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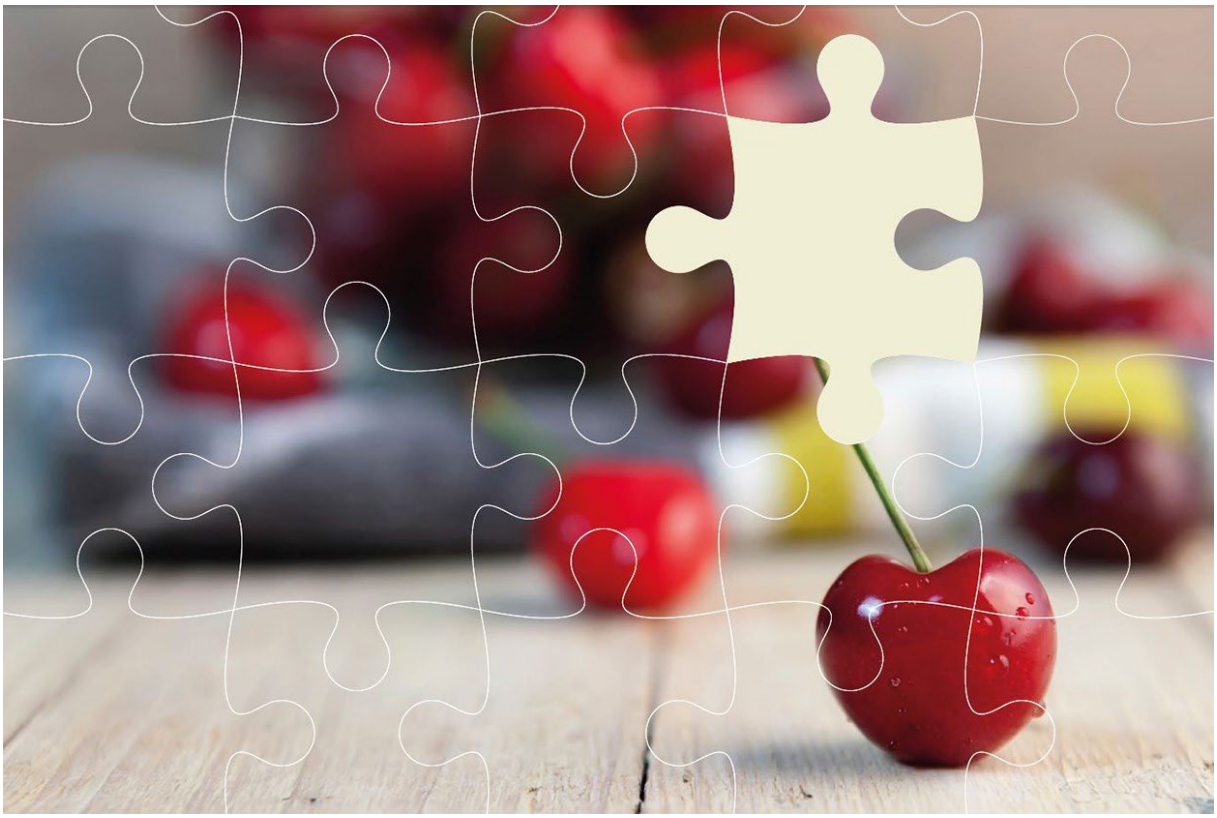

VKM 2022:31

Research needs of importance identified in VKM opinions within the fields of food and environment 2018-2022

Report of the Norwegian Scientific Committee on Food and Environment, the Secretariat

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Research needs of importance identified in VKM opinions within the fields of food and environment 2018-2022

This is a report from the VKM secretariat describing research needs and data- and knowledge gaps of importance identified by the scientific panels in the Norwegian Scientific Committee on Food and Environment (VKM).

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Background

The Norwegian Scientific Committee for Food and Environment (VKM) periodically prepares an overview of the research needs, data- and knowledge gaps identified in VKMs opinions.

VKM conducts and communicates risk-, benefit-risk assessments and other scientific opinions in the areas of nutrition, food and feed safety, animal health and welfare, plant health and biodiversity. The synergy and interplay between these areas are becoming increasingly evident, and interdisciplinary assessments are on the rise in VKMs portfolio. These assessments highlight the importance of holistic approaches to human and environmental safety, protection, and preservative measures, i.e., a One Health perspective.

VKM conducts opinions within these fields:

• Alien Organisms • Animal Feed • Animal Health and Welfare • Biological Hazards • Contaminants • Cosmetics • Dietetic Products • Flavourings • Food Additives • Food Allergens	• Genetically Modified Organisms • Materials in Contact with Food • Microbial Products • Natural Toxins • Nutrition • Pharmaceutical Drug Residues/ Pollution • Plant Health • Plant Protection Products • Processing Aids • Trade in Endangered Species (CITES)

Healthy and safe food is on the agenda both nationally and internationally. Since food production, food products on the market and dietary habits, as well as the presence of potential hazards, are constantly changing, there is a continuous need for new knowledge to ensure healthy and safe food. Likewise, protecting the environment is vital for biodiversity and the well-being and health of people.

Rapid changes in the environment due to climate changes, land-use, pollution, natural resource harvesting, and invasive alien species, directly affects ecosystems and the ecosystem services and other nature's benefits that people rely upon. Thus, a continuous monitoring of existing threats as well as updated knowledge on new threats to the environment is required.

Research and monitoring data from other countries are important and useful but may not be representative and directly relevant for Norway since critical factors such as environmental conditions and dietary habits vary. Knowledge on Norwegian conditions must therefore be generated nationally. Thus, it is necessary that we maintain active Norwegian research communities, strengthen international collaborations, and develop education in fields where the relevant knowledge is lacking.

Risk assessments and other VKM opinions

VKM's risk assessments typically contain three key elements: hazard identification and characterisation, exposure assessment, and risk characterisation. The risk characterisation element integrates knowledge on hazard and exposure. The assessment is based on the scientific documentation available, including peer-reviewed articles, grey literature, previous risk assessments from national and international institutions, data from national and international surveillance and monitoring – in particular intake/exposure data, as well as studies and data provided by the industry (VKM, 2020a).

The degree of confidence in the final estimation of risk depends on the variability, uncertainty and assumptions identified in all the previous steps of the assessment.

Uncertainty in risk assessments is related to the variability, representativity and availability of data that the conclusion is based on. There may be incomplete knowledge of the systems, organisms, variables, or models.

