detected values where LOQ/LOD is above the maximum detected value, the detection rate increases to 81.82% (and the ratio becomes 90% if one also disregards tests with LOQ/LOD above the minimum detected value). The effect on detection ratios can be summarized graphically for the subset of chemicals where LOQ/LOD is above the maximum detected value (260 compounds), using the cumulative density of the three versions of detection ratios, as shown in the figure below. It is clear that tests with censoring limits below the range of detected values have consistently high detection rates. For such tests, 71.92% of compounds have detection rates above 50%, compared with 46.15% of compounds when all tests are considered.

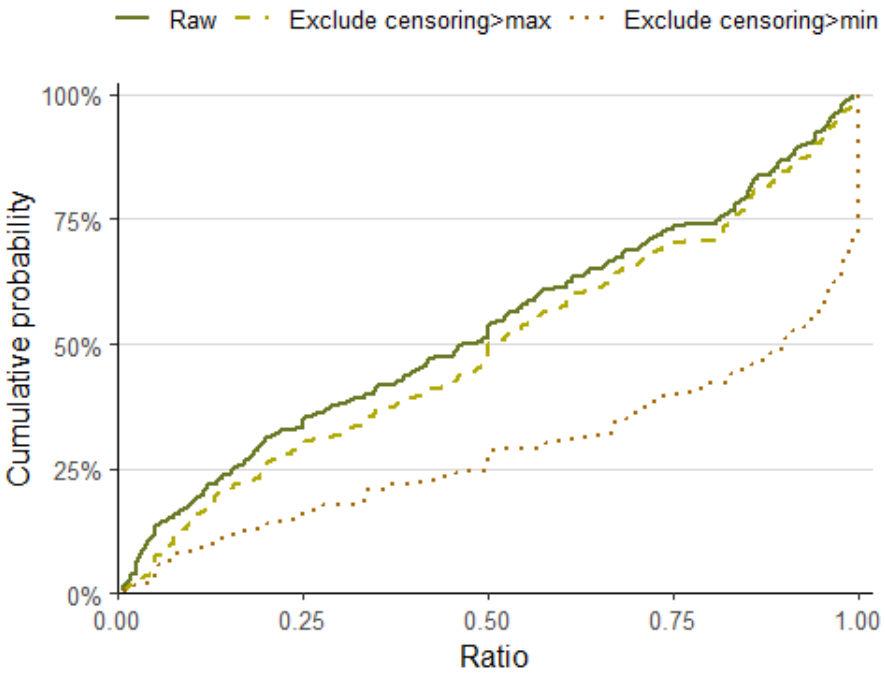


Figure 10.3.2-1*: Effect of test quality on detection ratios*

In fact, using poor tests with high LOQs/LODs may result in overestimation of the occurrence estimates. They introduce high, non-informative values into the dataset, which may lead to overestimation of the 90th percentiles. This effect is summarized in the table below for a sample of the most tested members of chemical groups represented among the 260 compounds with poor-quality tests, as identified above. If one discards tests with LOQ/LOD above the maximum, Q90 may remain unchanged (e.g., *Musk ketone*) or decrease, sometimes substantially (e.g., *Musk Moskene*). However, if one discards all tests with LOQ/LOD above the detected minimum, Q90 may actually increase (e.g., *Caffeine*), although not in all cases (e.g., *Bisphenol AF*). This is because the values being removed are now within the range of detected values and, therefore, the direction of the effect can be either positive or negative.

Table 10.3.2-2. Effects of poor-quality tests on Q90.

Group	Name	Test #	$UB_{.90}^{orig}$	$UB_{.90}^{LOQ<max}$	$UB_{.90}^{LOQ<min}$
Alkylphenols & derivatives	NPEEO	215	4,960.00	4,960.00	5,270.00
Antimicrobial biocides	PCMX	22	40.30	40.30	34.00
Antioxidants	2,4,6-TBP	165	27.00	23.00	26.30
Bisphenols & derivatives	Bisphenol AF	117	19.00	4.05	2.84
Coatings	MB 1	22	368.40	368.40	195.40
Corrosion inhibitors	5-MeBT	24	158.00	105.80	114.00
Cosmetics	Musk ketone	182	20.00	20.00	39.00
Drugs	Carbamazepine	147	5,800.00	5,800.00	5,800.00
Flame retardants	PBEB	116	10.00	5.00	10.00
Food additives	Caffeine	145	416.00	416.00	420.00
Fragrances	Musk Moskene	166	20.00	1.00	1.00
OPEs	TCPP	142	6,090.00	6,090.00	6,100.00
Organotins	DOT	60	20.00	10.30	10.48
Other chemicals	SCCP	137	1,544.00	1,544.00	1,610.00
PAHs	Acenaphthylene	291	100.00	100.00	100.00
PBDEs	BDE-100	317	6.32	6.32	6.84

PCBs	PCB-153	235	6.72	6.72	6.90
PFASes	PFOS	191	28.00	28.00	29.70
Pesticides	HCB	116	2.94	2.94	2.66
Phthalates	BBP	126	431.00	431.00	464.80
Pigments & dyes	Ac-SMX (N1)	39	7.22	2.73	2.73
Plasticisers	DBP	246	1,000.00	1,000.00	41,900.00
Plastics-related	Bisphenol A	234	3,182.00	3,182.00	3,200.00
QACs	TBAB	8	1.35	1.35	1.45
Rubber-related	MeBT	25	125.00	4.89	4.89
Siloxanes	L4	93	109.00	109.00	122.00
Solvents	Dichlorophen	7	6.70	5.78	5.78
Surfactants	4-Heptylphenol	155	100.00	20.00	20.00
UV compounds	UV-327	109	21.32	21.32	89.00

Hence, retention of poor test results (tests with unreasonably high limits relative to the underlying occurrence distribution) may have a significant effect on the estimated Q90s. This problem becomes much less of a concern if one adopts a probabilistic method for estimating the 90th percentile, rather than the simple approach used in this risk assessment.

There are several probabilistic methods available for estimating distributions for censored data originating from multiple disparate sources (in this case, WWTPs with different chemical profiles). The key limitation of these methods is that they can only be applied when there are at least some detected values.

Hierarchical Bayesian modelling can probably be considered the golden standard, as it can be applied to even very sparsely detected data: ≥ 1 detection at ≥ 2 sites per compound. With very sparse detections, the Q90 estimate will have very wide uncertainty bounds (confidence intervals). However, the simple upper-bound Q90 does not allow quantification of uncertainty bounds at all (except for the bootstrapped confidence interval for Q90).

Alternatively, one could perform separate maximum likelihood estimations for each WWTP. It is the simplest probabilistic approach, but it requires at least 3 detected values per compound–WWTP pair, and often more for reliable convergence. There are 5,863 compound–WWTP pairs in total; of these, 3,544 have at least one detected value, while 2,899 have at least three. 449 compounds have no detected values at all (note that this chapter was written using the most up-to-date version of the occurrence database).

10.3.3 Aggregating data from different water treatment plants

As different water treatment plants have been shown to produce sludge with systematically different chemical profiles, it is reasonable to estimate distributions separately for each compound–plant combination. However, in the risk assessment, the distributions from each plant are treated as equally important, with the final estimate taken as the unweighted median of the 90th percentiles across plants.

However, different plants produce different quantities of sludge available for agricultural purposes. Norway collects detailed data for each sludge production facility, and production quantities are itemized by category, allowing us to analyse production volumes for the last three available years, 2022–2024. The production volumes taken into account are those applied to soil, those used in soil-related products (e.g., planting soil mixtures), and those stored in warehouses (the latter are included to reflect production capacity not used for other non-agricultural products and therefore potentially available for agricultural use). In total, 85

facilities produce sludge used in agriculture. The relative importance of facilities with occurrence data, 18 out of 85, is summarized in the table below.

Table 10.3.3-1. Relative importance of sludge producers.

WWTP	Mean sludge share (%)
Grødaland RA	0.46
Sandefjord RA	0.61
Gardermoen RA	0.65
Lillevik RA	0.71
Fuglevik RA	0.79
Ladehammeren RA	0.98
HIAS	1.41
Rambekk RA	1.50
SNJ (Sentral-renseanlegget Nord-Jæren)	1.55
Høvringen RA	1.70
Bergen Biogassanlegg	1.72
Lindum	2.56
TAU (Tønsbergfjordens Avløpsutvalg)	2.83
Øra RA	3.23
Bekkelaget RA (STP)	3.57
Sentralrenseanlegget RA2 (NRA)	6.15
VEAS	7.79
Total	38.22

We conclude that the facilities together account for 38.22% of total sludge production for agricultural use. However, not all compounds are tested at all facilities, so for most compounds the representativity is much lower. The distribution of representativity by compound is summarized in the figure below.

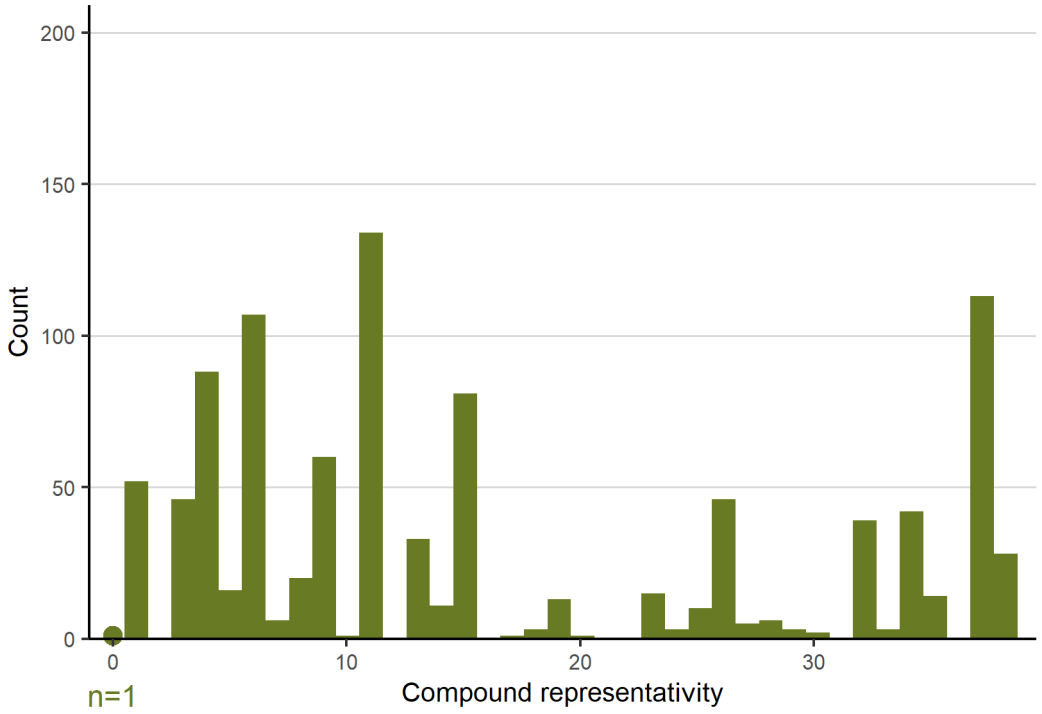


Figure 10.3.2-1: Analysed compound representativity relative to total production.
Note: This histogram shows the number of compounds (vertical axis) and the percentage of 'green' sludge production (sludge applied to soil) represented by the WWTPs where the compounds were tested (horizontal axis). One compound was tested only at the plant with no 'green' sludge production.

With respect to geographic relevance, none of the surveyed WWTPs are located within the five municipalities, although some are closer than others. Farmers can, however, choose sludge products from more distant facilities, and we do not have definitive data on how the likelihood of purchasing sludge products varies with distance to the farm. The figure below shows WWTP locations relative to the municipalities of interest. Surveyed WWTPs without sludge production for agricultural use are marked with diamonds, while other WWTPs are marked with circles. Circle size increases monotonically with production volume; because several facilities are in close proximity, making the figure difficult to read, the corresponding production information is instead provided in the table above as representativity weights for sludge producers.

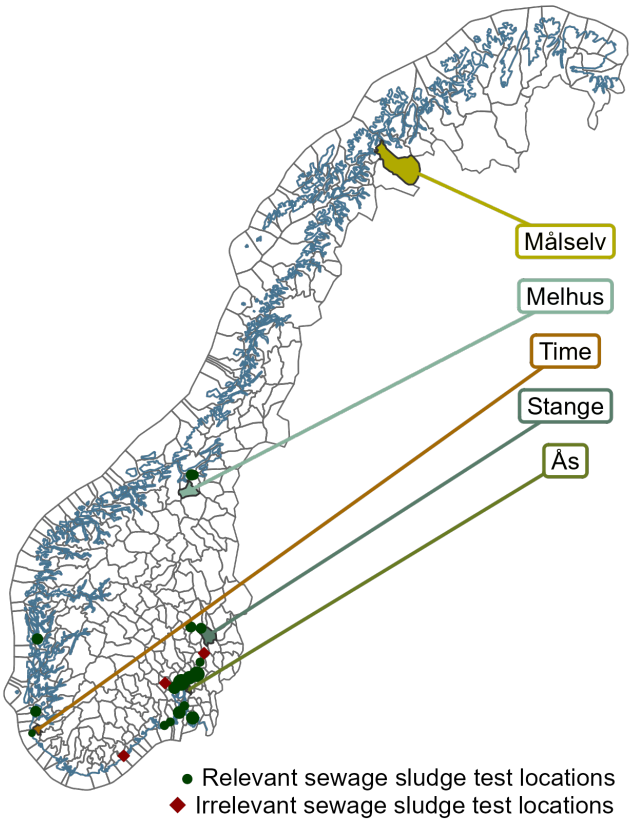


Figure 10.3.2-2: Sludge testing locations.
Note: Sludge testing locations are marked relative to the five chosen agricultural regions. Diamonds mark testing at WWTPs without 'green' sludge production.

