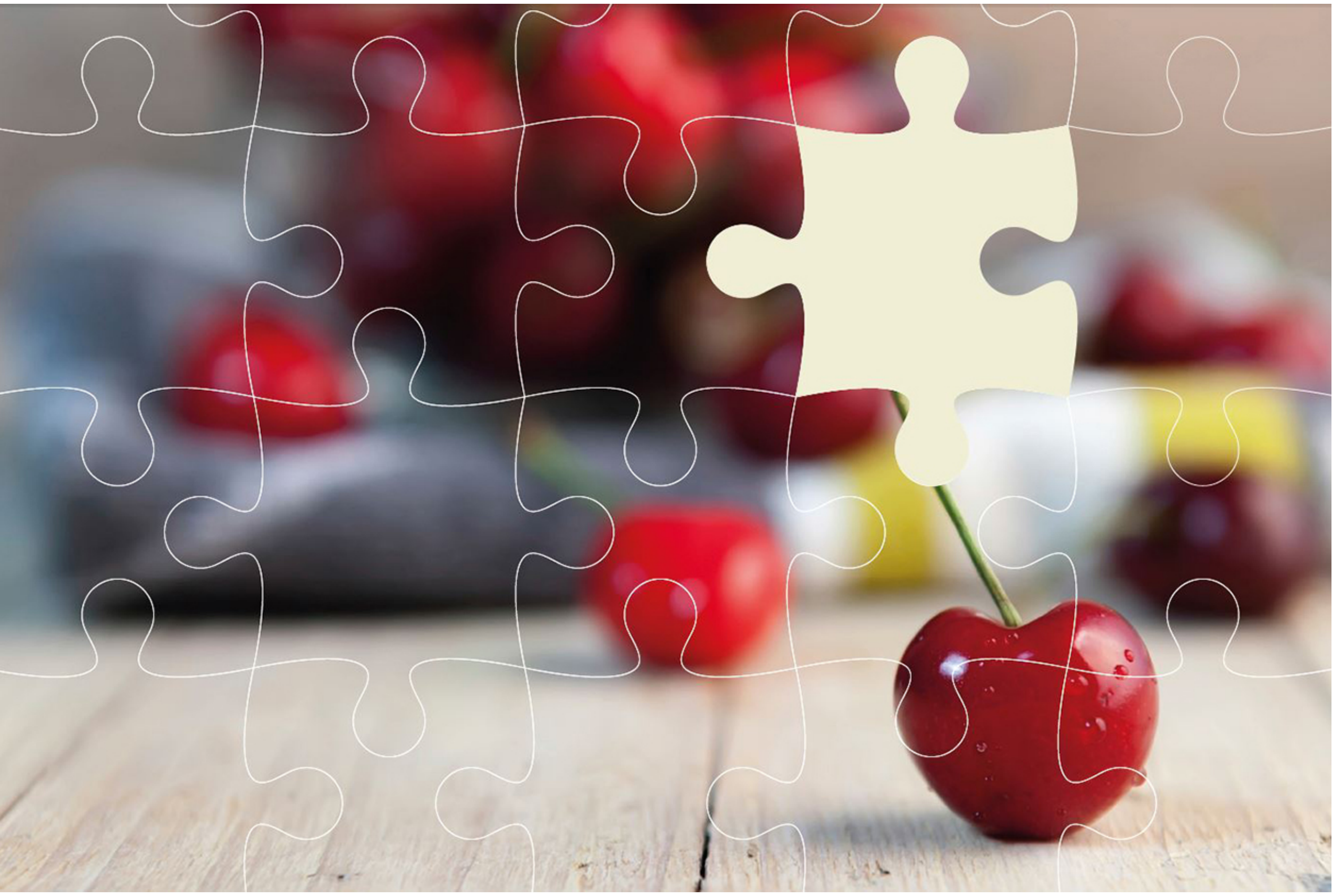

VKM Report 2018: 10

Research needs of importance for food safety and environmental protection as based on data gaps identified by VKM

Opinion of the Scientific Steering Committee of the Norwegian Scientific Committee for Food and Environment

Report from the Norwegian Scientific Committee for Food and Environment (VKM) 2018: 10
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Research needs of importance for food safety and environmental protection as based on data gaps identified by VKM

Preparation of the opinion

The Norwegian Scientific Committee for Food and Environment (Vitenskapskomiteen for mat og miljø, VKM) appointed a project group to draft this opinion. The project group consisted of VKM staff; Nana Asare, Dean Basic, Danica Grahek-Ogden and Micael Wendell. The Scientific Steering Committee evaluated and approved the final opinion drafted by the project group.