Factors critical for risk assessments include:

- Accessible high quality research data and/or knowledge generated by the international scientific community or by organised surveillance or monitoring by national or international organisations with transparent and systematic methods
- Access to scientific raw and processed data from developers/industry
- Country-specific high-quality research data and other knowledge
- Access to relevant expertise within the relevant fields are essential, especially for multidisciplinary assessments
- Systematic and transparent methods for evaluating the quality and validity of data and knowledge

VKM obligations to Norwegian authorities

VKM carries out independent scientific assessments in the form of opinions for the Norwegian Food Safety Authority (Mattilsynet) and the Norwegian Environment Agency (Miljødirektoratet). A VKM opinion can be a risk assessment, a benefit and risk assessment, a systematic review or other research summaries and comments. VKM follows international guidelines and standards for risk assessments within the various fields to ensure that Norwegian authorities receive independent scientific risk assessments related to food safety and the environment. Risk management is not conducted by VKM.

Introduction

The aim of this report is to highlight research needs, data- and knowledge gaps of importance for nutrition, food and feed safety, animal health and welfare, plant health and biodiversity identified in published VKM opinions, and to stimulate activities to fill these needs.

The aim is to contribute to improve the national knowledge base for decision-making and policy on food and environmental safety specific for Norway. The means VKM promotes to achieve this goal are as follows:

- Making existing data available in formats that can be easily accessed and used
- Conducting Norwegian dietary surveys on a regular basis
- Raising awareness of gaps in monitoring in areas critical for nutrition, food and feed safety, animal health and welfare, plant health and biodiversity
- Summarising and sharing information on research needs, data- and knowledge gaps related to Norwegian conditions with relevant authorities, directorates, departments, and ministries, as well as the Research Council of Norway

We would like to emphasize that this report is limited to outline research needs, data- and knowledge gaps identified in published VKM opinions. There are certainly several other research needs, data- and knowledge gaps in the subject areas within the topics of nutrition, food and feed safety, animal health and welfare, plant health and environmental protection that are not outlined in this report. For this reason, some chapters do not necessary reflect the whole range of research needs.

Previously prepared overviews of the data gaps and research needs identified in VKM opinions are:

- Research needs of importance for food safety and environmental protection as based on data gaps identified by VKM (VKM, 2018a).
- Research needs and data gaps of importance for food safety and protection of biodiversity - From VKM's scientific opinions in the period 2005 - 2015 (VKM, 2016a).
- Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010 (VKM, 2011).
- Additionally, VKM has recently prepared a report highlighting research needs and data gaps that are of future importance for food safety and protection of biodiversity (VKM, 2022a).

There might be some overlap between the previous reports and this report. However, by far not all data gaps reported in the previous reports are repeated in the present report.

Together with the investment areas presented in strategy documents from the Norwegian Food Safety Authority and the Norwegian Directorate of Environment (e.g., for fishery and

aquaculture), these papers pictures research needs for future scientific opinions in the field of food, food production and environment.

Data gaps in VKM opinions

Data gaps refer to missing, incomplete, or poor-quality data related to the subject matter in a risk assessment. Data gaps include everything that is uncovered as missing data during the work and not only the missing data that are associated with the basis for the conclusion. Data gaps can be associated with both variability and uncertainty. In the cases when data are absent, risks cannot be assessed.

Data gaps vs. knowledge gaps

A good analogy is that of a puzzle, where each piece represents individual data points of an image, the knowledge. The more missing pieces (data gaps) and the image gets more difficult or impossible to discern (knowledge gap). This report covers both data gaps and knowledge gaps.

How to read this report

The research needs reported by the scientific panels of VKM are organised below into six main chapters. Data gaps are presented under each chapter with a short description, followed by outlining of research and surveillance needs.

The structure of the report is as follows:

- Terrestrial food production (Chapter 1)
- Aquatic food production (Chapter 2)
- Human health (Chapter 3)
- Biodiversity (Chapter 4)
- Surveillance (Chapter 5)
- Methodology and models (Chapter 6)

To avoid repetition, we have aimed at presenting the data gaps and research needs only once even though they may belong under several chapters and headings.

1 Terrestrial food production

1.1 Agriculture - plant health

1.1.1 Distribution of plant pests

Changes in the food production may cause changes in a plant pest population, e.g., introduction of new organisms in new regions.

The domestic distribution of the vast majority of plant pests are not well mapped.

More systematic surveys for plant pests would contribute to the possibility to evaluate entry and establishment of plant pests in general and are needed.

Outlining of research and surveillance needs

- More systematic surveys for plant pests.
- Digitalization and availability of plant phytosanitary certificates.

1.1.2 Biological information on environmental stress factors relevant to potential plant pests

There is insufficient knowledge or access to biological information on environmental stress factors, such as cold period, heat period, or dependency of snow cover for survival for the vast majority of potential plant pests.

Outlining of research and surveillance needs

- Research is needed, or needs to be made available in English, on a species capacity to survive long-term or short-term exposure to low temperature at specific developmental stages and how this is affected by snow cover, i.e., overwintering.
- Establish an open Norwegian digital phytosanitary certificate database.

1.2 Livestock – animal health and welfare

1.2.1 Spread of transmissible diseases in farmed or semi-domesticated animals for food production

Keeping farmed animals healthy and free from diseases is an essential part of the early stages of food production. This includes detecting, preventing, and controlling any disease outbreaks in animal populations or farms. Assessments on terrestrial animal health conducted by VKM have uncovered knowledge gaps. For example, there was a significant

increase of imported roughage for livestocks in Norway following the drought in the summer of 2018. Pathogens that cause transmissible diseases in animals may be introduced and established in Norway through this commodity. However, there is a lack of scientific documentation of the occurrence and survival of any potential pathogens in animal feed in general. Further knowledge gaps include lack of standards for testing of roughage for potential pathogens. Information concerning transmission routes are often not fully known or missing for specific pathogens, all which prevent more thorough assessments (VKM, 2022b).

Populations of wild boar, which is defined as an alien organism in Norway, is expected to increase over time, presenting hazards for animal health. Wild boars are potential carriers of serious disease-causing pathogens, such as African swine fever, Classical swine fever or Foot and mouth disease, that can be transmitted to domestic pigs. Still, data on the role of wild boar in the transmission of several pathogens is lacking. There is also no information available regarding prevalence of several pathogens in the Scandinavian wild boar population. From a climate change perspective, there are concerns of vector-borne transmission of pathogens to domestic pigs or other animal species with increasing temperatures. However, scientific literature addressing the potential range expansion of these vectors, such as arthropods, in Norway is sparse (VKM, 2018b).

Outlining of research and surveillance needs

- More studies on the presence of disease-causing pathogens in roughage in general is needed. A better understanding of the transmission routes for specific pathogens combined with possibilities for testing roughage is critical to reduce uncertainties in assessments. The development of standards and protocols in screening and testing not only batches of roughage, but also populations at risk for specific pathogens, would also make the surveillance and status reports of notifiable diseases easier.
- Surveillance and testing programmes, together with close collaboration with Sweden, may fill some of data gaps concerning occurrence of pathogens in wild boars.