Using an unweighted summary metric, such as an equally weighted median, introduces error relative to a representative (weighted) estimate, and the sign of this error is unknown and may vary by compound. However, the main takeaway is that there is substantial uncertainty around any point estimate, given that 50% of compounds are tested in facilities that cumulatively represent under 11.36% of the relevant sludge production. This observation, together with the earlier finding that WWTPs differ systematically in the chemical composition of their products, highlights the main source of uncertainty when relying on the available occurrence data: occurrence in sludge products from WWTPs for which no sludge occurrence data are reported.

10.4 Climate data

Daily air temperature and precipitation were obtained from seNorge. These data are not direct point observations but gridded datasets produced through interpolation and modelling procedures that combine observations from meteorological stations with topographic and climatological information (Lussana, 2020). Consequently, the data are subject to uncertainties arising from measurement errors in the underlying observations, spatial interpolation methods, station density (varying over time), and the representation of complex terrain. These uncertainties are generally larger for precipitation than for temperature. The biggest rainfall uncertainties are connected to mountainous regions with strong spatial gradients. Since this risk assessment focuses on agricultural land use, characterised by smooth terrain, these gradients are assumed to be of moderate magnitudes.

In a *PEC* modelling context, the seNorge data should be regarded as best-estimate representations of historical meteorological conditions rather than exact local measurements.

Uncertainties in the meteorological inputs will propagate through the modelling chain and contribute to uncertainty in the resulting PEC estimates. The magnitude of this uncertainty is evaluated quantitatively, as described in section 10.7, in the context of sensitivity analysis.

10.5 Exposure modeling

The approach to the estimation of environmental concentration chosen in this study is a process based one. The primary reason for this is that it provides a mechanistic representation of the relevant transport and transformation processes, allowing environmental concentrations to be estimated under a range of conditions, typical for the different regions, and agronomic scenarios relevant for risk assessment. Risk assessments of this nature and with this scope in terms of compounds and conditions cannot rely on empirical data. Add to this the complexity of compound fluxes through an agro-ecosystem and it is clear that empirical methods are not feasible.

The main sources of uncertainty associated with this approach arise from assumptions and simplifications in the conceptual and mathematical representation of the processes that determine the concentrations in soil, water and biota. Natural systems are inherently complex and variable, whereas process-based models require abstraction of these processes and their interactions.

Some processes that may influence concentrations in soil have not been explicitly included in the current assessment. For example, removal through soil erosion and surface runoff can contribute to the transport of contaminants away from the application area and thus reduce local soil concentrations, while downward transport through leaching may result in redistribution of substances to deeper soil layers and reduction in concentrations in the considered soil compartment. Uncertainty is also associated with degradation and transformation processes, including biological and abiotic degradation, which may vary substantially depending on environmental conditions such as temperature, moisture content, and microbial activity. Soil temperature and moisture content are intricately linked to bio-degradation. In addition, preferential transport pathways and soil mixing processes, for example through macropore flow or bioturbation, can affect the spatial distribution and persistence of substances in soil.

The current assessment adopted simplified parameterisation of the agricultural practices. Soil depth, date of application and the distribution of sludge over a field can be expected to vary significantly. In this risk assessment, however, they are represented by a single value or not at all. The study works with climate averages as the driving forces behind seasonal variations in leaching, plant uptake and bio-degradation. The study therefore does not cover the full range of the weather conditions that may drive environmental fluxes. Incidental conditions such as heat waves, rainstorms, and prolonged drought can determine much of a compound's fate in the agro-ecosystem.

The implication of these simplified representations of the complex reality is that local values at any given time are lower or higher than the values predicted in this report. This is inherent to risk assessments. Consequently, the estimated environmental concentrations should be

considered as model-based approximations intended to support risk characterization rather than exact predictions stemming from environmental conditions.

10.6 Sensitivity assessment: PNECs

A key limitation of QSAR-derived PNECs is the substantial uncertainty associated with their predictive performance. Comparison with experimentally derived PNECs indicates that deviations can span up to 3–4 orders of magnitude in both directions, meaning that QSAR estimates may be either overly protective or insufficiently protective. This level of variability reflects limitations in model applicability, particularly for substances with specific modes of action, ionizable properties, or those outside the chemical domain of the training data. As a result, QSAR-based PNECs should be interpreted cautiously and primarily used for screening purposes, with explicit consideration of uncertainty ranges to avoid misclassification of environmental risk. Please refer to the comparison of QSAR-derived PNECs and experimentally derived PNECs in Chapter 3.3.

10.7 Sensitivity assessment: chemical properties and climatic drivers

A sensitivity and uncertainty analysis of the key chemical input parameters and the two most important climate drivers was performed. A brief description of the methodology and a more detailed overview of the outcomes is given in Appendix I 13. The outcome is summarized in Table 10.7-1. The impact of the uncertainty of the input parameters on the variance of the outcome variables depends on substance properties and on the known or assumed uncertainty of the parameter itself.

Overall, the input with the sewage sludge has the highest impact: it will directly affect all calculated concentrations (if the input is doubled, calculated concentrations also double). Concentrations in sludge can vary considerably. For many chemicals, only a few samples from few sewage treatment plants were analysed, and the true uncertainty of this parameter cannot be determined. Partitioning to organic carbon in soil K_{OC} has moderate impact on concentrations in soil and high impact on those in plants at harvest and in surface water. The bioconcentration factors in plants (*BCF*) affect only concentrations in plants, but do not matter for soil or surface water. Very difficult to quantify is the uncertainty of the degradation rates, expressed as half-life *DT50*. Generally holds that uncertain *DT50*-values affect calculated concentrations more if the half-life is short. While for persistent chemicals with half-lives of hundreds of years, the uncertainty does not change the outcome significantly – they are not degraded. Biodegradation rates in experiments and field studies can vary widely, but we did not systematically quantify the uncertainty. It is therefore well possible, that its impact on uncertainty for many chemicals is much higher than determined here. Soil temperature only acts via half-life in the model, and its uncertainty is therefore of little relevance. Precipitation, however, leads to loss by leaching and transfer of chemicals to surface water, in particular for chemicals with low K_{OC}. It therefore affects concentrations in soil, in plants at harvest, and in particular in surface water.

Tabel 10.7-1: Summary of the sensitivity and uncertainty analysis.

Parameter	Uncertainty	Impact on $PEC_{peak,soil}$	Impact on $PEC_{harvest}$	Impact of $PEC_{surface\ water}$

K*oc*	known, high	moderate	high	high
BCF	known, high	none	high	none
DT50	unknown, high	Low	low to high	low
Input I	unknown, medium	High	high	high
Soil temperature	known, low	Low	low	low
Rainfall	known, low	low to moderate	low to moderate	high

10.7.1 Uncertainty in contaminant hazard and exposure data for risk assessment of environmental organisms

PNECs used to predict risk to living organisms were derived using PNECs derived for aquatic living organisms ($PNEC_{sw}$) by and equilibrium partitioning (EqP) method. The use of EqP imply that the sensitivity of aquatic organisms are the same as soil living organisms. This is not necessarily the case. Soil living organisms have different exposure routes than aquatic living organisms. In general, more toxicity data are available for aquatic organisms than for soil living organisms. The use of EqP was therefore used here to prioritise compounds for further assessment. There are uncertainties linked to the derived PNECs, since time did not allow for quality assurance of the PNECs derived. Also, there was no time to scrutinise the toxicity data in detail. The derived PNECs should therefore only be used for the prioritisation of contaminants, and not for other purposes.

In addition, we also used QSAR derived PNECs to allow for prioritisation of compounds that otherwise would have no toxicity data. These data are presented in the tier 1 data for soil living and aquatic organisms (for example in figures 9.1.1.1 and 9.1.2.1). However, in tier 2, the focus was on experimentally derived PNECs and contaminants that were quantified in sludge samples. As shown in for example chapter 3.3, the QSAR developed PNECs may be overly protective, or not protective enough. The tier 1 mentioned contaminants predicted to result in RCR > 1 should therefore be investigated in follow up studies to this risk assessment. More qualified conclusions could therefore be drawn based on real data.

By focusing on compounds with experimentally derived PNECs and quantified concentrations, this assessment prioritises substances with relatively robust risk characterisation. However, this approach inherently excludes contaminants that were not analytically quantified or lacked sufficient ecotoxicological data. As a result, substances with potentially high toxicity but low concentrations, poor analytical detectability, or missing PNEC data may not be captured. This introduces a bias towards well-characterised chemicals and may lead to an underestimation of overall risk, particularly if potent but unquantified contaminants contribute to mixture effects.

One example is mentioned in chapter 9.1.2.1, levonorgestrel. The hormone has a very low PNEC for aquatic organisms and therefore exerts effects at very low concentrations. It was predicted to be the contaminant with the highest risk to aquatic living organisms. However, levonorgestrel has not been quantified in sludge, and therefore concentration data are lacking for this contaminant.

The need for high-quality analytical methods in sludge assessment is critical because sludge

represents a complex mixture of contaminants, often containing substances at low concentrations but with potentially high toxicity. Insufficient analytical sensitivity or selectivity can result in non-detects or unreliable quantification, leading to the exclusion of relevant

compounds from risk assessments. Consequently, the use of advanced, high-resolution and sensitive analytical techniques is essential to improve detection limits, increase chemical coverage, and reduce uncertainty, thereby ensuring that potentially significant but previously undetected contaminants are adequately captured and evaluated. Hopefully contaminants from tier 1 assessments of RCR for soil living and aquatic organisms can be used for complementing analyses of sludge in the future.

10.7.2 Uncertainty in contaminant hazard and exposure data for farm animal risk assessment

The hazards evaluated for farm animal assessment were contaminants analysed in minimum 10 sludge samples from minimum 2 sewage plants and detected/quantified in minimum 10 % of the samples. These contaminants constitute obviously only a small proportion of all organic contaminants in the sludge with potential for effects. The concentrations of quantified, selected contaminants used in the evaluation were median from 90-percentile levels from each sewage plants. Obviously, these analysis results have large variations, but most likely, the selected data are considered in the upper part of the scale, and thus conservative approach. We consider a fixed level of contaminants but most likely will their levels and the pattern of individual contaminants vary between sewage plants and within each plant through seasons and over time.

There are uncertainties in levels of the contaminants in the soil, in contaminant uptake in plants and in the plants eaten. Furthermore, there is uncertainty in animal total intake and composition of ration. Particularly, the intake of soil by grazing animals has large influence on contaminant exposure and is burdened with uncertainty.

There are uncertainties in the hazard evaluation of the various contaminants as there are close to zero available relevant data on tolerance levels for farm animals. The evaluation is largely based on available toxicological data for the contaminants for human risk characterisation (TDIs/ADIs) and relevant toxicological studies in rodents (NOAELs, LOAELs, BMDLs). Few data and inter species variations in tolerances imply uncertainties.

10.7.3 Uncertainty in contaminant hazard and exposure data for human risk assessment

A complete human exposure assessment for chemicals in food requires a large dataset for occurrence in all foodstuffs. To produce such a database is very time-consuming task for each chemical. In addition, the availability of data for most of the compounds from relevant food items is not available. Instead, an expert evaluation was made of how much a potential intake of the food with the predicted increases in concentrations could be compares with the available HBGV. For compounds where a national or international dietary intake estimates were available, an evaluation of the significance of the predicted increase in concentration in relation to the HBGV was made. This approach is less exact than a complete intake estimation.

There is a lack of established tolerance limits like TDI or BMDL for a large number of compounds for humans and even more so for relevant farm animal species. This leads to either no possibility to assess the exposure or in many cases large safety factors.

10.8 Effects of mixtures

Sewage sludge contains a very large number of contaminants and to foresee all potential mixture effects is not possile. nd the composition varies between batches and over time after application due to physical and biological processes. Furthermore, the mixture composition will vary in each compartment of the model due to different properties and the composition in plants is different from the composition in soil. This makes prediction of interactions even more complicated as the relation between compounds may affect the mixture effect.

Effect risks of combined exposure from the comprehensive conglomerate of various contaminants, such as the many contaminants that may act as endocrine disruptors or those influencing metabolism of endogenous and exogenous compounds, cannot be excluded. The probability for various effects from interactive operating contaminants may be considerable.

11 Answers to the Terms of Reference

11.1 Terms of Reference 1 - Mapping of relevant contaminants in sewage sludge

11.1.1 ToR 1a. Which contaminants in sewage sludge are relevant and possible to carry out a risk assessment of and what do we know about the level of these in sewage sludge today? The Norwegian Food Safety Authority wants VKM to use the Environmental Protection Agency's list of relevant contaminants.

The risk assessment should include organic contaminants in sewage sludge that are relevant for human health and the environment, and for which sufficient occurrence and hazard data are available to enable a quantitative or semi-quantitative risk assessment. The Norwegian Food Safety Authority requested that VKM uses the Norwegian Environmental Protection Agency (EPA) list of "relevant contaminants" as the principal basis for selecting substances. The following lists of priority contaminants were considered relevant for this risk assessment:

- The Norwegian priority list (106+ compounds)
- The EU priority substances in the field of water policy (WFD list) (92+ compounds)
- Hazardous compounds on the WFD list (58 compounds)
- The EU Watch list of substances in the field of water policy (29 compounds)
- the Norwegian Water Region-specific list (25 organic compounds)

Most (but not all) of the relevant compounds on these lists have been analyzed for in Norwegian treated (hygienized and stabilized) sludge, hence, there were measured concentrations that could be used in the risk assessment. Monitoring data for 947 single organic contaminants have been made available for the risk assessment, most of the data coming from the five-yearly sampling campaigns of treated sewage sludge from 19 different Norwegian sludge treatment facilities. The sampling campaigns have been organized by Norsk Vann and the Norwegian Environment Agency since 1996. Though only about 500 of these organic contaminants were detected in at least one sample, compounds that have not been detected in any samples were not excluded from the assessment if their toxicity to any relevant end point indicated lower concentration than the lowest analytical detection level. The data was supplemented with model-predicted concentrations for additional 83 high-consumption drugs (>25,000 patients in Norway in 2021) that had not been included in any sampling campaigns. The final list included 1,030 single compounds.