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VKM would like to thank all VKM Panel members as well as VKM staff that have contributed to this report. The draft report was prepared by VKM staff (members of the project group were Nana Asare (project leader), Dean Basic, Danica Grahek-Ogden and Mikael Wendell).

Competence 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 Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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Summary

The goal of this report is to highlight research needs and data gaps that are of future importance for food safety and protection of the environment and thereby improve the national knowledge-base. This report is the latest in a series of reports on research needs and data gaps published periodically by the Norwegian Scientific Committee for Food and Environment (VKM), former Norwegian Scientific Committee for Food Safety (VKM), and thus seeks to highlight research needs and data gaps identified in and related to VKMs scientific opinions for 2016 and 2017 only.

VKM conducts and communicates independent scientific opinions in the form of risk assessments as well as risk-benefit assessments in the areas of food safety and environmental protection.

Food safety is one of the prerequisites for good health, and 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 safe food.

Protecting the environment, that is, the biotic and abiotic surroundings of humans, animals and other species is vital for the benefit of both humans and the environment. Rapid changes in the environment at the different levels as well as complex interactions and various stressors requires continuous monitoring and surveillance measures to update existing data.

Research and surveillance data from other countries are not necessarily representative or relevant to Norway, since critical factors such as environmental conditions and dietary habits are distinctive. Knowledge on Norwegian conditions in particular, must therefore be generated nationally. It is necessary that we have active Norwegian research communities within the areas where we need this knowledge.

To ensure food safety and protection of our environment, VKM highlights that it is of importance that the following needs and data gaps are covered:

- The impact of climate change and globalisation on food safety and food production.
- The impact of climate change and globalisation on natural resources and biodiversity in Norway.
- The use of microbiological products, development and potential dissemination of antimicrobial resistance (AMR) in Norway.
- Radioactivity levels in Norwegian food and drinking water, national dietary surveys as well as epidemiological studies.

An overview of specific research needs and data gaps identified in VKMs reports for 2016 and 2017 are as follows:

<u>Agriculture, terrestrial food production and terrestrial animals</u>

- Driving factors in the development of AMR due to biocides and heavy metals
- The potential impact of microorganisms used in bioremediation and cleaning products
- Plant health regarding specific weeds and pests
- Animal health and welfare during poultry production
- Association between bumblebee mortality and lime (*Tilia*) trees
- Presence and concentration of pathogens in food and drinking water as well as analytical data for nutrients

<u>Fisheries, aquaculture, seafood production and aquatic animals</u>

- Animal health and welfare regarding introduction of novel pathogens in aquaculture through cleaner fish and marking of farmed fish
- Nutrients in fish and other seafoods

<u>Human health – diet, food and microbiological products</u>

- Norwegian occurrence/consumption data for inorganic arsenic
- Occurrence of foodborne pathogens and disease incidence/foodborne diseases
- Knowledge on the intake of food supplements
- Genetically modified (GM) food; herbicide residues in herbicide tolerant (HT) crops as well as safety assessments of genetically modified crops
- National dietary surveys as well as epidemiological studies on the association between diet and health
- The health effects of microorganisms used in bioremediation/cleaning products

<u>Biodiversity</u>

- Spread, climate tolerance, as well as ecological impact of alien organisms in Norway
- Association between bumblebee mortality and lime (*Tilia*) trees
- Genetically modified virus vaccines (GM-VV) in domestic animals
- Ecological impact of cultivating, import and processing of genetically modified crops in Norway

Surveillance data for food and diet

- Monitoring data on occurrence of radioactivity in Norwegian food and water
- Dietary surveys, nutrients, epidemiological as well as mechanistic studies on food and food groups