1.2.2 Housing conditions for livestock or other domesticated animals for food production

The welfare of animals kept for food production, on farm, in transport and at slaughter, depends on husbandry practices and management systems. Animal based measures are useful indicators for assessments of welfare consequences. At farm level, VKM has uncovered several knowledge gaps related to housing conditions in poultry production. For example, very few studies have addressed the welfare consequences in species, such as broilers, ducks, and turkeys, with regards to husbandry parameters such as optimal lightning conditions, restrictive feeding, or appropriate animal densities (VKM, 2022c). There is a lack of knowledge on the physiological and behavioral needs, in general, of breeding turkeys (VKM, 2016b).

Very few studies have addressed the long-term welfare consequences from the use of various technologies (like electric or virtual fences), that produce electrical shocks to modify the behavior of domesticated animals. Most of the current research appear to focus on the effectiveness of these methods rather than addressing animal welfare (VKM, 2017a).

Outlining of research and surveillance needs

- More studies examining light spectrum preferences, photoperiod and luminescence for each poultry species, especially other than broilers, to assess the welfare effects. For breeding turkeys, sufficient data on animal-based measure, health- and production parameters is needed for adequate assessment of animal welfare.
- More studies focusing on learning capabilities and welfare consequences in animals, both short- and long-term, after exposure to electric shock will reduce uncertainties in assessments.

1.2.3 Concerning welfare needs of pets or animals for other uses than food production

VKM has identified several welfare data gaps related to permanent outdoor housing of dogs. Knowledge on temperature tolerance limits for canines, which is also affected by weather conditions and individual factors, is lacking. Both tethering and housing of dogs in pens restrict the space and amount of stimulation. How well dogs cope under such conditions depends on various factors, such as type of housing, management routines, experience of the owner/handler and the individual dogs. However, scientific documentation comparing the effects of tethering versus pen-housing, is to our knowledge not available.

With regards to breeds participating in long-distance sled dog racing, scientific data on lower ambient temperature limits, including weather conditions, is lacking. There are no fail-safe indicators that can be used to identify sled dogs at risk of being subjected to strain-related injuries, insufficient rest or suffering from subclinical diseases, such as musculoskeletal or gastrointestinal disorders, during or before a race. Our knowledge on the underlying causes of many health-problems seen in sled dog races, to date, is based on relatively few scientific publications (VKM, 2017b).

Outlining of research and surveillance needs

- More studies on prevalence of diseases and disorder during and after sled dog races (including dogs that are retired during a race) would reduce the uncertainty in assessing health- and welfare status. Identifying dogs that are at risk of being subjected to unnecessary stress, strains and/or illness pre-race is important; thus, a better system with clear indicators would be useful.

1.3 Agriculture - environment

1.3.1 Antimicrobial resistance due to the use of biocides and potential toxic metals

There are insufficient data regarding antibiotics, biocides, and potential toxic metals (PTM's) that unintentionally end up in the environment, including soil, sediments, water, air, plants and animals in Norway.

There is lack of knowledge on the distribution of microorganisms with antimicrobial resistance in the environment as soil, sediments, water, plants, and wild animals.

There are insufficient data regarding the contribution of horizontal gene transfer of antimicrobial resistance between different microorganisms in the environment.

Although there are some studies regarding resistance of environmental bacteria to biocides and/or potential toxic metals and cross-resistance to antibiotics, there is a lack of information and knowledge about the clinical impact in humans and animals.

Analysis of antimicrobial resistance in environmental microbial samples is not standardized as it is for minimum inhibitory concentration (MIC) for clinical samples from humans and animals.

Outlining of research and surveillance needs

- Collect data on the amounts of PTM's (copper, zinc, cadmium, arsenic, and mercury) and biocides (phenols, triclosan and QACs) used in Norway, and an estimate of how much is released into different environments.
- Develop standard methods for testing the potential of PTM and biocides to induce antimicrobial resistance in microorganisms.

1.3.2 Potential toxic metals in fertilisers and soil and development of resistance in environmental bacteria

Due to the lack of such data, it is difficult to estimate the probability of development, transmission, and persistence of potentially toxic metal resistance in the Norwegian environment. More research is needed to explain the relationship between development of resistance against potential toxic metals and resistance toward antimicrobial agents in bacteria.

Outlining of research and surveillance needs

- Knowledge regarding bacteria with resistance to potential toxic metals in sewage.
- Knowledge regarding bacteria with resistance to potential toxic metals in agricultural areas where fertilisers have been used.

- Comprehensive longitudinal and quantitative data from studies that have examined the dissemination of AMR pathogens from livestock manure and sewage applications in the environment.
- Development of potential toxic metal resistance in environmental bacteria.
- Development of toxic metal resistance in "un-culturable" bacteria.
- Dissemination of potential toxic metal resistance genes via fertilisers.
- Links between the level and concentration of potentially toxic metals in fertilisers and soil, and development of resistance in environmental bacteria.

1.4 Wildlife

1.4.1 Health and welfare of semi-domesticated or free-ranging wild animals

Since the first reported case of chronic wasting disease (CWD) in reindeer in the Nordfjella region in 2016, extensive management strategies have been launched, aimed at containing spread of the pathogen, even eradicating it if possible. A risk assessment was conducted by VKM (2016c), with subsequent updates, requested by Norwegian authorities. Currently, data on prevalence in other reindeer populations as well as other cervids is lacking. No data on prevalence is available in Hardangervidda or other areas, following the reported case of CWD-positive reindeer in 2020. Information is still scarce with regards to transmission and disease following infection of the prion, the pathogen causing these symptoms (VKM, 2021a).

Monitoring individuals or populations of free-ranging wild animals provides important knowledge for conservation, research, and management purposes. This requires capture and/or marking of the individual animal, interfering with its normal behaviour and pose a risk to welfare. Very little data on welfare indicators of animals in the wild is available, as most studies tend to rely on mortality as the single measurable variable. In most cases, negative consequences of marking are not reported (VKM, 2013).

Outlining of research and surveillance needs

- To fill the knowledge gaps with regards to CWD, more basic research on infection, incubation period and disease progression is needed. Such studies would include, example, complete mapping of the *PRNP* gene variations in cervid populations, detailed characterizations of CWD-positive cases, susceptibility of other species, long-term persistence of infectivity of prions in the environment, just to name a few.
- Studies monitoring individual animals over time are needed, to determine how marking methods affects long-term survival and natural behaviour. More data on how marking methods affects normal behaviour and reproductive parameters to better assess the overall welfare.

2 Aquatic food production

2.1 Fish health and welfare

2.1.1 Diseases in farmed fish and cleaner fish in aquaculture

Aquaculture diseases are listed internationally and nationally to establish standards in the control of disease outbreaks. Listing is important as it enables competent authorities to quickly implement interventions. The process of adding new and emerging infectious diseases of aquatic animals to a national list by the Norwegian Food Safety Authority is important in ensuring animal health. According to VKM, there are 3 key factors to consider when assessing whether a disease should be listed: A) The infectious nature of the disease, including efficiency of transmission, B) Consequences of the disease for animal populations and C) possibilities for disease control. However, scientific literature or guidelines directly related to assessment of criteria for listing diseases is extremely limited. Data related to environmental stability of pathogens is also lacking (VKM, 2015).