The following groups of contaminants are considered particularly relevant:

- **Persistent organic pollutants (POPs)**:
  polychlorinated biphenyls (PCBs), dioxins and furans (PCDD/Fs), polycyclic aromatic hydrocarbons (PAHs), organochlorine pesticides (e.g. DDT and metabolites), and polybrominated diphenyl ethers (PBDEs).
- **Per- and polyfluoroalkyl substances (PFAS)**:
  particularly PFOS, PFOA, PFHxS and other long-chain PFAS characterised by high persistence, mobility and potential for bioaccumulation and secondary poisoning.

- **Plasticisers and industrial additives**:
  phthalates (e.g. DEHP, DiNP), chlorinated paraffins (SCCP, MCCP), bisphenols, organophosphate flame retardants (OPFRs), siloxanes and alkylphenols.
- **Drugs and personal care products (PPCPs)**:
  selected drugs (e.g. antibiotics, anti-inflammatories, beta-blockers, antiepileptics) and other substances frequently detected in municipal wastewater and sludge.

These contaminants are considered relevant due to one or more of the following properties: persistence in soil, potential for accumulation in the terrestrial food chain, toxicity to soil organisms, livestock or humans, and frequent detection in sewage sludge.

Current levels in sewage sludge
Data from Norwegian national monitoring programmes and databases (including *Vannmiljø*, reporting from wastewater treatment plants, and targeted screening studies) show that:

- A wide range of organic contaminants is routinely detected in municipal sewage sludge, although concentrations vary considerably between treatment plants and regions.
- For many legacy POPs (e.g. PCBs, PAHs, PBDEs), concentrations in sludge have generally decreased over time, but they remain detectable and relevant due to persistence and bioaccumulation.
- PFAS are consistently detected in sewage sludge, with PFOS and other long-chain PFAS often dominating the PFAS profile.
- Drugs and newer industrial chemicals are frequently present, typically at low concentrations, but with large variation and limited historical trend data.

The upper bound median values of the 90-percentiles measured at each treatment plant was used in the risk assessment. Compounds for which there had been a clear trend in concentrations over the covered period (1996-2023), only data from later years were considered. For compounds that were never found above the limit of detection (LOD) or limit of quantification (LOQ), the lowest LOD or LOQ after 2010 was used in the risk assessment.

Compounds for which a thorough risk assessment was possible
A relatively large number of chemical properties are needed for risk assessment. For the initial (low tier) assessment lower-quality data (i.e. model predictions) are considered appropriate, though for a final risk assessment high-quality data are mandatory. The main criterium that triggered exclusion of the highest number of contaminants from the initial risk assessment was the availability of PNEC values (relevant for aquatic and soil-living organisms as end points).

Table 11.1-1 below shows the number of compounds that it was possible to run a low tier and a high tier risk assessment for the different end-points

Table 11.1-1. Number of compounds that it was possible to run a low tier and a high tier risk assessment for the different end-points.

End-point	Tier level	Criteria	No. of comp.
All	Low	• Data available for Mw, log Kow or log D, VP, SolW	746
Soil-living organisms	Low	• Data available for MEC_{SS} or PEC_{SS}, Kd, $DT_{50,soil}$, $PNEC_{soil}$	623
	Higher	• Data available for Kd and $DT_{50,soil}$,	102

		• At least 10 sewage sludge samples from at least 10 facilities with at least 10% of samples >LOQ • Experimentally determined $PNEC_{aqua}$ (→ $PNEC_{soil}$)	
Aquatic organisms	Low	• Data available for predictive modelling of PEC_{sw}, $DT_{50,soil}$, $PNEC_{aqua}$	623
	Higher	• Data available for $DT_{50,soil}$ • Data available for predictive modelling of PEC_{sw} based on at least 10 sewage sludge samples from at least 10 facilities with at least 10% of samples >LOQ • Experimentally determined $PNEC_{aqua}$	102
Farm animals	Exposure	• At least 10 sewage sludge samples from at least 2 facilities with at least 10% of samples >LOQ	232
Humans	Exposure	• Non-drug compounds detected in the sludge at levels above the LOQ in at least one sample, and predicted to increase in food items as a consequence of sewage sludge applications • Drugs measured in sewage sludge and high predicted ecotoxicological potential, or high prescription volumes (>25,000 prescriptions per year)	134 123

11.1.2 ToR 1b. Which other contaminants, then those mentioned in point a) should also be assessed due to their potential for uptake and possible negative effects in the food chain? This point includes possible negative effects on grazing animals.

For human risk assessment, except drugs, all contaminants detected above the LOQ/LOD in at least 1 sample were included in the risk assessment. BCFs were modelled for all chemicals identified to be of interest by the experts within farm-animal and human toxicity (361 chemicals).

For drugs, see description in chapter 8.5.6.27.

For animal risk assessment, about 230 organic contaminants have been included in the risk assessment, i.e. about 75% of the contaminants on the original list of compounds have been excluded due to lack data for both for plants and soil, and due to low detection frequency in sewage sludge. It cannot be excluded that some of the excluded compounds could contribute significantly to the contaminant levels in the total rations for farm animals in a significant way.

11.1.3 ToR 1c. Which contaminants are relevant to investigate in biochar, ashes and struvite based on sewage sludge and what conditions (for example temperature and residence time) are needed for pyrolysis/combustion to break down and/or remove contaminants in the process that converts sludge into biochar/ash.

The contaminants that are relevant to consider when it comes to biochar, ash or struvite are those compounds that are expected to remain or generated during the production process, and which may pose a risk in the environment after application of the product due to their mobility, persistence, toxicity and/or ability to bioaccumulate.

Bottom ash (from Incineration)
Ash is primarily inorganic, composed of mineral-rich oxides and salts.

- Inorganic elements: Investigations should focus on trace levels of heavy metals such as zinc, copper, lead, nickel, cadmium, and chromium.

- Trace organic contaminants: While typically present at extremely low or negligible levels in bottom ash, investigations include PAHs (primarily low-molecular-weight compounds), PCDD/Fs (dioxins/furans), PCBs, drugs, and PFAS. These compounds preferentially partition into fly ash rather than bottom ash during thermal processing.
- Microplastics: While largely destroyed, some residues or transformation products may persist.

Biochar (from pyrolysis)
Biochar may contain residual contaminants from the feedstock or new compounds formed during the pyrolysis process.

- Thermal by-products: PAHs (the most frequently detected group), PCDD/Fs, and PCBs.
- Persistent organic pollutants: PFAS (with PFOS identified as the most recalcitrant congener) and stable plasticizers like Dechlorane Plus.
- Other organics: Volatile organic compounds (VOCs) and residual pharmaceuticals.

Struvite (from precipitation in N- and P-rich liquids)
Struvite may incorporate organic micropollutants into its matrix through adsorption, precipitation, and crystallization.

- Drugs: Particularly antibiotics such as carbamazepine, ciprofloxacin, norfloxacin, ofloxacin, and tetracycline.
- Persistent organics: PAHs, PCDD/Fs, dioxin-like PCBs, bisphenol A, PFAS and LAS.

Process conditions to reduce the presence of organic contaminants in the final products
The assessment shall describe how temperature, residence time and process conditions influence the fate of contaminants during sludge treatment:

Combustion (ash production)
Complete oxidation at temperatures typically ≥ 850–900 °C, combined with adequate residence time, leads to efficient destruction of most organic contaminants, including PAHs, PCBs and dioxins. PFAS may require even higher temperatures for full mineralization. Metals are generally retained and concentrated in the ash, however, major fractions of Hg and Cd may be lost due to volatilization during incineration.

Pyrolysis (biochar production)
The fate of contaminants during pyrolysis depends on the heating rate (preferably low), peak temperature, residence time, and gas atmosphere (oxygen-limited). Temperature ranges for removal:

- PCBs: Concentrations drop by over 97% at >600°C and up to 99.9% at ≥700°C.
- PCDD/Fs: While destruction is substantial at >500°C, these compounds can actually form at intermediate temperatures between 200–400°C.
- PAHs: Higher temperatures (700–800°C) generally decrease total PAH content, but in situ formation (pyrosynthesis) typically peaks around 500–600°C.
- Drugs: At a temperature of 400 °C, most drugs are lost from the feedstock, though some (e.g., acetylsalicylic acid and caffeine) may persist.
- VOCs: Most are produced at temperatures below 350 °C.

- Carrier gas: Using an inert gas (N_2 or CO_2) can limit the re-condensation of volatilized contaminants onto the biochar.
- Advanced Reactor Design: Efficient gas-solid separation and the use of a high-temperature post-combustion chamber (800–900 °C) for vapours ensure that volatilized contaminants are destroyed rather than remaining associated with the final product.

Struvite precipitation
As this process occurs at low temperatures, contaminant reduction depends primarily on upstream treatment and source control rather than destruction during the process itself. Maintaining organic carbon levels below 3% is suggested as the primary measure to minimize the transfer of organic contaminants such as antibiotics from the feed to the final struvite product.

11.2 Terms of Reference 2 - Risk of current practice

11.2.1 ToR 2a. Describe the mobility of the relevant contaminants in agricultural soil and the immediate vicinity of agricultural soil after the application of sewage sludge, as well as transfer to the target organisms in table 1 for selected scenarios.

11.2.1.1 General overview of fate processes

Organic contaminants in soil are subject to a range of processes determined by their chemical structure, physical properties, and the present environmental conditions and different influencing abiotic and biotic factors. These together, determine the fate processes such as transport processes from soil to water - leaching through the soil profile, reaching groundwater, and run-off and erosion to surface waters-, and transfer/uptake to plants, volatilization – which are part of a chemical's mobility. The critical factor for organic compounds which influence the mobility processes are the degradation rate.

Mobility and transfer of organic contaminants are influenced by e.g. the chemical's inherent properties, soil quality parameters (e.g. organic/clay/sand content influencing the infiltration rate), climate (precipitation and temperature), plant uptake potential (expressed as BCF for different tissues/crops), and degradation rate. In this risk assessment, best described by sorption to SOM and particle (e.g. Koc, Kd), annual precipitation, BCF_{plants}, and degradation rate (DT50soil).

Degradation rates in soil are influenced by a wide range of soil properties (e.g. soil organic matter (SOM)) and environmental conditions (e.g. temperature, humidity, redox-conditions), and the present of microbial activity. Even microbial degradation is the dominating process, also abiotic degradation - such as dehalogenation under anaerobic conditions, and photolytic transformation (e.g. surface water), will contribute to transform organic contaminants and influence the organic contaminants fate and final exposure level toward environmental organisms, farm animals and humans.

In chemical risk assessment, the chemical properties persistent (P), bioaccumulation (B), toxicity (T) and mobility (M), is critical for characterisation and categorisation of a chemicals but also give information about likely good for different exposure pathways. In a risk

assessment like this, in addition to mobility and degradation rate (persistent P), plant uptake and removal via harvesting of crops, might be a significant loss-from-soil pathway (**Figure 11.2.1-1**). With high plant uptake, this loss pathways, is not only a loss-process, but for chemicals which not degrade fast, this is a transfer to crops which might have a potential animal and human risk. Similarly ,for chemicals with high mobility and not easily degraded, transfer to surface water and potential risk for aquatic organisms and bioaccumulation in fish and further a potential risk for humans eating fish and for secondary poising for prays.

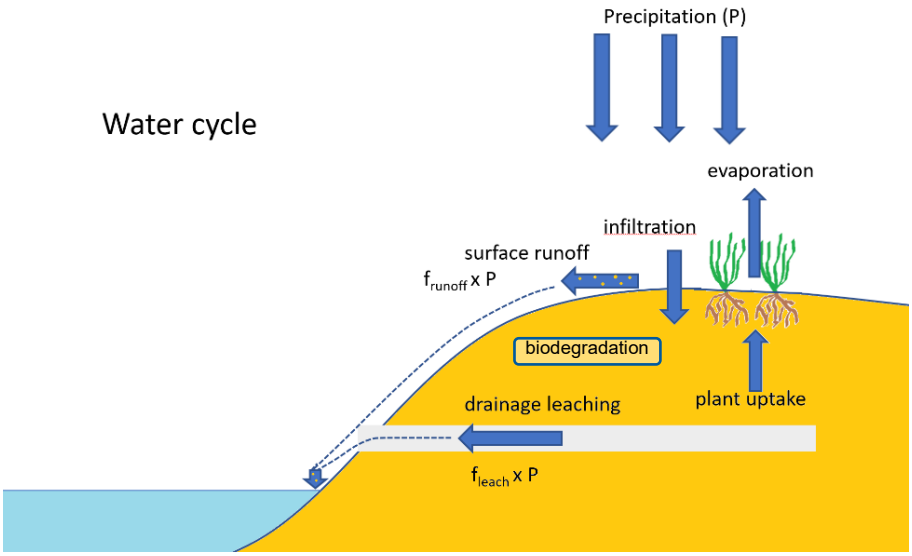


Figure 11.2.1-1. Illustration of water cycle and mobility processes (evaporation, surface runoff, infiltration and drainage leaching), plant uptake and biodegradation are part of a chemicals fate in soil.