Key words: benefit and risk assessment, biodiversity, data gaps, environmental protection, food safety, knowledge gaps, Norwegian Environment Agency, Norwegian Food Safety Agency, Norwegian Scientific Committee for Food and Environment, VKM

Sammendrag på norsk

Målet med denne rapporten er å synliggjøre kunnskapsbehov som er viktige for å sikre trygg mat og beskyttelse av miljøet i årene som kommer, og forbedre den nasjonale kunnskapsbasen. Rapporten er den siste i en serie av rapporter om kunnskapsbehov publisert av Vitenskapskomiteen for mat og miljø (VKM, tidligere Vitenskapskomiteen for mattrygghet). Den løfter frem kunnskapsbehov som er identifisert i VKMs vitenskapelige uttalelser i perioden 2016 til 2017.

VKM utarbeider uavhengige, vitenskapelige uttalelser, blant annet risikovurderinger og nytte-risikovurderinger, innen områdene mattrygghet og beskyttelse av miljø.

Trygg mat er en av forutsetningene for god helse, og vies mye oppmerksomhet både nasjonalt og internasjonalt. Stadige endringer i hvordan mat produseres, hvilke matvarer som er tilgjengelige, hva befolkningen spiser og hvilke potensielle farer som følger med maten, gjør at vi har et kontinuerlig behov for ny kunnskap for å sikre at maten er trygg.

Det er viktig å beskytte miljøet, det vil si de biotiske og abiotiske omgivelsene til mennesker, dyr og ulike arter. Raske endringer av omgivelsene på ulike nivåer, komplekse samspill og ulike stressfaktorer gjør det nødvendig med kontinuerlig måling og overvåking for å oppdatere eksisterende data.

Forskning og overvåkingsdata fra andre land er ikke nødvendigvis representative eller relevante for Norge, og kunnskap om særnorske forhold må derfor genereres nasjonalt. Det forutsetter at vi har aktive norske forskningsmiljøer innenfor fagområder hvor vi trenger kunnskap om særnorske forhold.

For å sikre trygg mat og beskyttemiljøet, mener VKM det er særlig viktig at følgende dekkes:

- Kunnskap om hvordan klimaendringer og globalisering påvirker mattrygghet og matproduksjon i Norge
- Kunnskap om hvordan klimaendringer og globalisering påvirker naturressurser og biologisk mangfold i Norge
- Kunnskap om bruk av mikrobiologiske produkter, utvikling og mulig spredning av antimikrobiell resistens i Norge
- Kunnskap om nivå av radioaktivitet i norsk mat og drikkevann, nasjonale kostholdsundersøkelser og epidemiologiske studier

Oversikt over spesifikke kunnskapsbehov som er identifisert i VKMs rapporter fra 2016 og 2017:

Landbruk, landbasert matproduksjon, landdyr

- Kunnskap om hvilke faktorer som er drivere for utvikling av antimikrobiell resistens på grunn av biocider og tungmetaller
- Kunnskap om hvordan mikroorganismer brukt i bioremediering og rengjøringsprodukter påvirker helse og miljø
- Kunnskap om plantehelse knyttet til spesifikt ugras og planteskadegjørere
- Kunnskap om dyrehelse og dyrevelferd i fjørfjeproduksjon
- Kunnskap om sammenheng mellom humledød og lindetrær
- Kunnskap om tilstedeværelse og konsentrasjon av patogener i mat og drikkevann, samt analysedata for næringsstoffer

Fiskeri, havbruk, sjømatproduksjon og akvatiske dyr

- Kunnskap om dyrehelse og dyrevelferd ved introduksjon av nye patogener i akvakultur via rensefisk og merking av oppdrettsfisk
- Kunnskap om næringsstoffer i fisk og annen sjømat