With regards to cleaner fish in aquaculture, there is limited knowledge on the introduction of pathogenic agents/diseases either from relocating aquaculture species domestically or through trade across land borders. More knowledge on known and potential vectors of spread is needed, along with methods for minimizing the risks of geographical spreading of pathogens. Being a relatively new species in aquaculture, knowledge on transmission of pathogens from cleaner fish to farmed salmonids is currently poor (VKM, 2017c). In particular, data on the disease status in wild-caught cleaner fish is scarce. Knowledge on pathogens relevant in salmonid farming, like for example lumpfish flavivirus, lumpfish ranavirus, *Piscirickettsia salmonis* and *Vibrio* spp., is limited or lacking. Unknown viral pathogens in the process of adapting to salmonid hosts are hard to detect at an early stage. Cleaner fish may act as mechanical vector of Salmonid alphavirus, however, methods for detection may not be sensitive enough. The biology of cleaner fish is less studied compared to salmonids, thus, there is a lack of cell lines for cultivating viruses.

Trade in sexual products, i.e., eggs, has been important for the progression of farming of salmonid fish. Transmission of certain pathogens through fertilized eggs is well documented. However, data on transmission of pathogens through cryopreserved milt is lacking (VKM, 2019a). Information on the presence of almost all listed and non-listed pathogens in milt is unavailable. Data on vertical transmission, i.e., whether milt infected with pathogens infect eggs at fertilization, is missing.

Outlining of research and surveillance needs

- In order to provide better assessment for diseases to be added to the national list, field observations to assess infectivity or contagiousness are valuable, especially before experimental trials are able to provide conclusive results.

- Since knowledge on diseases and infections in wild-caught cleaner fish generally is poor, quarantine stocking of wild-caught fish and screening for pathogens prior to mixing with salmon is an effective biosecurity measure. Access to cell lines for cultivation of viruses and development of more reliable methods for screening and detection of viral infections will provide better diagnostic tools and new insights on disease development. In particular, more research on the transmission and adaptation of pathogens specific for cleaner fish to salmonids (including the potential consequences) is needed. Overall, more studies on cleaner fish biology and physiology are needed.
- More studies on the presence of infectious pathogens in milt in general is needed. Certain pathogens, such as *Renibacterium salmoninarum* (which causes Bacterial Kidney Disease) and Infectious pancreatic necrosis virus, can be transmitted either vertically or horizontally, i.e., between individual animals. Surveillance ensuring that the broodfish is free of the agents will therefore be a significant risk-reducing measure.

3 Human health – food and food groups, pathogens, nutrients, and contaminants

3.1 Pathogens in foods

3.1.1 Presence and concentration of foodborne pathogens in food and drinking water

Foodborne pathogens naturally transmitted between animals and humans that cause diseases and infections are named zoonoses. Our main sources of knowledge on the presence and concentration of zoonoses in food production and processing are national annual Zoonosis Reports and surveillance programs (by the Norwegian Veterinary Institute). However, not all zoonoses of interest are included.

The presence and concentration of pathogens in food processing, food products and drinking water is an important basis for setting priorities in measures taken by authorities. It is also linked to the burden of food-borne disease in the human population, which is determined by how many people are sick, duration of the illness itself, the number of lost working days, number of visits to the doctor and hospital days, sequelae, mortality, costs related to diagnosis, treatment, and possible needs for local, regional, or national screening and environmental surveys. Since the presence and concentration of pathogens in food and drinking water may vary significantly between different areas, international data may not be of relevance for Norwegian conditions.

Outlining of research and surveillance needs

- Data on trends in the presence and concentration of pathogens in animal populations, food and drinking water are needed.
- Data on presence and concentration of Toxoplasma, Cryptosporidium, Giardia and Listeria monocytogenes is needed.
- Data on trends in the presence and concentration of zoonotic pathogens in food is needed.

3.1.2 Incidence of food borne diseases

The main source of knowledge on incidence of food-borne infections, caused by domestically produced food as well as imported foodstuffs, is the Norwegian Surveillance System for Communicable Diseases (MSIS) at the Norwegian Institute of Public Health. However, the degree of under-reporting varies considerably with the severity of a particular disease. It may therefore be difficult to determine the incidence and prevalence of a disease based on the MSIS data.

Outlining of research and surveillance needs

- Knowledge on the incidence and prevalence of a disease in a population is needed.
- Time-limited projects in which a representative population group is followed, current symptoms/diseases are registered, and patients are examined with more thorough methods than available in routine diagnostics, is needed.
- Data on the burden of foodborne diseases need updating for Norwegian conditions.

3.2 Nutrients in foods

3.2.1 Analytical data for nutrients

Food Composition Databases represent fundamental information resources for nutrition science, and are also used by the food industry, food policy and legislation, and consumers. There is continuous ongoing international collaboration to systematically quantify and tabulate the nutrients present in food, mostly macronutrients and micronutrients necessary to maintain a healthy diet or compounds associated with adverse effects on health.

New and modified food products are introduced to the Norwegian food market. Changes in food production and food fortification may cause changes in the nutrient content in food products. Nutrient content in all foods constitutes essential background data in several assessments of nutrient intakes in relation to average requirements and tolerable upper intake levels.

A periodical update of nutrient content in raw and processed foods is needed to estimate intake of nutrients, and to conduct benefit and risk assessments of nutrients or foods/food groups. Foods available only on the Norwegian market is of special importance when values are not similar to products in other countries. The concentration of nutrients in both raw and processed foods must be analysed due to changes during processing.

Analyses of the concentrations of iodine in dried macroalgae (seaweed) and supplements made from algae is needed (VKM, 2020b).

Norwegian food composition data for certain nutrients, e.g., vitamin K, is lacking.

A Norwegian Total Diet study (TDS, see 5.1.3) would give a better data basis for assessing the intake of nutrients in food.

Outlining of research and surveillance needs

- There is a need for analyses of concentration of nutrients in both raw and processed foods, including fortified foods and vitamin and mineral supplements on the Norwegian market.

3.2.1.1 Analytical data for nutrients in fish and fish products

Fish is the major source of EPA (eicosapentaenoic acid), DPA (docosapentaenoic acid) and DHA (docosahexaenoic acid) in the Norwegian diet. Fish is also an important source for vitamin D, iodine, selenium, and vitamin B_{12} (VKM, 2022d). In recent years, there has been a change in raw materials used in fish feeds for farmed Atlantic salmon and rainbow trout. Terrestrial plant proteins and vegetable oils now account for a major part of the feed. The changes are reflected in nutrient concentrations and compositions of farmed fish. Updated data on the content of EPA, DPA, and DHA in fish and fish products is needed.