Loss rates are generally proportional to the amount of contaminant present, and local factors such as microbial activity, temperature, and moisture can cause regional differences in contaminant fate. Thus, under similar input of organic contaminants to soil, concentrations may increase in one region while decreasing in another, depending on the removal processes. Even there are variation in temperature and soil properties in different regions in Norway, precipitation (e.g. annual precipitation (mm/yr) Time 1507 vs Stange 720/yr) the most influencing one but temperature (days frost in soil (Time 5 d – Målselv 110 d) will play a role for the more easy degradable compounds.

In order to reach surface water, chemicals must be persistent (long degradation time) (P) and it is not only enough to be mobile. Rapid degradation inhibits transfer of chemicals to other compartments. Mobility in our calculations means leaching and/or plant uptake. Volatilization was not considered because very volatile chemicals would quantitatively be lost during wastewater treatment in the aeration tanks in WWTPs. This removal is dependent on sorption properties (expressed as Kd) which for organic contaminants are influenced particularly by SOM, but also pH and cation exchange capacity (CEC) for dissociable contaminants like many drugs, and of degradation rate.

Atmospheric contribution can be of significant contribution to background/present concentration and also have high regional differences. Due to lack of analysis of atmospheric deposition and background concentration in agricultural soil in Norway, these additional

sources were not included in the modelling, only discussed based on data from references sites and urban monitoring program in urban cities (MILBY).

11.2.1.2 Loss processes and parameters influencing fate

In the models used for calculating fate and exposure levels, these processes were accounted for. A comparison of the loss-processes mobility, plant uptake and degradation is illustrated in **Table 11.2.1-1.**

Even lack of a robust and experimental based half-lives (DT50) and therefore use of QSAR-generated DT50, inclusion of degradation in fate modelling allows for a much more accurate prediction of contaminant persistence and potential risk.

By this procedure, the chemicals most likely to leach to groundwater and reach adjacent environments were identified. At the same time, chemicals that have a high leaching potential also have a high potential for plant uptake: soil water and the chemicals dissolved herein that are not leaching are mostly taken up by plants. The ratio of loss by leaching to loss by plant uptake in scenario 1 is 5.6 for all chemicals.

Highly persistent and mobile chemicals (PM-chemicals)
Chemicals that are highly persistent (less than 50% biodegradation in 10 years) and have a leaching rate higher than 10% per year in scenario 1 are listed in the **Table 11.2.1-1**.

Top of the list is monophenyltin (MPhT), followed by fluvastatin, perfluorononanesulfonic acid, atorvastatin, PF-3,7-DMOA, fluticasone, perfluorononansulfonic acid (PFNA) and others: apart from MPhT mostly fluorinated compounds and medical drugs.

Interestingly, the chemicals on the list are also classified as M (mobile) with the new CLP of the EU: Koc values of the chemicals in the table (except the last three) are below 1000 L/kg, which is the threshold for the classification as M.

Table 11.2.1-1. List of chemicals identified as highly mobile, characterized by high persistence and high potential for leaching and plant uptake. Rates are expressed as % loss per year, based on cereal growth in Ås (scenario 1).

CAS Nr	Name	k_{leach} (%)	k_{biodeg} (%)	k_{plant} (%)	sum (%)
2406-68-0	monophenyltin (MPhT)	662.6	0.06	118.1	780.8
93957-54-1	Fluvastatin	145.0	0.61	25.8	171.4
68259-12-1	perfluorononanesulfonate	123.6	0.02	22.0	145.6
134523-00-5	Atorvastatin	106.0	0.61	18.9	125.5
172155-07-6	perfluoro-3,7-dimethyloctan acid (PF-3,7-DMOA)	66.4	0.02	11.8	78.3
90566-53-3	Fluticasone	53.1	0.61	9.5	63.2
10238-21-8	Glibenclamide	50.2	0.61	8.9	59.8
474511-07-4	perfluorononan sulfonate	26.3	0.02	4.7	31.0
797-63-7	Levonorgestrel	23.7	0.06	4.2	28.0
153212-75-0	6-hydroxypaclitaxel	22.4	0.20	4.0	26.6
54048-10-1	Etonogestrel	19.2	0.61	3.4	23.3
57-83-0	Progesterone	13.9	0.06	2.5	16.5

CAS Nr	Name	k_{leach} (%)	k_{biodeg} (%)	k_{plant} (%)	sum (%)
57678-03-2	1H,1H,2H,2H-perfluorodecylphosphate (8:2 PAP)	11.4	0.02	2.0	13.5
83919-23-7	mometasone furoate	11.4	0.61	2.0	14.0

Highly persistent and mobile chemicals with high RCR_{soil} (PMT_{soil})

The persistence and mobility were investigated likewise for the chemicals with the highest RCR. The result is shown in **Table 11.2.1-2**. Only one of these chemicals, azithromycin, has a biodegradation of < 1% per year (highly persistent), but several have biodegradation of only 6.1% per year (half-live 1.13 years, 55% of chemical mass remains after 10 years) and are thus also quite persistent. Azithromycin has at the same time a leaching rate of 4.7% per year. It is thus highly persistent and very mobile. Among the other persistent chemicals, only isosyklemon E (1.7%) and octocrylene (1.1%) have a leaching rate above 1%. The highest leaching rates have methylparaben (363.5% per year), sulfapyridin (157% per year) and bisphenol S (135% per year), but these chemicals are degradable (half-lives 1.1 year or less) and are thus less likely to be mobile over larger distances.

The half-lives taken from the table in the JRC report are not comparable to those from a OECD 307 test requested in REACH R.11, where P is > 120 days half-life and vP is > 180 days. In the TGD, chemicals count as inherently biodegradable when the half-life in soil is 300 days, 3000 d or 30 000 days (depending on Kd). Here we took instead < 6.1% per year (half-live > 1.1 year) as threshold for persistence. The CLP classification of the EU sets M to a Koc < 1000 L/kg. The Koc below 1000 L/kg leads to a calculated 12% leaching per year in scenario 1. Thus, none of the RCR chemicals really fulfils the CLP classification for mobile AND is persistent. Of the RCR-chemicals in Table 2, bisphenol A and S, diclofenac, methylparaben, clyndamicin and sulfapyridine have Koc-values below 1000 L/kg.

Table 11.2.1-2. List of chemicals with high RCR, including judgements of persistence and mobility. Rates are expressed as % loss per year. Chemicals showing highest estimated RCR across scenarios evaluated in ToR 2, representing current application practices for dewatered sewage sludge.

Name	RCR_{soil}	judgement	k_{leach} (%)	k_{biodeg} (%)	k_{plant} (%)
UV-329		none	0.2	61.5	0.04
Octocrylene		low M, P	1.1	6.1	0.19
2-Ethylhexyldiphenylphosphate (EHDPP)		none	0.3	61.5	0.05
sertraline/norsertraline		P no M	0.6	6.1	0.11
diclofenac		M no P	24.8	61.5	4.4
Isocyclemone E		low M, P	1.7	6.1	0.3
Bisphenol S		M no P	135.0	61.5	24.1
Bisphenol A		M no P	13.6	61.5	2.4
Octylmethoxycinnamate (EHMC)		none	0.7	614.9	0.13
Methylparabene		M no P	363.5	614.9	64.8

Examples in change in PEC_{soil} up to 90/100 yrs and the percent change over time is shown for selected chemicals with high potential environmental risk in Table 11.2.1.3. Information about environmental risk (RCR), number of samples analysed, detected above LOD, frequency of

detection, measured or estimated concentration in sewage sludge or sewage sludge based products, including kinetics-parameters, are collected in Table 9.1.1.1.

Table *11.2.1-3*. *Ratio of concentration of Y90/Y1. The maximum and minimum ratio over scenarios, location and rotation are given*.

Name	group_2	CAS	Min ratio	Max ratio
Perfluoroctylmetacrylate	PFAS	3934-23-4	8.67	8.75
Benzo[a]pyrene	PAH	50-32-8	8.57	8.64
Indeno[1,2,3-cd]pyrene	PAH	193-39-5	8.52	8.60
Tridecafluorohexylethylmetacrylate	PFAS	2144-53-8	8.38	8.55
Decabromodiphenylethane	PB	84852-53-9	8.38	8.54
Benzo[b]fluoranthen	PAH	205-99-2	8.36	8.48
UV-360	cosmetics	103597-45-1	6.70	6.84
Ocktadecamethyloctasiloxane (L8)	cosmetics	556-69-4	6.69	6.84
Hexadecamethylheptasiloxane (L7)	cosmetics	541-01-5	6.67	6.83
Pigment Red 112	dye	6535-46-2	6.67	6.82
Tetradecamethylhexasiloxane	cosmetics	107-52-8	6.62	6.78
Benzo[ghi]perylene	PAH	191-24-2	6.60	6.77
Permetrin	pesticide	52645-53-1	6.51	6.70
Deltamethrin	pesticide	52918-63-5	6.44	6.64
op'-DDT	pesticide	789-02-6	6.41	6.62
Pentabromethylbenzene	PB	85-22-3	6.40	6.61
Tetracycline	drug	60-54-8	6.05	6.34
Triclocarban	cosmetics	101-20-2	6.01	6.31
Clotrimazole	drug	23593-75-1	5.80	6.13

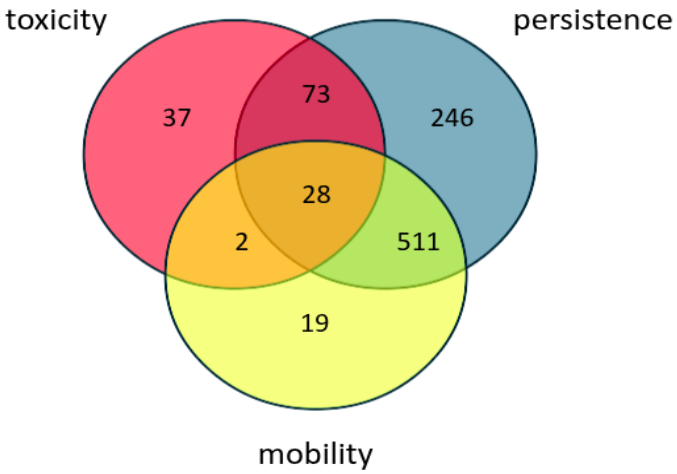


Fig. 11.2.1-2: Venn diagram displaying overlap between compounds. Groups limited to: Persistence: DT50soil,20°C > 120 days, Mobility: KOC> log3 and Toxicity: PNECaqua > 10.

Effect of pH

For ionizable organic chemicals, pH can affect adsorption: typically, anions adsorb less than the corresponding (neutral) acid, while cations adsorb stronger than the corresponding neutral base (Fanco and Trapp 2008; Franco et al. 2009). However, this only affects Koc and thus Kd if

the pKa is close to the pH of the soil. Within the REACH chemical space are about 50% ionizable chemicals (Franco et al. 2010), hereof half acids, and half bases or zwitterions. In the dataset of the chemicals measured in Norwegian sewage sludge, the fraction of ionizable chemicals is somewhat less, only a third is ionizable chemicals within the environmental pH range. The likely reason is that ionizable chemicals tend to be more polar, hence adsorb less to sewage sludge and thus are less present than neutral chemicals.

Nonetheless, several chemicals present in Norwegian sewage sludge with high risk quotient are ionizable, among them clotrimazole (weak base, pKa 6.98, log Kow 5.25), sertraline (weak base, pKa 9.44, log Kow 5.14), diclofenac (weak acid, pKa 4.35, log Kow 4.48) and bortezomib (weak acid, pKa 6.5, log Kow 1.63). All of these are medical drugs. Among medical drugs, the fracvtion ociprof ionizable chemicals is particular high (Manallack 2007).

The effect of varying pH in soil, or a pH shift in soil, is shown in Figure 11.2.1-1, where the change of log Koc with pH in the range of 3.5 to 8 for clotrimazole, sertraline, bortezomib and diclofenac is shown. The curves were calculated with the regression equations of Franco and Trapp (2008), as described elsewhere.

For sertraline, with a pKa outside the range of soil pH, the change with soil pH 3.5 to 8 is marginal. For clotrimazol, the base with pKa at 6.98, adsorption declines somewhat when soil pH is above pKa, and the base is present as neutral molecule. For the two acids, adsorption increases with falling soil pH and increasingly neutral molecules. The effect is strongest for the lipophilic weak base diclofenac, where Koc falls from 2977 L/kg at pH 3.5 to 110 L/kg at pH 7.5 and remains at this value with higher pH. Overall, the effect of pH on the adsorption of organic chemicals is much less pronounced than that on the adsorption of heavy metals (Allison and Allison, 2005).

The change of Koc with pH can affect leaching and plant uptake: lower Koc means lower Kd and thus more leaching and more plant uptake. The average pH range of the soil of the Norwegian regions is narrow, from pH 5.7 (Målselv) to pH 6.25 (Ås), but moorland soils or forest soils may have much lower pH. However, growth of agricultural crops is inhibited at soils with too low pH.