Human helse – kosthold, mat og mikrobiologiske produkter

- Norske data om forekomst og inntak av uorganisk arsen
- Kunnskap om forekomst av matbårne patogener og matbårne sykdommer
- Kunnskap om inntak av kosttilskudd
- Genmodifisert mat: kunnskap om rester av ugressmidler i avlinger som er tolerante for ugressmidler, og risikovurderinger av genmodifiserte avlinger
- Nasjonale kostholdsundersøkelser og epidemiologiske studier om sammenheng mellom kosthold og helse
- Kunnskap om helseeffekter av å bruke mikroorganismer i bioremediering og rengjøringsprodukter

Biologisk mangfold

- Kunnskap om fremmede organismer i Norge - spredning, klimatoleranse og økologisk påvirkning
- Kunnskap om sammenheng mellom humledød og lindetrær

- Kunnskap om genmodifiserte virusvaksiner for husdyr
- Kunnskap om hvordan kultivering, import og prosessering av genmodifiserte avlinger påvirker økologi i Norge

Overvåking av mat og kosthold

- Overvåkning av forekomst av radioaktivitet i norsk mat og drikkevann
- Kostholdsundersøkelser, studier av næringsstoffer, epidemiologiske studier og mekanistiske studier om mat og matvaregrupper

Background

Periodically, the Norwegian Scientific Committee for Food and Environment (VKM) prepares a report with an overview of the knowledge requirements that are identified in VKMs risk assessments. This is in line with VKMs strategy for 2015-2018, with a strategic focus area, which includes but is not limited to highlighting research needs and knowledge gaps.

The goal of this initiative is to improve the national knowledge-base. The means to achieve this goal are as follows:

- VKM promotes that existing data is available in a format that can be used
- VKM promotes that Norwegian dietary surveys should be done on a regular basis
- VKM provides input on the lack of monitoring in the areas of food safety and environmental protection
- VKM actively provides knowledge needs relating to Norwegian conditions to the various authorities, directorates, departments and ministries as well as the Research Council.

1 Introduction

The Norwegian Scientific Committee for Food and Environment (VKM), former Norwegian Scientific Committee for Food Safety, conducts and communicates risk as well as risk-benefit assessments in the areas of food safety and environmental protection. The synergy and or interplay between the aforementioned areas is becoming increasingly clear as VKMs interdisciplinary assessments are on the rise, highlighting the importance of holistic approaches to safety, protective and preservative measures.

The goal of this report is to highlight research needs and data gaps that are of future importance for food safety and protection of the environment. This report is the latest in a series of VKMs reports on research needs and data gaps published on VKMs website, and thus mainly highlights research needs and data gaps identified in and related to VKMs scientific opinions for 2016 and 2017.

As previously described in VKMs 2016 report, food safety is one of the prerequisites for good health, and 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 safe food.

Protecting the environment, that is, the biotic and abiotic surroundings of humans, animals and species is vital for the benefit of both humans and the environment. Rapid changes in the environment at the different levels as well as complex interactions and various stressors requires continuous monitoring and surveillance measures to update existing data.

Research and surveillance data from other countries are not necessarily representative or relevant to Norway, since critical factors such as environmental conditions and dietary habits are distinctive. Knowledge on Norwegian conditions in particular, must therefore be generated nationally. It is necessary that we have active Norwegian research communities within the areas where such knowledge is needed.

1.1 Risk Assessments and data gaps

A risk assessment consists of three key elements: hazard identification/characterisation, exposure assessment and risk characterisation. The risk characterisation 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.

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 basis/foundation that the conclusion is based on. This may be incomplete knowledge of the systems, organisms, variables or models.

Data gaps are missing data related to the subject matter in the risk assessment. Data gaps include everything that is uncovered as missing data during the work and not only the missing data which is associated with the basis for the conclusion. Data gaps can be associated with both variability and uncertainty. In some cases, it may be that the data is missing completely, and thus VKM has been unable to assess the risk. Additionally, some data gaps do not effect uncertainty in the risk estimate directly.

Factors critical for risk assessments include:

- Accessible high quality research and/or data generated by the international scientific community or by organized surveillance or monitoring by international organizations.
- Country-specific high quality research and/or data. Research and surveillance data from other countries may be of little to no relevance for risk assessments related to Norwegian conditions, as environmental conditions and population trends such as dietary habits among others may differ greatly. Such knowledge should be generated nationally.
- Highly competent experts within all the different fields of VKM's mandate are essential, especially regarding multidisciplinary assignments. An open recruitment system from highly competent and active research institutions including universities and other organisations across the country makes this possible.