To estimate nutrient intakes and conduct benefit and risk assessments, a regular update of nutrient concentrations in fish, fish products and other seafood is needed. New and modified food products are introduced to the Norwegian food market and there is a need for nutrient analysis in these products.

Outlining of research and surveillance needs

- The concentration of nutrients in both raw and prepared fish and fish products must be analysed.
- For farmed fish, there is a need for knowledge about how new changes in the feed affects the content of nutrients in the farmed fish fillet.
- For wild-caught fish, data on the content of various nutrients in various fish species is needed. Regular sampling of the same species from the same area over a long period will enable evaluations of trends over time.

3.3 Contaminants in foods

3.3.1 Analytical data for contaminants

The Norwegian Food Composition Database does not contain information on contaminants and other toxic substances.

There is generally a lack of concentration data available for contaminants/chemicals in different types of products, i.e., foods, drinking water, personal care products etc.

Analyses of the concentrations of arsenic, cadmium, and mercury in dried macroalgae (seaweed) and supplements made from algae is needed.

Lack of available database with concentration data, few data analyses, and scarce information on intakes of less frequently consumed foods with high levels of contaminants (see dietary surveys in Chapter 5.1) often makes it very challenging to calculate reliable exposure estimates.

In 2022, VKM published the report Food and chemical substances relevant for monitoring. The aim of this report was to establish a knowledge base useful as a tool to identify food

groups and food items consumed by the Norwegian population that are relevant for monitoring regarding content of one or more undesirable chemical substances (VKM, 2022e).

Outlining of research and surveillance needs

- A national database over contaminants in food including e.g., dioxins, dioxin-like PCBs, PFASs, brominated flame retardants, heavy metals, and mycotoxins is needed.
- There is a need for analyses of concentration of contaminants in foods on the Norwegian market (see VKM, 2022e for details).

3.4 Health effects of foods/food groups or substances in foods

3.4.1 Epidemiological studies – design and quality

There is evidence from prospective, observational epidemiological studies concerning the relationship between intake of food/food groups or substances in foods and the prevention or development of major chronic diseases such as cancer and cardiovascular disease, while the evidence is more limited for many other disease outcomes. To provide useful data, prospective cohort studies should preferably be performed in large samples with repeated measurements of dietary intake and a long follow-up, with reliable and valid detailed measurements of exposure and objective outcome measurements. Observational studies typically provide knowledge about habitual food and nutrient intakes associated with increased or reduced disease risk, but they rarely provide useful information on health effects of excessive intakes.

Randomised controlled trials (RCTs) are considered the best design for evaluating health effects of interventions. A valid RCT design requires a sufficient sample size to ensure even distribution of confounders, a high compliance throughout the duration of the study and a low and non-differential dropout. Disease-preventive or risk-increasing effects (and unintentional side effects, including adverse events) of supplementation with various doses of single nutrients may be successfully studied in RCTs. RCTs should be of long duration since chronic effects (e.g., development of cancer) may become evident only after several years.

Lack of well-designed studies and adequate systematic reviews on negative health effects is often a major limiting factor in several of VKM's reports, leading to increased uncertainty in the conclusions.

For contaminants there may be little evidence from human studies. The critical endpoints for setting the tolerable weekly intakes (TWI) may be intermediary (e.g., change in a biomarker, or change in sperm concentration in the case of dioxins and dl-PCBs) rather than a clinical outcome (e.g., infertility). For conducting benefit- and risk assessment of foods, more human studies investigating foods and clinical outcomes related to critical endpoints for several contaminants are needed. The critical endpoints for establishing TWI for dioxins and dl-PCBs

and PFASs are sperm quality and vaccine response in children, respectively. As fish highly contributes to intakes of dioxins and dl-PCBs and PFASs we need human studies investigating if fish consumption affects male fertility and vaccine response in children.

Outlining of research and surveillance needs

- Long-term RCTs on diets are unfeasible. Concerning knowledge gaps, our recommendation is to ensure that detailed data on food and nutrient intake is collected in future large long-term well-defined cohort studies covering wide exposure ranges. The data reporting should be detailed enough to allow dose-response meta-analyses which are necessary for characterization of benefits and risks associated with food intake.
- More epidemiologic studies on the role of nutrition and diet in the etiology of diseases and health outcomes should apply available statistical methods and formal methods for causal inference to handle or assess the potential impact of problems such as selection bias due to e.g., low response rates and missing data, measurement errors in exposures and outcomes, and different types of confounding. Most evidence from observational studies is still based on complete case analysis.
- More review studies or assessment of current epidemiologic evidence should apply a systematic review approach according to established guidelines rather than a traditional, narrative review approach, to reduce bias in conclusions.
- Quantitative synthesis of epidemiologic evidence on diet and nutrition in the etiology of some health outcomes, neurodevelopment in children in particular, is currently very difficult due to high diversity across studies in the instruments used to assess the outcome and how results are reported. Greater consensus and common standards are needed, as well as awareness of or statistical correction for multiple testing when interpreting results.
- Compounds in foods (nutrients and environmental contaminants) are often studied separately but may co-occur in the same foods or diets. More studies should investigate to what extent nutrients could confound (due to co-occurrence) or modify (due to biological interaction) the effects of environmental contaminants (or vice versa) in etiologic studies. The biological effect of eating the whole food, could in some cases differ from the separate effects of nutrients and contaminants for which the food is an important source.
- Although the critical endpoint for setting a tolerable weekly intake for dioxins and dl-PCBs is reduced sperm concentration, it remains unknown if fertility is affected and if the same effects are seen for fish intake as for the contaminants because epidemiological studies are lacking for fish intake and fertility (VKM, 2022d).
- Human studies investigating foods and clinical health outcomes related to intermediary critical endpoints for setting tolerable weekly intakes for several contaminants are needed (e.g., male infertility is the clinical health outcome related to reduced sperm concentration). Focus should be on foods that are significant sources in the diet to the various contaminants.

- There is a lack of epidemiological studies with data on both nutrients and environmental contaminants that apply formal mediation analysis to examine to what degree health effects of foods are mediated through specific contaminants and/or nutrients.

3.4.2 Average requirements and tolerable upper intake levels for vitamins and minerals

The tolerable upper intake level (UL) is the maximum level of total chronic daily intake of a nutrient judged to be unlikely to pose a risk of adverse health effects to humans. For several nutrients, an UL is not established, or has not been updated for several years. However, updates are currently ongoing for some vitamins and minerals in European Food Safety Authority (EFSA).

In benefits and risk assessments VKM has used average requirement (AR) as comparison value with estimated intakes. For several nutrients an AR has not been established in all age groups. Suboptimal (i.e., poor status without overt clinical symptoms) status is common for many nutrients.