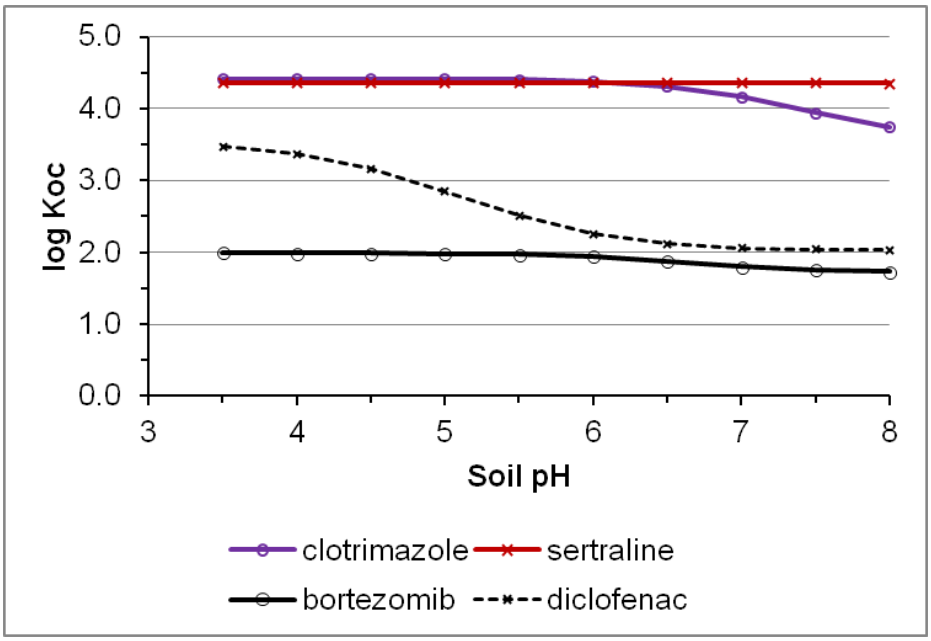


Figure **11.2.1-1. Change of log Koc with pH in the range of 3.5 to 8 for clotrimazole, sertraline, bortezomib and diclofenac.**

11.2.1.3 Transfer to surface water and transfer to human via fish

Transfer from soil to surface water was calculated based on a monthly mass balance. The main driver behind the process is the transfer of excess water from the soil profile. Excess water is defined by means of the monthly water balance; the difference between rainfall and snowmelt on the input side, and evapotranspiration and overland runoff on the output side. In case of a positive difference, the surplus is drained. Artificial (tile) drainage is assumed in all production systems. Tile drain systems are shortcuts in the agro-hydrological system, and the transfer from the soil profile to recipient surface water is instanteneous (i.e. occurs within the month). Contributions of particle bound compound fluxes to surface water were not included in this risk assessment. While erosion risk rates are known in Norway, sediment delivery rates, required for the mass transfer to recipient, are not. They are highly variable on local soil physical, terrain and weather conditions and are not readily available for the study areas.

The concentrations in infiltration/effluent water are then used to estimate the concentration in surface waters by means of generic values for dilution and background sediment concentration. No accumulation in water bodies is calculated; this would required parameterisation for concrete instances of such lakes or ponds. As a consequence, the surface waters that this assessment evaluates can be assumed to be limited to waterways (rivers, creeks with year-round discharge) in agricultural catchments. For concentrations in fish, finally, the surface water concentrations are multiplied with bioconcentration factors for muscle mass in fish.

11.2.1.4 Transfer to crops – removal from soil and transfer to animals and humans

Uptake of organic contaminants by plants is an exposure pathway to farm animals and humans. Exposure toward farm animals is more complicated **(Figure 1.5-3. and Chapter 8.5).** In addition, plant uptake can contribute to removal via harvesting of crops (high uptake in crops – high yield – might contribute to reduce soil concentration).

The chemicals were ranked by the calculated concentration in plants after 10 sewage sludge applications PEC_Plant_c10. The top 15 ranked chemicals for cereal grain, potato, grass and root vegetables are shown in Table 2. There is almost no overlap between table 1 (mobility, leaching) and table 2 (highest concentrations in plants). This may surprise, because the most mobile chemicals (with low Kd) typically show the highest BCF-values and should thus have the highest transfer into plants. However, mobile chemicals do not accumulate in soil, they are quantitatively lost by leaching in the waiting time between application and cultivation (4 months for cereals, 3 years for potato and vegetables and 10 months for grass). Chemicals remaining in soil from the time of application of sewage sludge to the harvest of the plants (or, at least to the main growth phase of plants) must have high adsorption to soil and must be persistent towards biodegradation. This explains why several lipophilic chemicals are found in the list of Table 2, besides a number of medium lipophilic chemicals and acidic chemicals.

Two chemicals with known good plant uptake (and medium to high BCF) listed in table 2 are carbamazepine and TCPP (Nightingale et al. 2025, Eggen et al. 2012). Both are medium lipophilic (log Kow 2.28 and 2.31), which enables efficient transfer into plants and also translocation to leaves and grains. Both are also known as very persistent to biodegradation.

Carbamazepine is a medical drug, and several other drugs are also listed in Table 2: bortezomib, valsartan, entacapone, adapalene, doxorubicin, tetracycline, doxycycline, docetaxel and 6-hydroxypaclitaxel. These drugs are widely used and often very persistent to degradation (antibiotics). Most of these drugs are ionizing. If multiple ionizing groups are present in the molecule (doxorubicin, tetracycline, doxycycline, docetaxel and 6-hydroxypaclitaxel), predictions become rather uncertain. Plant uptake of medical drugs has repeatedly been observed in field studies.

Several surfactants show up high on the list, that is bis(2-ethylhexyl) phosphate (CAS 298-07-7), sodium p-n-dodecylbenzenesulfonate (CAS 2211-98-5), sodium p-n-decylbenzenesulfonate and sodium laureth sulfate. These surfactants are widely used and have thus high occurrence in sewage sludge. All four also have calculated medium to high BCF-values, which can be contributed to their acidic nature. Non-ionized, these chemicals would be rather lipophilic. However, studies have shown that their degradation in the root zone is rapid, with half-lives in the order of days to weeks (Martín et al. 2026, Mortensen et al. 2011). The result is thus not in line with real world observations (too slow degradation rate).

Siloxanes are ranked high in all crops. Siloxanes are very lipophilic and transported particle-bound to plants. There occurrence in plants is no sign of mobility, but of wide usage, chemical persistence and strong adsorption. Particle deposition is mostly outside on the plant surface, moreover, siloxanes are volatile. It can be expected that siloxanes are partly or mostly removed from plants during processing (washing, peeling, cooking).

Summarized, there is little relation between mobility of chemicals and high predicted concentrations in crops. The more important factors for occurrence of chemicals in crops after sewage application are:

1. High input (high concentration in sewage sludge), which is connected to wide usage and strong adsorption to sewage sludge (high lipophilicity).

2. Persistence and accumulation in soil. Only chemicals with high adsorption (typically high lipophilicity) will resist leaching and remain months or years in the top soil. Also,

biodegradation occurs in the water phase, and biodegradation half-life in soil increases with increasing Kd.

High concentration of chemicals in soil pore water (due to low Kd) is generally correlated with good uptake into plants and translocation to leaves and grains. Mobile chemicals with low K_d (labeled "M" in the CLP) thus have the highest BCF-values in experimental laboratory studies. This does, however, not translate to high concentrations in plants for the scenario of sewage sludge application followed by month-long or longer waiting period until plants are cultivated harvested. To be present in the harvest products, *chemicals need to be persistent and have small loss with leaching*.

Chemicals with high PECplant. High concentrations in plants are predicted if high concentrations in soil and high BCF come together. High concentrations in soil origin first of all from a high input, that means, high concentration in sewage sludge. This is more likely the case for non-polar compounds that show high adsorption to the sludge, while polar chemicals with low log Kow do not adsorb as much to sewage sludge. Second, biodegradation and other loss processes must be slow, else the chemical is lost before plant uptake can happen. The most polar chemicals with the highest BCF have typically the lowest Kd-values and therefore show the fastest loss by leaching.

Cereals. The chemicals predicted to have highest concentrations in cereals (scenario 1, Ås, PECplant/harvest year 10) are bis(2-ethylhexyl) phosphate > sodium p-n-dodecylbenzenesulfonate > bortezomib > carbamazepine > sodium dodecylsulfate > sodium laureth sulfate > tris(1-chloro-2-propyl)phosphate (TCPP) > sodium p-n-decylbenzenesulfonate > valsartan > entacapone > doxorubicin > benzothiazolone > octadecamethyl octasiloxane (L8) > doxycycline > hexadecamethyl heptasiloxane (L7). Among the highest ranked chemicals are five surfactants, detergents or emulsifiers with ubiquitous and high usage, mostly lipophilic acids and with medium log D; medical drugs with ubiquitous use, also mostly weak acids or neutral, with medium polarity (bortezomip, carbamazepine, valsartan, entacapone); three antibiotics with multiple charges (doxorubicin, doxycycline, tetracycline); one flame retardant with wide usage and again medium polarity (TCPP log Kow 2.31); one fairly water soluble corrosion inhibitor (benzotriazole) and two highly lipophilic siloxanes (L7, L8) used in lubricants, coatings, silicone polymers and cosmetics.

This is in line with the expectation that the most polar chemicals show low input with sewage sludge and rapid loss from soil, while the lipophilic chemicals have high input and accumulate in soil but show little plant uptake, and therefore chemicals with medium lipophilicity (2 < log Kow < 5) are most likely to be found in crops. However, the silicones have very high log Kow, their occurrence in plants is less due to favorable physico-chemical properties but due to their wide use, high adsorption to sewage sludge, and recalcitrance against degradation. Uptake into plants is particle-bound by soil resuspension.

The plant uptake calculations of the three antibiotics, doxorubicin, doxycycline, tetracycline, are very uncertain: these chemicals have multiple charges, and none of the uptake models was designed or tested for such compounds. Moreover, also the K_d-values are uncertain.

A comparison of PEC_harvest_c1 to PEC_harvest_c10 moreover shows that the same chemicals are listed high, with one exception, that is valsartan. The comparison of calculated concentrations PEC_harvest_c1 to PEC_harvest_c10 shows furthermore that the chemicals with the highest Kd, that is tetracycline, L7 and L8, have seven times higher concentrations at

the later time; valsartan also shows an increase, but only factor 2. All other chemicals have the same calculated concentration at PEC_harvest_c1 and PEC_harvest_c10. Within ten years, the bulk of these chemicals is degraded or lost by leaching, and each ten years new chemicals are added with sewage sludge application.

Sodium p-n-dodecylbenzenesulfonate (CAS 2211-98-5) (rank 2) and sodium p-n-decylbenzenesulfonate (rank 8) are members of the class of linear alkylbenzene sulfonate (LAS) surfactants which are used in high amounts in detergents such as washing powders. Levels in sewage sludge are therefore high. Widespread application of sewage sludge to agricultural soils had led to concerns about the possible accumulation and effects of linear alkylbenzene sulfonate (LAS) earlier. However, uptake and degradation studies of LAS found no plant uptake, and rapid degradation was observed (Mortensen et al. 2001). A recent study looked into fate and risk of linear alkyl benzene sulfonates (LAS). The scientists found that LAS biodegraded quickly in soil, with half-lives from 2 to 13 days, and concluded that LAS poses minimal ecological risk, except lagoon sludge; composting was recommended for reducing LAS levels (Martín et al. 2026). Similar compounds, though not LAS, are sodium dodecyl sulfate (rank 5), sodium laureth sulfate (rank 6) and bis(2-ethylhexyl) phosphate (HDEHP, rank 1), for which rapid degradation can be expected, too. Bis(2-ethylhexyl)phosphate (HDEHP or HDEHPA) is an organophosphorus compound that has quaternary structure. It can be used as lubricant additive, antiwear additive, as surfactant and for the extraction of rare earth metals and uranium.

Grass. Scenario 2 Ås. The top 15 chemicals with the highest calculated concentrations are octadecamethyl octasiloxane (L8), sodium p-n-dodecylbenzenesulfonate, hexadecamethyl heptasiloxane (L7), carbamazepine, tetradecamethyl hexasiloxane, galaxolide, bis(2-ethyl hexyl) phthalate, doxorubicin, tetracycline, bis(2-ethylhexyl) phosphate HDEHP, sodium p-n-decylbenzenesulfonate, sodium laureth sulfate, sodium dodecyl sulfate, doxycycline and docetaxel. The super-lipophilic siloxanes rank high because of transport with resuspended soil particles, which was assumed to be high for leaves and grass (default BCF 0.01 kg/kg). Whether this translate to high siloxane concentrations in the fields and meadows may be questioned because siloxanes possess very high partition coefficients air-water K_{AW} and are thus quite volatile. They may thus be lost again from aerial plant parts. The same holds for galaxolide, a musk fragrance with K_{AW} 0.013 L/L, which is a rather high value. High on the list are again LAS (sodium p-n-dodecylbenzenesulfonate), which are known to be degraded, and carbamazepine. The latter is a widely used pharmaceutical and has been found all over the world in various plants (Nightingale et al. 2025). New among the top 15 are bis(2-ethyl hexyl) phthalate (also known as diethlyhexyl phthalate DEHP) and docetaxel. DEHP is a widely used lipophilic plasticizer, though, typically rapidly degraded. Docetaxel is a very complex chemical with multiple ionizable groups, and the calculations are uncertain because none of the uptake models was designed or tested for such compounds, nor the Kd-regressions.