1.2 About VKM

VKM carries out independent scientific assessments in the form of opinions for the Norwegian Food Safety Authority (Mattilsynet) and the Norwegian Environment Agency (Miljødirektoratet). An opinion can be a risk assessment, a risk-benefit assessment, a research summary or other scientific reviews and comments. VKM follows international guidelines and standards for risk assessments within the different fields to ensure that the authorities get independent scientific risk assessments related to food safety and the environment. VKM neither performs research nor gives advice or opinions on risk management.

VKM assesses risk within these fields:

Food safety and production	Environment
• Biological Hazards • Plant Protection Products • Genetically Modified Organisms • Flavourings • Food Additives • Processing Aids • Materials in Contact with Food • Cosmetics • Contaminants • Animal Feed • Nutrition • Dietetic Products • Novel Food • Food Allergies • Animal Health and Animal Welfare • Plant Health	• Genetically Modified Organisms • Alien Organisms • Trade in Endangered Species (CITES) • Microbial Products • Plant Protection Products

1.3 How to use this report

VKM has identified research needs and data gaps related to specific topics. This report is thus divided into different chapters in order to make it easier for the reader. Each chapter starts with a short summary of important identified research needs and data gaps, followed by detailed descriptions.

Additionally, selected data gaps have been strategically placed under a separate chapter, surveillance data for food and diet to highlight surveillance-related knowledge needs and data gaps and enable relevant stakeholders, easy access to these.

Synergy and/or complex interplays exist in the areas of food safety and environmental protection, thus knowledge needs or data gaps might be of significance in several areas. More so, the various aspects of food safety throughout the production chain reveals a complex pattern of interplay between human health, plant health, animal health and welfare, and the environment. Knowledge needs or data gaps might be of significance at several steps in the production chain. Therefore, some research needs and data gaps are described in more than one chapter.

The structure of the report is as follows:

- Agriculture, terrestrial food production and terrestrial animals (Chapter 2)
- Fisheries, aquaculture, seafood production and aquatic animals (Chapter 3)
- Human health – diet, food, and microbiological products (Chapter 4)
- Biodiversity (Chapter 5)
- Surveillance data for food and diet (Chapter 6)

2 Agriculture, terrestrial food production and terrestrial animals

Summary

Significant research needs and data gaps regarding the field of agriculture, terrestrial food production and terrestrial animals identified in VKMs assessments are mainly:

- Driving factors in the development of AMR due to biocides and heavy metals
- The potential impact of microorganisms used in bioremediation and cleaning products
- Animal health and welfare during poultry production and association between bumblebee mortality and lime (*Tilia*) trees

- Presence and concentration of pathogens in food and drinking water as well as analytical data for nutrients

Detailed descriptions follow in this chapter.

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2.1 Environment

2.1.1 Toxic metals in fertilising products and soil and development of resistance in bacteria

There is a growing consensus regarding links between the level and concentration of potentially toxic metals in fertilising products and soil and development of resistance in bacteria. Data regarding the routes and frequencies of transmission of AMR from bacteria of environmental origin to bacteria of animal and human origin were lacking in the published articles reviewed here. 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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Toxic metal resistant bacteria in sewage.
- Toxic metal resistant bacteria in agriculture areas where fertilising products have been used.
- Toxic metal resistant bacteria in soil in Norway ("background resistance").
- Activity of toxic metals against different bacterial species in fertilising products (manure, sewage, etc.) and in soil.
- Comprehensive longitudinal and quantitative data from studies that have examined the dissemination of AMR pathogens from livestock manure and sewage application in the environment.
- Updated data on the concentration of toxic metals in fertilising products, organic (sludge and livestock manure) as well as inorganic, and soils in Norway.
- Development of toxic metal resistance in environmental bacteria.
- Development of toxic metal resistance in "un-culturable" bacteria.
- Dissemination of toxic metal resistance genes via fertilising products.
- Links between the level and concentration of potentially toxic metals in fertilising products and soil and development of resistance in bacteria.
- Sub-inhibitory concentrations of metals that induce resistance in different bacterial species at laboratory level, in sewage, manure, soil, and environment.