Ideally, to provide data to inform ARs or ULs for nutrients, preferably human studies with graded oral supplement doses should be performed. There is a lack of good quality dose/response studies to establish average requirements and tolerable upper intake levels in all age groups for several vitamins and minerals.

Outlining of research and surveillance needs

- The extent to which such suboptimal status poses a health risk needs to be addressed in well-designed human studies. Observational studies should capture relevant confounding variables and ensure that all relevant variables are captured with minimal misclassification. When intervention studies are possible, these studies should ensure that the baseline nutrient status is well described, and that the population of interest is being studied (i.e., populations with suboptimal status). Studies in children are often absent.
- Good quality human and animal studies on high intakes of vitamins and minerals are vital for benefit and risk assessments of nutrients. For several vitamins and minerals, there is a lack of long-term well-designed studies with a high number of participants that specifically examine possible adverse health effects. Studies in children are often absent.

3.4.3 Hazard data on active substances in plant protection products

There is a frequent absence of toxicological data on certain endpoints, even on well-regulated substances such as plant protection products. Especially with respect to endpoints like endocrine disruption, metabolic effects, immunotoxicology and neurodevelopment.

Outlining of research and surveillance needs

- Identifying legacy compounds that are widespread in the environment and where human exposure is likely. Use existing hazard and risk assessments to identify existing knowledge gaps. Establish a group(s) of experts to design studies needed to close the identified knowledge gaps.
- To obtain additional knowledge, studies compliant with OECD guidelines may be supplemented with (academic) research of other endpoints, mechanisms etc. by sharing tissues, cells, and data from large animal studies with those performing smaller, more specific, studies.

3.4.4 ADME/toxicokinetic data on chemicals

Absorption, distribution, metabolism, and excretion data (ADME) are important to demonstrate that internal exposure of chemicals is achieved in standard toxicology studies. The maximum concentrations in blood and organs, the half-life in blood and organs and the total area under the curve (standardised toxicological parameter) might explain toxicological findings and might help in extrapolating among species.

Outlining of research and surveillance needs

- Identify chemicals related to food where no ADME/toxicokinetic data are available. Use existing assessments and reports to identify the chemicals. Design experiments to close this knowledge gap. Feed the data back into the hazard and risk assessment processes.

3.4.5 Studies on mechanisms of beneficial or harmful effects

To evaluate the evidence for beneficial or harmful effects of foods or substances in foods, studies of biological plausibility are needed. Mechanistic studies are lacking in some areas.

Outlining of research and surveillance needs

- Mechanistic studies are needed in the absence of adequate human data.

3.4.6 Adverse health effects from substances in food supplements

Human studies and toxicological data from substances used in food supplements, e.g., amino acids, isoflavones, L-citrulline, D-ribose, collagen from fish skin, curcumin, lycopene, piperine, and inulin, is needed for children, adolescents, adults, pregnant and lactating women.

Outlining of research and surveillance needs

- Well-designed human and animal studies on negative and beneficial effects of food supplements are needed.

4 Biodiversity

4.1 Empirical data on populations of native and alien species

In most risk assessments on biodiversity, VKM need basic knowledge about population size and area of distribution for focal species. This knowledge underlies assessment of cause-effect relationships, magnitudes of impacts, and trends in biodiversity and environmental impacts. However, major research gaps relate to the lack of data on population size and area of distribution for a large number of native and alien species. The assessors also need to know whether the population is fragmented and occurs at few locations, and whether the population fluctuates in size, area of distribution and number of sub-populations. Species in this context includes invasive species, endangered species in international trade, as well as parasitic and pathogenic species affecting risk-assessed species and biodiversity.

Examples: There is a lack of information on the population size of alien species already established in Norway, such as wild boar (VKM, 2018), *Batrachochytrium salamandrivorans* (Bsal), *Batrachochytrium dendrobatidis* (Bd) (VKM, 2019b) and pink salmon (VKM, 2020c). There is also a lack of information on their climatic tolerance and, most importantly, the ecological impact these organisms have on ecosystems in Norway. Knowledge on impact is critical when VKM assess the risk that they impose to native biodiversity.

Repeated assessments of numerous intentionally imported species of terrestrial arachnids and insects (VKM, 2016e), freshwater plants (VKM, 2016f), terrestrial gastropods (VKM, 2017d), freshwater crustaceans (VKM, 2021b) and foreign cattle (VKM, 2021c) have unveiled a recurring gap of knowledge regarding the climatic tolerance and suitability of these species in Norway, as well as possible impact on biodiversity of these organisms in Norwegian habitats.

Similarly, for alien species that are not intentionally imported, like Asian giant hornets (VKM, 2022f) or hitchhiking organisms related to land-locked salmon in Sweden (VKM, 2021d), VKM repeatedly see a lack of knowledge related to their pathways of entry, means of spread and potential establishment, in addition to the impact on native biodiversity.

VKM have also uncovered a recurring knowledge gap relating to potential adverse effects of relocating non-alien species within Norway, like cleaner fish (VKM, 2019c) and vascular plants (VKM, 2021e), especially regarding the effects of genetic mixing of distant populations.

In addition, a lack of knowledge about the occurrence, spread and survival of parasites and diseases that infect the invasive species, e.g., pink salmon (VKM, 2020c), cleaner fish (VKM, 2019c) and wild boar (VKM, 2018), adds to the uncertainty of risk caused by pathogens. Lack of knowledge about the distribution of the pathogenic fungi *Batrachochytrium salamandrivorans* (Bsal) and *Batrachochytrium dendrobatidis* (Bd), and amphibians in

Norway, including connectivity among populations, represents major obstacles to assess the risk of chytridiomycosis (VKM, 2019b).

Assessments on whether trade will be detrimental to the survival of endangered species listed in CITES are often associated with high uncertainty because there is a lack of information about population size and area of distribution (VKM, 2019d; VKM, 2019e).

Outlining of research and surveillance needs

- To fill the knowledge gap, basic biogeographical data and studies are needed. That is, to survey the spatial variation in the numbers and types of organisms across geographical areas, as well as to take sub-samples of the population to screen for pathogens. Such studies are often straightforward to perform, however, studies or monitoring on biogeography are time consuming and require expert taxonomists which both present obstacles to this work.
- Such research is needed in general and for many species. However, priority should be given to species that are in danger of becoming extinct and species that potentially may pose a threat to biodiversity in Norway, for example pink salmon, wild boar, wrasse, lumpfish, Bsal, Bd, amphibians and minke whale.

4.2 Knowledge about ecological preferences

In order to assess potential impacts caused by an alien organism on biodiversity in Norway, we need information on the environmental conditions and resources that define the requirements of the species. Especially, we need information about the range of environmental conditions necessary for persistence of the species, potential influence on other species, food preference, breeding periods, ability to spread and reproduction rates. Such information is often scarce or lacking.