Potato. Scenario 4, Stange. A similar pattern as seen before emerges for uptake into potato (Stange, scenario 4), PEC_harvest10 (Table 1). The top 15 chemicals are sodium p-n-dodecylbenzenesulfonate (LAS), bis(2-ethylhexyl)phosphate (HDEHP), octadecamethyloctasiloxane (L8), hexadecamethylheptasiloxane (L7), galaxolide, tetradecamethylhexasiloxane, Tri(2-butoxyethyl) phosphate (TBEP), tris(1-chloro-2-propyl) phosphate TCPP, adapalene, doxorubicin, isocyclemon E, carbamazepine, octocrylene, decamethylcyclopentasiloxane (D5) and sodium p-n-decylbenzenesulfonate. For potato, the volatility of the siloxanes and of galaxolide is not relevant. However, due to their high

lipopilicity, these chemicals will mainly reside in the peel of potatoes (Trapp et al. 2007). TBEP and TCPP are two organophosphate compounds. TCPP has been found to show good uptake into plants. TBEP was not measured in this study, but chemically similar organophosphates also showed good plant uptake (Trapp and Eggen 2013).

Chemicals not ranked among the top 15 for cereals showing up high in potato are galaxolide (a musk fragrance with K_{AW} 0.013 L/L, high), TBEP (plasticizer and flame retardant, log Kow 3.46, K_{AW} 3.e-4 L/L), isocyclemon E (cosmetics, fragrance, log Kow 4.72, K_{AW} 8.2e-3 L/L), BAC-C12 (log Kow 2.42, K_{AW} 8.2e-5 L/L), which are all three somewhat volatile, which reduces efficient accumulation in aerial plant parts such as leaves, grains and fruits but not in potatoes. Adapalene has as neutral chemical a very high log Kow (7.18), but is mostly present as medium lipophilic anion in soil (acid pKa 4.38).

Root vegetables. Chemicals ranked highest for uptake into roots are tri(2-butoxyethyl) phosphate (TBEP) > doxorubicin > galaxolide > tris(1-chloro-2-propyl) phosphate TCPP > isocyclemon E > octadecamethyloctasiloxane (L8) > carbamazepine > octocrylen > dekamethylcyclopentasiloxane (D5) > hexadecamethylheptasiloxane (L7) > tetradecamethylhexasiloxane > bortezomib > bisphenol A > benzyldimethyldodecylammonium (BAC-C12) > 6-hydroxypaclitaxel. Most of these chemicals are also ranked high in other crops. New on the list is bisphenol A, a hormonally active plastic ingredient of medium lipophilicity, and 6-hydroxypaclitaxel a metabolite of the anti-cancer drug paclitaxel. 6-Hydroxypaclitaxel is again a very complex molecule with multiple ionizable groups, and predictions should be considered highly uncertain.

11.2.1.5 Removal from soil via degradation

Degradation is urgently important for the uncertainty for the outcome of the modelling. Organic contaminants are transformed and degraded all through their way to sewage sludge, during sludge treatment and in soil and water. Different processes are involved, e.g. hydrolysis, photolysis and biodegradation, and for soil, the latter, biodegradation, is usually the most important transformation process.

Mineralization or ultimate biodegradation is the process where the carbon of the parent chemical is oxidized to carbon dioxide, while primary biodegradation is just the alteration in the chemical structure of a substance by biological action.

Degradation of organic chemicals is influenced by several factors, including the chemical structure, biotic and abiotic factors. Dehalogenation is an example of abiotic processes which might be of importance for some hard degradable brominated and chlorinaged organic contaminants.

It is important to address Non-Extractable Residue Formation (NER). NER can originate from several processes. NER type I (sequestered and entrapped residues) are contaminants bound so strongly to SOM or clay minerals that they cannot be extracted with the usual chemical extraction methods. If NER I is released at later times, the parent substance becomes available again. NER II is chemical covalently bound to the soil matrix. Later release as parent is very unlikely. Finally, NER III is assimilated carbon and of no concern (ECHA CHEM 2023, R.11).

Degradation rates determine the period chemicals are present in the environment and thus how long different target organisms are exposed to a given chemical. Transformation processes change the chemical structure but do not necessarily lead to these end products.

Formation of metabolites is of high concern, particularly for precursors for certain PFAS compounds.

For the risk assessment it was necessary to apply half-lives, DT50, where all were estimated (Comptox). Half-lives for compounds with high risk are shown in Table 11.2.1.5.

11.2.1.6 Estimated background concentration

A comparison of $PEC_{soil/backgrouond}$ concentration after 5 times application of sewage sludge, estimated as a worst-case scenario with application each time at the same field, with measured soil concentration in urban soil (MILBY program) and PFAS concentration in field experiments with application of sewage sludge in Sweden (Kärrman et al. 2024), is shown in **Table 11.2.1.6-1.** Chemicals with RCR>1 in Melhus (cereal production and today's common sewage sludge application) are compared with available measured background concentrations.

Table 11.2.1.6-1. Overview of background concentration of selected contaminants in urban soil (Heimstad et al., 2025, MILBY program), predicted background ($PEC_{soil,50\ yr}$) after 5 times application of sewage sludge (one month before application 6th time, scenario cereals Melhus, ToR), together with measured PFOS concentration from field experiments in Sweden (Kärrman et al., 2024). A3: previous no sewage sludge application, B3 and C3 with 4 tonnes dw/ha/4 yrs and 12 tonnes dw/ha/yr, respectively. Data before (b) and after (a) application is given in µg/kg dw.

	PEC_{soil}	**Milby**			**Surface 0-25 (Sweden)**					
	$PEC_{soil,\ 50\ yr}$	Mean	Q75	Q90	A3 ref	B3	C3	A3 ref	B3	C3
						Before			After	
Octocrylene	***91.99***	***6.86***	***10.0***	***23.8***						
2-Ethylhexyldiphenyl-phosphate (EHDPP)	***12.29***	***0.98***	***1.51***	***2.4***						
Octylmethoxycinna-mate (EHMC)	2.57	15.37	22.8	40.0						
Bisphenol S	0.86	9.36	22.40	22.4						
Isosyclemone E	***95.98***	***0.11***	***0.11***	***0.13***						
PFOS	0.07	5.81	1.36	3.8	0.43	2.1	3.3	0.41	1.9	3.3
Bisphenol A	12.39	17.46	36.0	36.0						
Methylparabene	9.01	n.d.	n.d.	n.d.						
Dinonylphthalate	2.46	0.83	1.15	1.3						
Pentabromoethyl-benzene	0.32	0.10	0.07	0.28						
Decabromodi-phenylethane	1.81	25.15	43.4	45.9						

11.2.2 ToR 2b. What levels of the relevant contaminants in agricultural soil pose a risk of harmful effects on the selected target organisms in table 1

Plant toxicity: Some of the organic contaminants present in sewage sludge and sewage sludge-based products may interfere with seed germination, root development, and early plant growth, particularly when present at elevated concentrations shortly after sludge application.

Reduced germination and growth cannot be excluded for certain organic contaminants, particularly under worst-case scenarios, and should be assessed on a substance-specific basis using relevant plant toxicity endpoints.

There are several publications, also review publications, addressing phytotoxicity both at molecular and genetic level (Feng et al 2017; Xie et al 2025; (Boxall and Brooks 2024; Garduño-Jimenez and Carter 2024), physiological and biochemical level (e.g. oxidative stress and inhibition of photosynthesis (Garduño-Jimenez and Carter 2024; Xie et al 2025, Feng et al 2017; Tziourrou and Golia 2025), and effects on growth and yield production (e.g. visible symptoms, reduced seed germination, stunted root development, and leaf chlorosis (Garduño-Jimenez and Carter 2024; Nwankwo et al 2025; Tziourrou and Golia 2025).

PNECsoil living organisms: There is a huge lack of experimental tolerance values for soil living organisms. This is of urgent importance in order to give a more precise risk evaluation for soil living organisms. **Table 11.2.2-1** give an overview of the $PNEC_{soil,est}$ data used in the present risk assessment and other $PNEC_{soil}$ values (Pedersen et al., 2019; Heimstad 2025 (MILBY). $PNEC_{soil}$ from Pedersen et al., 2019 are all soil living experiments.

Table 11.2.2-1 $PNEC_{soil,est}$ data used in the present risk assessment compared with other $PNEC_{soil}$ values.

Name	Groups	RCRsoil / peak/ 100yr	DT50	Koc	# samples	# plants w/ data	Freq. all plants	MEDIAN sludge conc Q90	PNEC soil	PNEC soil/ exp[1]	PNEC soil[2]
UV-329	UV compounds	104.6	158	787	17	3	0.88	3075	0.17		10000
Chlorhexidine	Drugs	6.3	1582	20614	11	3	0.91	1600	2.47		84
Ibuprofen	Drugs	3.7	158	139	13	1	0.00	500	0.03	1690	
Octocrylene	Cosmetics	15.3	1582	13866	112	13	1.00	7400	5.63		1250
EHDPP	OPEs	15.0	158	2491	124	14	1.00	2070	0.79		302
Benzo[a]pyrene	PAHs	5.8	158188	391858	300	17	0.71	120	1.18	53	
Diclofenac	Drugs	3.2	158	589	141	16	1.00	300	0.53	66	
Bisphenol A	Plastics-related	2.6	158	1080	251	17	0.99	2105	4.60	3700	
PFOS	PFASes	2.4	527292	821	198	17	0.84	9.5	0.03	200	373

Tetracycline	**Drugs**	**2.0**	**15819**	**59969**	**13**	**1**	**0.92**	**4540**	**95.22**	**6000**	

Human:

The human dietary intake of contaminants depends on a range of factors, like concentrations in edible part of each food crop plant, animal exposure data, transfer to animal-derived food products, the consumption pattern and amount for each food items. In addition, a defined safe human intake level for each contaminant in addition to potential interactions between the contaminants is required for a risk evaluation. Currently there are uncertainties and missing information related to all these factors. To assess the significance of predicted concentrations in plants is less uncertain than calculating safe soil concentrations based on safe dietary intake levels.

In conclusion, it is currently not possible to define soil contaminant limits that pose no risk to soil organisms, aquatic organisms, farm animals, or humans.

11.2.3 ToR 2c. What do we know about the current and future exposure (up to 100 years) of the relevant target organisms in table 1, both in terms of average input and a realistic worst-case scenario?

Humans

For most of the chemicals the human exposure from food is not currently known. EFSA has evaluated the current exposure so a part of the contaminant, and VKM has estimated the exposure and risk to some for the Norwegian population.

The exposure and risk from chemicals in sewage sludge here is assessed **(Chapter 9.5)** and is predicted to cause undesired increases in the dietary exposure to particularly PFAS, dioxins, PCBs, PAHs, PBDEs and bisphenol assuming current levels in the sewage sludge. A. The assessment is performed using the highest predicted concentrations in plant-based food within a timeframe of 100 years. For accumulating chemicals, the assessment is based on crop concentrations after the final application. For non-accumulating substances, the concentrations in plants will be the same after the first and the last application. As the prediction is based on high concentrations in the sludge, aand also taking high consumers of the food into consideration the assessment may be considered as a realistic worst-case scenario.

In addition, there is a large number of documented and suspected endocrine disrupting compounds, including compounds affecting the oestrogen, androgen, thyroid receptors and the steroidogenesis. Both natural and synthetic oestrogens may be present in the sewage sludge. In addition, a range of other contaminants, including parabens, alkylphenols, phthalates and bisphenols are known to have hormonal effects in animals.

Studies have demonstrated effects of sludge-amended grazing areas on grazing animals probably related to a mixture of compounds affecting the steroid hormonal systems (see **chapter 8.5.3**).

11.2.4 ToR 2d. If the average scenario described in 2c) shows a risk of adverse effects, will there still be a risk of such effects by reducing the dosage quantity to 8 tons per hectare per 10 years or 1 ton per hectare per year?

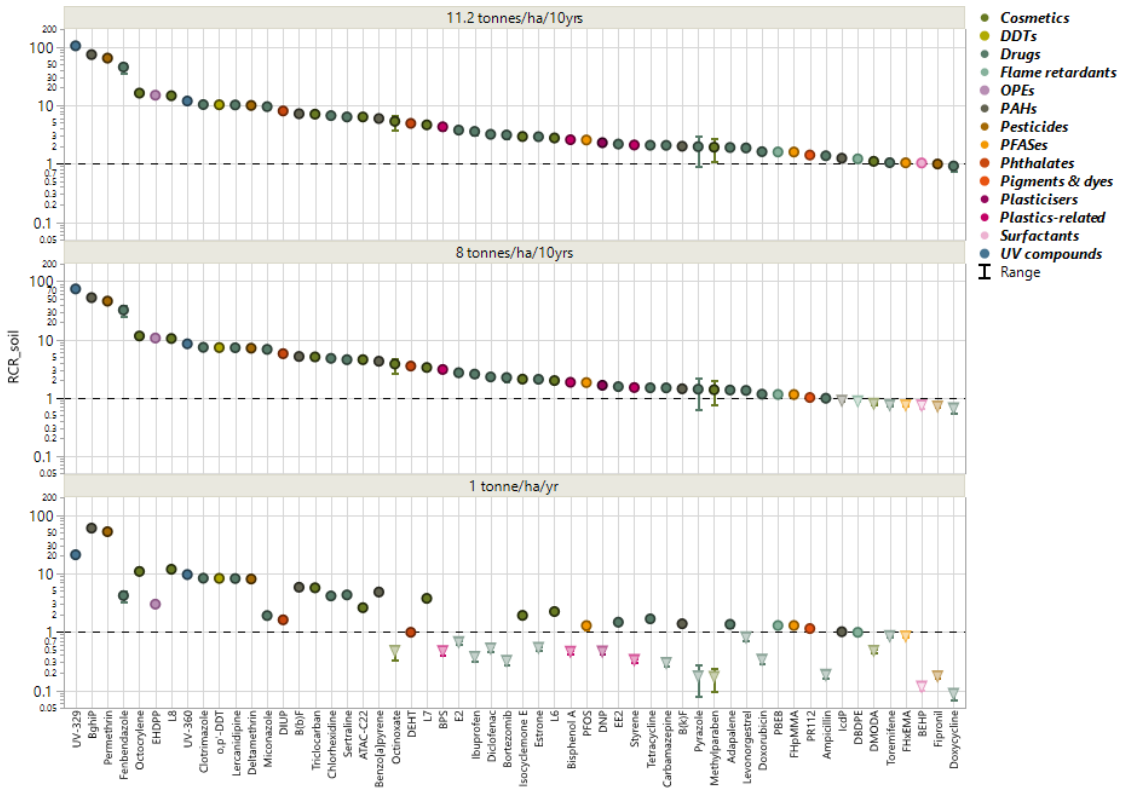


Figure 11.2.4-1**. RCR peak in soil ($RCR_{soil/peak}$) after 100 years with application reduced (TOR2-1) and yearly application (TOR2-2). The mean RCR are shown as a point with the range at different locations and scenarios indicated with range. RCR 1 is shown as a dotted line. The compounds are coloured by the group they belong to.**

11.2.5 ToR 2e. Give a comment on how the "cocktail effect" is expected to affect the risk to the target organisms in Table 1?