Expected effects/impact:

- Relationship between development of resistance against potential toxic metals and resistance against antimicrobial agents in bacteria.
- Data from evidence-based studies regarding the impact of heavy metal resistant bacteria in the environment on animals and humans.

For additional information, see «Research needs and data gaps of importance for food safety and protection of biodiversity from VKM's scientific opinions in the period 2005 - 2015» (2016) and assessments produced by the Panel on Biological hazards since then.

2.1.2 Antimicrobial resistance due to the use of biocides and heavy metals

- There are insufficient data on the amount of biocides and heavy metals that unintentionally end up in the environment, including soil, sediments, water, air, plants, and animals in Norway, and the extent to which such exposure, alone or in combination with other antimicrobials, may result in development of antimicrobial resistance (AMR) in microbial communities.
- There is lack of knowledge on the distribution of microorganisms with antimicrobial resistance in the environment as soil, sediments, water, plants and wild animals.
- Limited data are available regarding use/misuse/presence of disinfecting agent, as chlorhexidine and quaternary ammonium compounds (QACs), and heavy metals, in consumer products (such as cosmetic products), and their effect on the selection of cross-resistance against antibiotics.
- Analysis of antimicrobial resistance in environmental microbial samples is not standardized as it is for minimum inhibitory concentration (MIC) for clinical samples.
- Most data regarding biocide/heavy metal resistance are collected from studies using planktonic phase microorganisms (unattached microorganisms living freely in suspension) rather than microorganisms in more natural conditions, such as in a biofilm.
- Data regarding the contribution of horizontal gene transfer of antimicrobial resistance between different microorganisms in the environment are sparse.
- Although there are some studies regarding resistance of environmental bacteria to biocides and/or heavy metals and cross-resistance to antibiotics, there is a lack of information and knowledge about the clinical impact in humans and animals.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

Data collection:

- Collect data on the amounts of heavy metals (copper, zinc, cadmium, arsenic and mercury) and biocides (phenols, triclosan, QACs used in Norway, and an estimate of how much is released into different environments.

Methods:

- Develop standard methods for testing the potential of heavy metals and biocides to induce antimicrobial resistance in microorganisms.

Research:

- Characterize the presence of antimicrobial resistant microorganisms in different environments with known concentrations of heavy metals and biocides.

Investigate the dose response and the threshold of heavy metals and biocides for triggering the emergence of antimicrobial resistance in microorganisms.

Expected effects/impact:

With more knowledge on which biocides and heavy metals used in cosmetics, agriculture and human and veterinary medicine may induce antimicrobial resistance, we will be able to reduce the danger of creating new antimicrobial resistant pathogenic microorganisms.

For additional information, see « Research needs and data gaps of importance for food safety and protection of biodiversity from VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Microbial Ecology since then.

2.1.3 Microorganisms used in bioremediation and cleaning products

The products

- There is limited knowledge on specific products on the Norwegian market and the extent of usage.
- Poor characterization of the microorganisms used in bioremediation and cleaning products, and the lack of knowledge on the risks linked to the use of strains which belong to species known to include opportunistic pathogens, makes it difficult to assess the risks related to their use and potential risks to vulnerable groups like pregnant women, children, elderly, immunocompromised persons, and people with respiratory ailments.
- The shelf-life or the viability of the microorganisms used in microbiological bioremediation and cleaning products are unknown.
- The effectiveness of microbial cleaning products in relation to chemical-based cleaning products is not known.
- The available information on the mechanisms of action for microorganisms in microbial cleaning products are considered inadequate.

Environmental aspects

- There is no information on the ecological impact of products produced by microbial degradation of polycyclic aromatic hydrocarbons (PAH).

- The long-term effects of microbial bioremediation in halo-organic (organic compounds that contains at least one halogen such as chlorine and fluorine) mixtures is unknown.