For example, we lack information on the niche of wrasse and lumpfish in source and recipient populations, such as prey composition, competition with other species and spawning periods (VKM, 2019c). When it comes to pink salmon, we lack information on interactions with native salmonids, feeding behaviour, growth rates and survival rates (VKM, 2020c). Basic ecology of Bd and Bsal in Norwegian species is not known. Factors that prevent spread may be a result of host immunity, environmental factors, or both (VKM, 2019b). When it comes to assessing whether trade will be detrimental for an endangered species listed in CITES, we need knowledge about environmental preferences, vulnerability to extreme events, breeding grounds and migratory patterns. However, such information is often lacking (VKM, 2019d; VKM, 2019e).

Outlining of research and surveillance needs

- Research is needed that seeks to explain the distribution and abundance of species by studying organisms and their environments. Such research is needed for many species. However, priority should be given to species that are in danger of becoming extinct and

species that potentially may pose a threat to biodiversity in Norway, for example pink salmon, wrasse, lumpfish, Bsal, Bd, amphibians and minke whale.

4.3 Microbial-based products

Fundamental knowledge on the species and strains used in microbial-based cleaning products (MBCPs), including their potential synergistic and antagonistic effects when used in mixtures, as well as their persistence and stability in MBCPs upon storage and release, is lacking. This is a prerequisite for conducting environmental and health risk assessments of such products.

Short- and long-term impact on local microbial ecosystems based on relevant release scenarios, is unknown.

In vitro as well as animal studies prior to testing for general usage of MBCPs in various settings, is needed. In addition, data from long-term quantitative studies are needed, particularly in household and industrial settings addressing specific exposure scenarios (inhalation, ingestion, dermal).

Outlining of research and surveillance needs

- Molecular typing and biochemical characterization of the species and strains used in MBCPs will enable the proper identification and characterization of the potential hazard. Laboratory-scale studies of MBCPs, including possible antagonistic and agonistic effects of the microorganisms when used in mixtures, including the biochemical basis for cleaning effects, particularly when it comes to potential biocidal effects. Data collection and surveillance of the fate and survival (long- and short-term) of the microorganisms in their final formulations and storage conditions as well as in relevant release scenarios (e.g., when mixed with sewage).

4.4 CITES

4.4.1 The precautionary principle in CITES

In the role as CITES' Scientific Authority, VKM is responsible for preparing scientific assessments needed to effectively carry out the convention in Norway.

Resolution Conf. 9.24 (Criteria for Amendment of Appendices I and II) of the convention on international trade in endangered species of wild fauna and flora (CITES) states that the precautionary principle should be invoked. Annex 4 concerns proposals to amend Appendix I or Appendix II. As such, the annex includes several precautionary measures that do not directly relate to non-detrimental findings. However, paragraph A of Annex 4 can be applied by Scientific Authorities that do not have adequate information when trying to make a non-detrimental finding. According to paragraph A, "When considering proposals to amend the

Appendices, the Parties shall, in the case of uncertainty, either as regards the status of a species or as regards the impact of trade on the conservation of a species, act in the best interest of the conservation of the species."

There is a lack of guidelines and consensus on how to apply the precautionary principle. The implication is that the Scientific Authorities, such as VKM, are left to interpret when the precautionary measures should be invoked and to what degree such measures should be invoked.

Outlining of research and surveillance needs

- An agreement among scientific authorities that work with CITES is needed to ensure common practices across nations. Research could focus on constructing a risk-impact matrix for different precautionary parameters that could be used to guide non-detrimental findings.

5 Surveillance of food consumption and substances in food/ food chain

5.1 Monitoring of food intake – dietary surveys

Changes in eating habits/diets, food production methods and the continual development of new food products, including fortified foods, call for regular national dietary surveys to ensure food safety.

Dietary surveys and food databases including nutrients, non-nutrients, contaminants, and additives are vital elements to enable risk assessments and benefit/risk assessments. This knowledge is critical for exposure estimation and to relate food intake to health effects. Biomarker data, biobanks and health registries linked to dietary surveys may provide better knowledge about the relationship between food, the diet and health.

5.1.1 National dietary surveys

A program for continuous national dietary surveys is lacking. National dietary surveys provide information on dietary habits (food sources and amounts).

The national dietary surveys cover different population and age groups. «Sped- og småbarnskost» is based on a food frequency questionnaire and covers the ages 6 months, 1- and 2-year-olds. «Ungkost» is a web-based 4-day food diary and covers the ages 4-, 9- and 13- year-olds. «Norkost» covers the adult population from 18-70 years and the dietary assessment method used is two times 24-hour recalls. All the three methods aim to cover the usual food and drink intake at an individual level, both at mean level and for the lower and the higher end intakes like the 5th and 95th-percentiles. Conducting regular dietary surveys which give comparable results from survey to survey enable us to follow trends in dietary habits. All Norwegian food dietary surveys should be performed with a methodology that allow for submission of the data to the EU food consumption database. Currently, this is not the case for "Sped- og småbarnskost".

Outlining of research and surveillance needs

- A continuous rolling programme for national dietary surveys for all age groups is needed (every 8-10 years).
- The surveys should be designed to capture variations in intake of foods/food groups, and substances and include high consumers.
- Enough participants must be recruited, to allow for exposure calculations of the outer limits of the intake (5th and 95th percentiles).

5.1.2 Other dietary surveys

It is necessary to develop and implement valid and appropriate supplementary dietary survey methods to ensure knowledge about consumption of foods and food groups with particularly high concentrations and highly exposed population groups, and consumption of vitamin and mineral supplements and fortified foods (e.g., VKM, 2021f; VKM, 2020b).

Outlining of research and surveillance needs

- Data on consumption of foods that can contribute substantially to contaminant exposure due to high presence and concentration of specific contaminants (e.g., certain fish species, crab meat, offal, seagull eggs, fish liver, macroalgae (seaweed), wild mushrooms, game, grilled foods etc.) are needed.
- Data on population groups that follow special diets (e.g., vegetarian and vegan) and ethnic food patterns are needed.
- Data on other population groups such as pregnant women and the elderly (>70 years) are also needed.
- Data on food packaging materials, product name/brand, production method and country of origin are needed.
- Data on consumption of vitamin and mineral supplements and other food supplements are needed.
- Data on consumption of fortified foods are needed.

5.1.3 Total diet study

A total diet study (TDS) denotes an internationally recognised method to establish the average concentration of different substances in prepared food. In the TDS, samples of food at retail outlets throughout Norway is collected, prepared and the «ready to eat» food is analysed. Updated food lists from the national dietary surveys in different population groups are used to collect and analyse the food that consumers eat.