Currently, the knowledge on effects of mixtures is insufficient to evaluate the effects of such complex mixtures as found in sewage sludge. The sewage sludge contains a very large number of chemicals with large variation in chemical and toxicological properties. Furthermore, the composition of the mixture will continuously change over time as the sludge is changing and the degradation of the chemicals on the mixture will also change the composition of compounds with highly variable biodegradation in the soil.

However, the available studies of effects of sewage-sludge amended grazing areas indicate that a hormonal effect on grazing sheep was observed even though no individual compounds measured in the studies could explain the effects (see **chapter 9.5**), indicating a mixture effect. Several of the compounds are known or suspected to affects the hormone regulation as compounds with documented or suspected effects on oestrogen, androgen and thyroid hormone receptors and steroidogenesis are found in low levels in the sludge. Even though no

single compound are documented in levels known to affect these systems, it is currently not possible to exclude effects of the combination of so many different chemicals simultaneously.

11.3 Term of Reference 3 - Risk when using sewage sludge in new ways

11.3.2 ToR 3a. If it is permitted to use sewage sludge in areas where vegetables are grown, ten months before the vegetables are grown, how will this affect human health risks? How will the treatment method and amount applied affect the risk?

Reducing the interval between sewage sludge application and the cultivation of vegetables/potatoes to 10 months (compared to the current 3-year rule) primarily affects human health risk through plant uptake of contaminants. The assessment concludes that the use of sewage sludge is a low risk for most non-drug compounds, but it predicts "undesirable increases" in the dietary intake of several persistent groups: PFAS, dioxins, PCBs, PAHs, and PBDEs. This is particularly concerning because background exposure to some of these (such as PFAS4 and dioxins) already exceeds established health-based guidance values.

Effect of treatment and amount:

- Accumulating contaminants: For persistent compounds, the risk is driven more by the total amount applied over 100 years than the specific interval of a single application.
- Mobile contaminants: For non-accumulating but mobile substances (e.g., certain drugs or bisphenols), a shorter 10-month interval may lead to higher peak concentrations in root and leafy vegetables.
- Biochar/ash: These high-temperature treatments significantly reduce the levels of many organic contaminants compared to dewatered sludge (if optimum operational conditions are applied), thereby lowering the risk of plant uptake, though some persistent pollutants like long-chain PFAS may remain.

11.3.3 ToR 3b. If the use of sewage sludge is permitted three weeks before grazing or harvesting fodder, how will this affect the risk to grazing animals and animals that eat harvested fodder? How will this affect human health when consuming animal products? How will the product's condition, spreading method and amount of use affect risk?

Existing studies of effects of applying hygienized sewage sludge three weeks before grazing on animal health clearly document that exposure to the sewage sludge during gestation through the maternal grazing affects foetal, neonatal and pubertal development as well as reproductive and metabolic function in adult life (Evans et al., 2014; Bellingham et al., 2025). Based on the available studies, it is not possible to attribute the biological effects to specific contaminants in the sludge. According to the authors of the original papers as well as the review papers, the concentrations of each of the analysed single component were considered too low to have any impact on the grazing animals, and hence the effects were considered to be a result of the mixture of contaminants present in the sludge (Evans et al., 2014, Bellingham

et al., 2025), but the effects could potentially also be attributed to some unknown compound not analyse for.

Even though the composition and levels of contaminants in the applied sewage sludge may be different, it is hard to exclude potential effects on animals grazing on sewage-sludge amended pastures as long as the contaminants or the combination of contaminants in the sludge causing the effects remains unknown. Other treatment methods of the sludge may also alter the composition, but the potential effect of such treatment is hard to know as long as the compounds causing the effects is unknown.

These studies also analysed transfer to food products in sheep like milk and meat, without detecting any difference compared to controls, indicating that the risk to humans from ingesting food from animals kept on sewage-sludge amended pastures may be low. Such studies were, however carried out for a limited number of contaminants.

The risk is probably directly related to the concentrations of contaminants in the plants and topsoil, indicating that any application form, condition or amount of sludge applied that would reduce the concentrations also would reduce the risk. This means that injecting the sludge into the soil will probably reduce the concentration of contaminants and hence the risk to grazing animals.

11.3.4 ToR 3c. How will using the hygienisation method thermal hydrolysis affect the breakdown of contaminants and possibly reduce the risk in the scenarios mentioned in points a and b, compared to other common sludge treatment methods?

The thermal hydrolysis process (THP), typically operating at 125–170°C and 6–9 bar, is an effective hygienisation tool but does not provide a uniform solution for reducing chemical risks. A direct comparison of the THP against the specific problematic compounds identified in ToR 3a (human health risks from vegetable cultivation) and ToR 3b (animal and human health risks from grazing) reveals that it is largely ineffective against the persistent pollutants and specific pharmaceuticals that drive the primary chemical risks in this assessment. See **Table 11.3.3**.

The primary chemical risks for ToR 3a and ToR 3b are driven by "forever chemicals" (PFAS) and persistent pollutants (PCBs, Dioxins, PAHs). Because these compounds are thermally and chemically stable, THP does not significantly reduce their mass in sludge, meaning the long-term accumulation risk in the food chain remains unchanged.

While THP improves the removal of certain common drugs like ibuprofen, it fails to reduce others that are specifically flagged for their ability to transfer into edible plant parts (such as carbamazepine) or their potential for endocrine disruption in livestock (such as triclosan).

THP is highly effective for the pathogen sterilization required for Class A biosolids, which is vital for the shortened 3-week grazing interval in ToR 3b. However, this “biological” safety does not translate to “chemical” safety; the biosolids produced still contain the same load of persistent and resistant organic contaminants, even at higher concentrations (due to higher “loss” of carbon to biogas).

For more information see Chapter 6.2.

Table 11.3.3. Comparison of THP efficacy on key contaminants identified to cause challenges to human health risks from vegetable cultivation (ToR 3a) and animal and human health risks from grazing (ToR 3b).

Compound group	Relevance to ToR 3a & 3b	Effect of THP pretreatment
PFAS (PFOS, PFOA)	Primary driver of "undesirable increases" in human dietary intake (milk, meat, cereals).	No significant reduction. Terminal perfluoroalkyl acids (PFAAs) are resistant to THP temperatures (up to 170°C). THP may even reduce the conversion efficiency of precursor PFAS during subsequent digestion.
Persistent organics (PAHs, PCBs, dioxins)	Major concern for long-term accumulation in soil and carry-over to animal products.	Minimal **impact.** THP temperatures are insufficient to destroy these chemically stable compounds; they largely persist through the process and remain in the biosolids.
Mobile Drugs (carbamazepine)	Identified as a high-risk score drug that transfers into leafy plants immediately after application.	Highly **resistant.** Carbamazepine shows no significant improved removal by introducing THP compared to conventional anaerobic digestion.
Endocrine disruptors (bisphenol-A, triclosan)	Linked to reproductive and developmental alterations observed in grazing sheep.	Generally **resistant.** Both bisphenol-A and Triclosan are highly resistant to THP degradation.
Alkylphenols & phthalates	Plasticisers found in soil and predicted to accumulate over time.	Redistribution. THP does not destroy nonylphenols (losses are due to volatilization) and can actually **increase** concentrations of phthalate metabolites like MEHP faster than conventional treatment.
Removable Drugs (ibuprofen, naproxen)	Compounds often found in sludge but with lower persistence scores.	Significantly **improved.** Removal efficiencies for these specific pharmaceuticals can reach ~80% in combined THP-AD systems, compared to 54% in conventional systems.

11.3.5 ToR 3d. How will surface spreading of sewage sludge as mentioned in points b affect the risk to the environment?

Surface runoff of constituents in applied sewage sludge applied to grassland

When organic fertilizers are applied to grassland, constituents may be lost via surface runoff to surrounding rivers and lakes. These losses occur in both dissolved (readily bioavailable) and particulate (sediment-bound) forms and occur mainly following heavy rainfall shortly after application. A literature search did not identify studies specifically examining organic contaminant in sewage sludge products applied to grassland. However, surface runoff losses following application of animal manure, predominantly liquid cattle manure, have been studied, with primary focus on nitrogen (N) and phosphorus (P). Based on these studies, surface runoff losses have been reported to range from approximately 0.1 to 3% of applied N (Uusi-Kämppä and Mattila 2010, Heathwaite et al, 2006 and from 0.3 to 1% of applied P (Uusi-Kämppä and Heinonen-Tanski 2008, Heathwaite et al, 2006). Heathwaite et al (2006) found that most of the N lost in surface runoff was particle-bound, accounting for approximately 60-70 % of total N loss. For P, Elliot et al. (2005) reported that between 10 and 80% of total P loss occurred as dissolved P, depending on source material and solubility, while Heathwaite et al. (2006) observed that 40 - 70% of P losses were in dissolved form.

The influence of application techniques on nutrient runoff has been evaluated in some few studies (Uusi-Kämppä and Heinonen-Tanski 2008, McConnell et al 2016). Compared with splash-plate broadcasting, applications using a trailing shoe reduced P runoff by approximately 30-40%, while soil injections below the soil surface reduced P runoff by 65- 85%.

Taken together, these studies suggest that surface runoff losses of nutrients following application of organic fertilizers are generally small. The timing of heavy rainfall shortly after application appears to be more critical than the spreading method used, although injection of organic fertilizers substantially reduces the risk of runoff losses. While these findings are based on studies of animal manure, they provide a useful basis for assessing potential runoff risks associated with liquid fraction of sewage sludge digestate applied to grassland, in the absence of sludge-specific studies.

Table 11.3.4-1 Showing groups of contaminants that have an RCR >1 in surface water in one or more locations after 1 and 9 application(s). The minimum and maximum RCR for all locations and rotations are shown.

Group	Name	Minimum RCR sw after 1 application	Maximum RCRsw after 1 application	Minimum RCRsw after 9 applications	Maximum RCRsw after 9 applications
Cosmetics	Octocrylene	0.0015	0.56	0.0074	2.2
	Triclocarban	0.000079	0.068	0.005	1.2
DDTs	o,p'-DDT	0.000071	0.081	0.0049	2.2
Drugs	Adapalene	0.0013	0.98	0.023	2.5
	Chlorhexidine	0.0028	1.3	0.015	2.5
	Clotrimazole	0.00014	0.1	0.0085	1.6
	Doxorubicin	0.015	1.3	0.031	1.3
	Fenbendazole	0.066	12	0.07	12
	Lercanidipine	0.000044	0.047	0.003	1.4
	Levonorgestrel	0.049	64	0.24	69
	Pyrazole[1]	0.0011	1.5	0.0011	1.5
PAHs	B(b)F	0.000078	0.11	0.0064	3.7
	Benzo[a]pyrene	0.000025	0.034	0.0021	1.4
	BghiP	0.000087	0.064	0.0031	2.1
Pesticides	Deltamethrin	0.000071	0.084	0.0048	2.3
	Permethrin	0.00018	0.17	0.013	4.9
Plastics-related	BPS	0.01	1.1	0.01	1.1

1 Pyrazole is not a drug, but used as a precursor to drug(s)

Table 11.3.4-1 shows the groups and contaminants that exceeded RCR 1 in surface water after application of sewage sludge-based products by new application methods. 17 contaminants exceeded RCR=1 in one or more locations/scenarios after 9 or less applications. Drugs was the group with most contaminants, and levonorgestrel had the highest risk followed by fenbendazole. Also, classical contaminants like PAHs, DDTs and pesticides may pose a risk in surface water after several applications. These contaminants pose a low risk initially, but since they accumulate over time, their risk increases over time. This can clearly be seen by comparing RCR after 1 and 9 applications in the table.

12 Conclusions

VKM has assessed the risks associated with organic environmental pollutants in sewage sludge and sewage sludge-based products used as fertilisers in agriculture. The assessment has been carried out over a 100-year timeframe and includes in total over 100 scenarios.

Compared to the previous VKM risk assessments on contaminants in sewage sludge used as fertiliser, alternative application forms and fertilising products were included this time, which introduced extra aspects with high uncertainty. In addition, the effect of reducing the time period between application of sewage sludge and cultivation and harvesting was evaluated, which required another precision in the modelling than previously. This calls for a more comprehensive approach.

For sewage sludge products other than dewatered sewage sludge, evaluations are based on assumptions and predictions rather than direct measurements, and thus, have even a higher uncertainty.