Most of the work on bioremediation are laboratory experiments or *in situ* pilot trials. Data is missing from full-scale field experiments.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

The products

- Higher requirements on the characterization of the microbial species utilized in products

Research on:

- The shelf-life, viability and mechanisms of action of microorganisms employed in microbial products.
- The effectiveness of microbial cleaning products in relation to chemical based cleaning products.

Environmental aspects

Research on:

- the long-term ecological impact of the various intermediate degradation products
- full-scale field experiments on bioremediation

Expected effects/impact:

Filing the above-mentioned knowledge gaps will enable risk assessors to perform semi-quantitative/quantitative assessments that will better inform regulators in decision-making and setting appropriate standards.

For additional information, see «Health and environmental risk evaluation of microorganisms used in bioremediation» (2016) and «Health and environmental risk assessment of microbial cleaning products» (2016) produced by the Panel on Microbial Ecology.

2.2 Plant health

2.2.1 Manure and digestive tract content from slaughterhouses as a pathway for weeds and plant pests

Little is known about temperature and other conditions important for the survival of plant pathogens and seeds of the most important weed species in haylage stored in plastic wrapped bales, processing of animal feed, passage through the digestive tract, and during manure storage and handling.

Information is scarce on the geographical distribution and economic importance of many of the plant pathogens assessed in related opinions. Systematic surveys are badly needed.

Statistics are lacking on the amount of home-grown concentrates, by-products and waste from the food industry and groceries (bread, fruits, vegetables etc.) that are used as animal feed in Norway.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Research on the temperature and other conditions important for the survival of plant pathogens and seeds of the most important weed species.
- Systematic surveys of the geographical distribution and economic importance of specific plant pathogens.
- Data collection and statistical analyses on the amount of home-grown concentrates, by-products and waste from the food industry and groceries (bread, fruits, vegetables etc.) that are used as animal feed in Norway.

Expected effects/impact:

- Better knowledge in this field will reduce the risk in slaughterhouses and manure of viable plant pathogens and seeds, and make the use of manure from slaughterhouses in agriculture safer.
- Knowledge of distribution and importance of plant pathogens and seeds will improve safety measures in handling animals in the slaughterhouse, and the risk of distributing manure to agricultural land.
- Statistics would make it possible to evaluate more precisely to what extent animal feeds contribute to the spread of plant pests and seeds through slaughterhouse manure and animal manure in general.

For additional information, see « Research needs and data gaps of importance for food safety and protection of biodiversity from VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Plant Health since then.

2.2.2 Cockspur grass (*Echinochloa crus-galli*)

Systematic survey of occurrence of *E. crus-galli* in Norway is missing. The method of site-referenced infestations applied in Vestfold could be copied.

There is lack of data on contamination with viable seeds in the different steps of the identified pathways for spread.

There is some lack of knowledge on the biology and temperature requirements of Norwegian biotypes of *E. crus-galli*. Biology includes germination, early growth, and seed production

Empirical data on the perceived extraordinarily wide germination period of *E. crus-galli* is missing. Knowledge on how the timing of the germination of the weed relative to the germination of the crop affects the yield is also missing.

Yield effects under Norwegian or Nordic conditions in crops relevant to Norway is missing.

Data on how herbicide efficacy varies with growing conditions. Population dynamic in different soils and under different tillage practices is missing.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Systematic survey of occurrence of *E. crus-galli* in Norway.
- Data collection on contamination with viable seeds in the different steps of the identified pathways for spread.
- Research on the biology and temperature requirements of Norwegian biotypes of *E. crus-galli*.
- Collection of empirical data on the perceived extraordinarily wide germination period of *E. crus-galli* and crop yields effects under Norwegian or Nordic conditions in crops relevant to Norway.
- Data collection on how herbicide efficacy varies with growing conditions. Population dynamic in different soils and under different tillage practices.

Expected effects/impact:

With site-referenced infestations of the weed, precautions can effectively be taken to avoid spread, for example by machinery and relocation of soil. This would be very helpful for farmers renting agricultural land and using their machines over large areas. A systematic mapping would also be very useful when identifying and evaluating the importance of pathways for spread.