Outlining of research and surveillance needs

- TDS, including analyses on levels of nutrients, contaminants, toxins, selected pesticide residues, radionuclides, and non-nutrient elements, is needed.
- To investigate time trends (change over time), a continuous data collection program with yearly or cyclic data collections is required.

5.2 Monitoring of substances in foods - pathogens, nutrients, contaminants, and other factors

5.2.1 Concentrations of nutrients and contaminants in foods

See Chapters 3.2 and 3.3.

5.2.2 Mapping and monitoring of potentially toxic elements (PTE), including cadmium, in Norwegian agricultural soil, groundwater, and surface waters

Arsenic, cadmium, chromium, copper, lead, mercury, nickel, and zinc are found in the soil and as pollution in fertilizer products. The technical term for this is "potentially toxic elements" (PTE's).

High agricultural crop productivity depends on optimal presence of macro- and micronutrients for crops as well as for the soil organisms including mycorrhizal fungi and microorganisms. When nutrients are present in optimal amount, geochemical resources can cause excess of potentially toxic elements (PTE) within the biomass (too high uptake) or cause to deficiency of essential elements for food production.

Through the EU water frame directive Norway is obligated to address pollution from urban wastewater and agriculture.

Background (natural present) concentrations of PTE and other chemicals are needed for predicting the effect of further addition to agricultural soil. Measured PTE in groundwater, including private drinking water wells and surface water in selected areas/regions, should be included.

Data on heavy metals such as cadmium (Cd) and other PTE in soil and groundwater/surface water are available through databases such as vannmiljo.no, however, these data are obtained from different labs, with different sampling equipment and procedures. Harmonized data on a national scale are needed to be able to compare different regions/areas. A mapping campaign would provide background information at a national scale needed by several important parties in Norwegian society and industry, not only the farmers. Knowledge provided will enable decision makers at local, regional, and national levels to preserve agricultural soil, facilitate and develop fertilisation schemes and promote biomass.

Outlining of research and surveillance needs

- Four harmonised datasets at the Norwegian scale are needed: 1) geochemical data on soil, analysis of PTEs, 2) data on 'classical' soil properties, 3) chemical data on water and 4) new data on distribution of soil organisms and their spatial variability via DNA bar-coding. This combination of data, which opens for establishment of new links and connections, has not before been analysed in Norway.
- The whole of Norway should be included to gain information on the entire range of soil properties and processes that are due to variable geology, agricultural practice, and climatic factors, in addition to all chemical elements. Three regions with extensive agricultural activities can be selected for more detailed case studies, e.g., Østlandet, Jæren, and Trøndelag.
- Soil samples should be stored at a national archive as reference samples for monitoring campaigns performed in the future in different areas of Norway.

6 Methods and models

6.1.1 Benefit and risk assessment methodology

There are several methodology papers from the BRAFO project (Benefit-Risk Analysis for Foods) in EU describing the various steps in a benefit and risk assessment, including suggestions for how to quantify and weight benefits versus risks. There are, however, still problems to be solved.

The evidence for conclusions on beneficial effects from foods or substances in foods often differs from the evidence for adverse or harmful effects and can be difficult to compare. This can be due to inherent differences between disciplines (e.g., nutrition, toxicology, microbiology) in the methods used and the nature of the compounds being studied. For compounds with potential adverse effects, there may be little evidence from human studies, or the critical endpoints evaluated may be intermediary outcomes (e.g., change in a biomarker, or change in sperm concentration in the case of dioxins and dl-PCBs) rather than a clinical outcome (e.g., infertility), and results may to a larger extent be based on modelling than for compounds with beneficial effects. Also, a precautionary principle may be applied to compounds with potential adverse effects, but not beneficial effects. Thus, there is a need for guidance documents on how to compare and weigh scientific evidence on benefits and risks when arising from different disciplines or methods, and when different principles may apply.

In some cases, a food-based approach (e.g., a study of fish intake) may provide a better answer to the net health effect of foods than studies on individual compounds for which the food is an important source (e.g., specific nutrients and contaminants in fish). The latter do not capture yet unknown effects of mixtures and potential biological interactions between compounds. However, there might be knowledge gaps in research investigating whether the critical endpoints for setting tolerable weekly intakes for various contaminants (e.g., sperm quality for dioxins and dl-PCBs) are consistent with studies on food intake as a cause of clinical outcomes (e.g., does fish intake, a source of dioxins and dl-PCBs, affect sperm quality and to an extent leading to male infertility) (see also Chapter 3.4.1).

Outlining of research and surveillance needs

- Improved models for benefit and risk assessment in general, and quantitative benefit and risk assessment.

6.1.2 Statistical methods for handling non-consumers of foods in exposure assessment

EFSA recommends that national food consumption data is collected on two non-consecutive days using a 24-hour food diary (infants and children), or 24-hour recall (adults) in

combination with a food-propensity score for less frequently eaten foods and dietary supplements. However, short-term measures can provide some challenges to the modeling of habitual intake of episodically consumed foods when there are few registration days. Challenges include separating true "never consumers" from episodic consumers with zero intake on all registration days, and skewed intake distributions. Statistical research indicates potential problems with model fitting when "never consumers" need to be taken into account using only two days of available intake data.

Outlining of research and surveillance needs

- There is a need for improvement of statistical methods to model habitual intakes for episodically consumed food.

6.1.3 Improved models and input data for predicting fate and transfer of chemicals in soil, to recipients and target organisms

There are many models and methods used to predict fate of chemicals, including PTE's, in soil and transfer and uptake in crops. The outcome may vary significantly depending on the choice of model/method used. Thus, an improvement of models/methods is still needed. Experimental data are needed for adjustment and verification of models to make them produce more precise exposure estimates for humans, farm animals and other terrestrial and aquatic organisms. More knowledge about the sensitivity to the different parameters is also needed.

Outlining of research and surveillance needs

- Comparison and evaluation of selected methods and models: their strength and weaknesses.
- Performance of controlled lysimeter studies investigating both leaching and runoff processes under different environmental and climate conditions.
- Performance of uptake and translocation studies with a wide range of chemicals and types of forage and food plants.
- Performance of a probabilistic risk assessment, which does not use one fixed input data but reflects the real range of such data to predict a likely range of outcomes.

6.1.4 Methodology for calculating the effective dose of radioactive exposure

To convert an ingested dose of a radioactive element into effective doses, a dose coefficient for the specific radioactive element is used. The dose coefficients developed by the International Commission on Radiological Protection (ICRP) and used by VKM are based on physiological and dosimetric modelling and lean towards conservative assumptions. Especially for small children/infants, there is limited data available for validation of models

for several radioactive elements and the coefficients are very conservative to ensure that doses are not underestimated.

Outlining of research and surveillance needs

More data on absorption, distribution, metabolism, and excretion of the different radioactive elements at different ages and developmental stages would enable ICRP to reduce the need for conservative estimates.

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