The present risk assessment is based on a conservative risk assessment, where realistic worst-case scenarios are chosen. With this in mind, the main conclusions are:

Environmental risk
Adverse effects for organic contaminants for soil and aquatic living organisms based on predicted environmental concentrations (PEC) in soil and surface water, and the predicted no effect concentration (PNEC) for aquatic organisms ($PNEC_{aqua}$) and for soil living organisms ($PNEC_{soil}$) were shown. The applied risk characterisation ratio (RCR = PEC/PNEC) is based on predicted risk immediately after application in a long-term perspective (91-100 years: $RCR_{peak/100yr}$). RCR<1 indicates no risk, while RCR>1 indicates a risk.

In order to address and reduce the uncertainty, quality criterions were used to prioritise the compounds with less uncertainty. The criteria were (i) availability of experimentally based PNECs for aquatic organisms ($PNEC_{aqua/exp}$) and (ii) detection in sewage sludge.

Soil living organisms
Application of sewage sludge according to today's practices and Norwegian Fertiliser use regulation (approximately 11.2 tonnes/ha/10 years) indicated long-term risk for 56 organic contaminants. After filtering out compounds that do not fulfil the data-quality criteria, 19 compounds still indicated risk. These include pharmaceuticals, cosmetics, plastics-related compounds, PAHs, a pesticide, a flame retardant, an organic phosphate ester, and a PFAS.

Among these, special attention should be paid to persistent compounds which will accumulate in soil over time. The compounds with a combination of high half-lives and exceedance of RCR were three PAHs (benzo(b)fluoranthene, benzo(a)pyrene and benzo(ghi)perylene), one pesticide (permethrin) and one PFAS (PFOS).

The PNECs used are based on toxicity to aquatic organisms, and care should therefore be taken when interpreting the results. Four PNECs for soil living organisms were found which were higher than the ones found for aquatic living organisms. However, this information is not sufficient to conclude that the risk is lower for these substances. In general, more knowledge is needed about toxicity towards soil living organisms.

Reducing the application amount (to 8 tonnes/ha/10 years) reduces the risk accordingly (by a factor of 0.7 – around 30%). But the RCR for the 19 compounds are still predicted to exceed 1 for all of the compounds.

When reducing the application amount and increasing application frequency (to 1 tonne/ha/year), risks are predicted to reduce to RCR < 1 for several compounds with low half-life and low RCR (Octinoxate, BPS, diclofenac, bisphenol A, methylparaben, styrene and carbamazepine), while the risk increases for persistent compounds, when comparing to applying 8 tonne/ha/10 years. The reason is that the total amount of sludge applied over time will be higher (a total of 10 tonnes after 10 years) compared to the scenario of 8 tonnes/ha/10 year. Persistent compounds do not degrade substantially enough during these years, and therefore the RCR is higher after 10 years.

Depending on the chemical properties (persistency and mobility) together with concentration in sewage sludge and sewage sludge products, the predicted soil concentration (PECsoil) evolves over time, from one application to the next application (every year or 10^{th} year).

Application of sewage sludge in new ways. In addition to the already mentioned 19 substances with RCR>1, a few more contaminants were predicted to represent risk when sludge is applied in new ways: a cosmetic (BP3), a drug (sulfapyridine), a plastic-related compound (4-octylphenol) and a solvent (ethylbenzene). Of these, all had relatively short half-lives, while 4-octylphenol and ethylbenzene had low detection frequencies.

Therefore, the same 5 compounds as identified in today's practices are predicted to represent the highest risk when sewage sludge is applied in new ways: three PAHs (benzo(b)fluoranthene, benzo(a)pyrene and benzo(ghi)perylene), one pesticide (permethrin) and one PFAS (PFOS).

Aquatic organisms

Potential long-term risk ($RCR_{sw/peak/100yr}$ >1) of applying dewatered sewage sludge based on today's practice and the Norwegian fertiliser use regulation identified five drugs as a potential risk for aquatic organisms. The drug with the highest predicted risk, levonorgestrel, has no occurrence data in sludge because the LOQ employed is not sufficiently low. Of contaminants which had occurrence data in sludge *and* estimated PNECs, only fenbendazole (drug) remained of the original five pharmaceuticals. Fenbendazole had a low detection frequency (<10 %) and was quantified in 12 sludge samples. Therefore, fenbendazole does not satisfy all data-quality criteria set. The half-life is estimated to 158 days, which is much shorter than the persistent contaminants mentioned in soil. When reducing the application, a decrease in RCR was observed. By applying annually instead of every 10 years, the RCR was reduced to RCR <1.

For application of sewage sludge in new ways (ToR3), 79 contaminants were predicted to potentially pose a risk to aquatic organisms. When considering only experimentally derived PNECs and also setting quality criteria for the concentrations in sludge, 9 contaminants were estimated to potentially have an RCR>1.

Both for soil living organisms and aquatic living organisms the lack of experimental PNECs, the lack of analyses of contaminants in sludge and lack of sufficiently sensitive analytical methods have limited the risk characterisation. Also, knowledge about mixture effects is very limited.

Farm animals

For several of the chemical contaminants, the tolerable levels for farm animals are highly uncertain, and the knowledge about effects from contaminant mixtures is almost absent. Thus, the considerable uncertainty requires a cautious approach.

Because contaminant residues in soil seem to be the major source of exposure for grazing animals, a possible measure could be to hinder that animals ingesting soil from grazing after a sludge application. As the contaminants have highly different elimination times in soil, the period animals should be prevented from grazing on sludge treated pastures depends on the contaminant profile in the sludge.

The contaminant groups that contribute quantitatively the most to the daily rations for farm animals, are cosmetics, drugs, organic phosphate esters (OPEs), plasticisers, antioxidants and surfactants.

For most of the contaminants, the calculated concentrations of individual organic contaminants in the total rations (µg/kg DM) for farm animals ingesting compound feed, grass/forage and some soil from field where dewatered sewage sludge had been used are far below compared with human TDIs/ADIs or NOAELs, LOAELs or BMDLs for rodents. However, some contaminants are considered of concern. Those are particularly the plasticizers bisphenols and the cytostatic drug doxorubicin. In addition, also the progestin drug levonorgestrel, the oestrogen estrone, the anticonvulsant/analgetic drug carbamazepine and the plasticizers phthalates may be of concern.

Furthermore, the effect risks from combined exposure of the large repertoire of various contaminants cannot be excluded. The probability of subtle or more pronounced health effects from interactive operating contaminants is evaluated to be considerable.

The level of contaminants in the total rations for animals living and feeding indoors are averagely 2- to 3-times lower than for animals being outside (grazing) after the application of dewatered sewage sludge. Soil ingestion is the main reason for this difference.

Exposure risks are significantly elevated when using surface-applied liquid digestate compared to dewatered sewage sludge. The total ration of organic contaminants for grazing animals, such as high-lactating cows, is predicted to be 4- to 6-times higher when liquid digestate is applied. This increase is primarily driven by the direct ingestion of the liquid product adhering to grass and the soil surface, which accounts for 50% of the total contaminant intake for grazing livestock, and uptake in gras (45%).

Postponing grazing and harvesting on treated areas will reduce animal exposure. For some contaminants, a few weeks will imply a considerable reduction or elimination. For others, several years are needed to reduce the contaminant level properly.

Concerning microbial resistance, the concentrations of residues of antibiotics and biocides available for farm animal exposure from use of sewage sludge on soil to be used as pasture or forage/feed production, seen isolated, are probably too low to imply a risk to influence on the development of microbial resistance in the farm animals. However, environmental spreading of resistant microorganisms and resistance genes by use of sewage sludge into the soil may occur.

Human health risks
Sewage sludge application applied as today assuming the present concentrations in sewage sludge is predicted to increase dietary intake of several contaminants. In general, the application will increase the current exposure to a few groups of chemicals (PFAS, dioxins, PCBs, PBDE, brominated flame retardants, and bisphenol A) that are already higher than the HBGV, worsening of an existing exceedance. An undesired increase of the dietary intake of siloxanes and octocrylene is also predicted, but the sewage sludge alone is not expected to increase the intake to a level exceeding the threshold for toxicological effects. As the compounds that may be of concern are accumulating over time, monitoring of the levels of these groups be monitored in plants and soil over time with continuous use of sewage sludge.

A number of drugs is predicted to reach levels of human exposure of concern in relation to their ADI or predicted ADIp following sewage sludge applications on agricultural soil. Some highly potent cardiovascular, anti-cancer and antidepressants/nervous system acting drugs are of particular concern.

For some drugs that are frequently prescribed in Norway, there are no analytical data available and future monitoring is recommended. In addition, some drugs detected with high frequency in sewage sludge do not accumulate in crop plants, but may be absorbed into fish.

Impact of alternative products (ash, biochar, and struvite) related to environmental risk
High-temperature thermal treatments are highly effective at destroying most organic contaminants, provided optimal operational conditions are maintained. Combustion into **ash** at temperatures ≥850-900 °C ensures the efficient destruction of persistent pollutants such as PAHs, PCBs, and dioxins. Similarly, **biochar** production at ≥500-700 °C reduces the majority of organic chemicals, though exceptionally stable compounds like long-chain PFAS and certain flame retardants (e.g., Dechlorane Plus) may persist in the carbon matrix. It is noted that the in-situ formation of PAHs during pyrolysis typically peaks between 500-600 °C, requiring process optimization to ensure product safety. Biochar may act as both a mitigation and a potential long-term source of contamination, as it can initially reduce exposure by sorbing hydrophobic organic compounds from the liquid phase, but may subsequently release these substances over time as the biochar weathers, degrades, or undergoes physicochemical changes in soil. In contrast, **struvite** production via chemical precipitation does not actively degrade contaminants but incorporates few organic pollutants into its mineral matrix; consequently, the predicted environmental risk from struvite application remains low (RCR < 0.02).

Thermal hydrolysis process (THP) related to human health risk: While THP is a powerful tool for pathogen sterilization required for Class A biosolids, it is not a universal solution for reducing chemical risks. THP is largely ineffective against the persistent pollutants—specifically PFAS, PAHs, PCBs, and dioxins—that drive the primary human dietary increases identified in this assessment. While the process improves the removal of certain common pharmaceuticals (e.g., ibuprofen), others, such as the mobile drug carbamazepine, remain highly resistant.

13 Data/Knowledge gaps

The venture of increasing the reuse of biological resources in Norway urge for actions when it comes to availability of empirical data. This is crucial for the validation of the different steps in risk assessments of contaminants in sewage sludge, as well for other bioresources.

VKM has in previously published risk assessments regarding fertiliser and soil improvers, addressed a list of data gaps which have been repeated over time.

The project group has identified the following data and knowledge gaps in the present risk assessment:

Present concentration of organic contaminants in the environment

At present, there are no regional nor national datasets available that provide the concentration levels of organic contaminants in Norwegian agricultural soil.

Sources to map for are:

- atmospheric contribution in regions with high crop production (not only Oslo and a reference point in Birkenes)
- previous use of sewage sludge. There are farms which have applied sewage sludge every 10 year. This will give valuable in information.
- use of pesticides which might contribute to ultra-short PFAS due to use of fluor-containing pesticides which are metabolized to e.g. FTA. The pesticides found in sewage sludge are not typically used by farmers as pesticides for crop production,

Harmonised monitoring programmes/campaigns of soil, but also ground- and surface water in regions with high agricultural activity. In order to get good quality data, both related to sampling and analytical quality, such monitoring programmes / campaigns should be included in existing monitoring programmes /campaigns as possible.

Generally, few or no analyses are available for present concentrations of organic contaminants in different sewage sludge-based products. Quantification of organic contaminants in sewage sludge-based products such as pellets, biochar, struvite and liquid digested sewage sludge should therefore be performed.

Environment fate processes

It is important to gain more experimental half-lives values and bioconcentration factors for different agricultural crops and fish for a long range of organic contaminants. Priority are compounds with high potential risk to target organisms such as humans, farm animals, and soil living and aquatic organisms. In addition, experimental based Kd-values should be established.

Test fields for agricultural soils receiving sewage sludge from various sewage treatment plants (e.g. the five biggest plants) are unfortunately not yet established in Norway.

The soil concentrations of “old and new” POPs, as well as of other relevant organic contaminants, should be determined at these plants. Important fate processes like degradation (most important) and plant uptake should be determined at all sites, possibly also leaching, volatilisation and aging processes (POPs).

Secondary poising terrestrial mammals and birds:

In Chapter 3.5 Methodology for the characterisation of hazards to wildlife from secondary poisoning, knowledge gained from MILBY program is summarised. No theoretical calculation of bioaccumulation of organic contaminants in earthworm based on predicted background concentration in soil has been performed. However, compared with measured soil from urban areas in Oslo (Heimstad et al., 2025 MILBY), predicted background soil on agricultural land after 50 year application with sewage sludge (soil concentration the last months before application year 61, $PEC_{soil,background}$) shows higher estimated background concentration for some compounds (e.g. EHDPP and Isosyclemone E) (Table 11.2.1.6-1). For two PFAS compounds (PFHxS and PFTDA), the concentration was in the same range (Table A-8-1).

Secondary poising terrestrial mammals (including birds) is urban areas an important for Norwegian Environmental Agency, which are responsible for MILBY program (*Miljøgifter i bydyr*). More knowledge about concentration in earthworm in areas where sewage sludge has been applied in many years, is recommended.

Tolerance values

Experimentally based tolerance values for organic contaminants with potential risk for all target organisms.

Human exposure

There is a lack of data for background intake for most of the compounds in the evaluation, making an assessment of the total oral exposure impossible.

There is a lack of data for intake of self-caught fish. Such data could improve the possibilities to make a real estimation of the intake for a subgroup of the population.

Toxicological reference values

The available toxicological data for long-term oral exposure is limited for a large number of compounds, particularly for farm animal species.

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