Such data are necessary to range the relative importance of the suggested pathways for spread of *E. crus-galli*. This knowledge would help the Norwegian Food Safety Authority to decide if, and to identify which, regulations would be appropriate to implement. For the farmers' community, successful regulations would contribute to less laborious and less costly crop protection. This will ultimately serve the society.

With more knowledge on this subject, it would be possible to decide which features seem to make the Norwegian biotypes more expanding and competitive in cereals compared to reports from other Nordic countries. With data on temperature requirements, optimal timing of inspection and control measures may be predicted.

With this data, models predicting the optimal timing of herbicide application could be established and made available on the web-based decision support system VIPS (NIBIO and Norsk Landbruksrådgiving, 2016). Such models enable a more targeted timing of spraying, resulting in less herbicide use without reducing efficacy and yield.

Such data is necessary to give a more certain evaluation of the impact of the weed on yield in Norway.

With such data recommendation for more targeted timing of spraying will be given, resulting in less herbicide use without reducing efficacy. With such data recommendation for controlling severe infestation may be improved.

For additional information, see « Research needs and data gaps of importance for food safety and protection of biodiversity from VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Plant Health since then.

2.3 Animal health and welfare

2.3.1 Norwegian turkey production

Studies on the physiological and behavioural needs of turkeys kept for meat production are often performed with specific hybrids. However, findings between hybrids are often not comparable.

Scientific data is lacking with regards to effects of housing conditions on animal health/welfare. For example, data on risk factors such as lack of environmental enrichment, insufficient space for movement, resting and escape, poor air quality, stocking density, and light recommendations is scarce.

Adequate registration of production data as well as data on animal health and welfare in breeding flocks is lacking. Furthermore, data on methods for assessing techniques for artificial insemination and semen collection is lacking.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- More studies aiming at elucidating whether health- and welfare data are comparable between turkey hybrids.
- More studies on turkey behavioral needs (i.e. light regimens and housing types) under Norwegian conditions. Interacting risk factors should in particular be emphasized.
- Adequate registration of animal welfare indicators, health parameters and production parameters including environmental enrichment.

Expected effects/impact:

- Provide more standardised housing practises for turkey, further improving animal health and welfare.
- Better assessment of health and welfare in breeding turkeys. This includes training of personnel with regards to knowledge, experience and attitude towards animal welfare and animal handling during semen collection and artificial insemination.

For additional information, see « Research needs and data gaps of importance for food safety and protection of biodiversity from VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Animal Health and Welfare since then.

2.3.2 Genetically modified virus vaccines (GM-VV) in domestic animals

Currently, no experience exists on the use of GM-VV in animal domestication in Norway, thus, there exists knowledge-gap on field, post-field and post-marketing of such products in Norway.

Climate change will impact some factors relevant for environmental risk assessment (ERA) of GM-VV, especially within the Norwegian context. These factors are currently unknown and the extent of such impact cannot be deduced.

Information on the effectiveness of conventional vaccines in disease management of domesticated animals (especially of companion animals), in Norway was not available at the time of preparing the report on this subject. Thus, no knowledge on vaccine type, dose requirement and potential spread exists, should current conventional vaccines be replaced by GM-VVs in the future.

Baseline information on naturally circulating virus-relatives of the commonly used GM-VV strains in the Norwegian environment is lacking. It was not possible to map the occurrence, nature and geographic distribution of these virus-relatives in Norway.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Permission from relevant institutes/departments e.g. the Norwegian Institute of Public Health, to access data on the vaccination status of domestic animals. If the data is not available, steps should be taken to extract such information through retrospective study.
- Research to document circulating virus-relatives in Norway of the commonly used vectors is required. A starting point can be to document the relatives of the commonly used strains of viruses (poxvirus, adenovirus and herpesvirus) around established farm areas in Norway.

Expected effects/impact:

- Availability of post-release data in countries with experience in the use of GM-VV would allow for extrapolation/modelling of event scenarios, such as spread to non-targets, in the event of use of GM-VV in Norway.
- Data on the vaccination status of domestic animals in Norway will provide an indication of vaccine need, dose and potential spread, in the case of replacement of conventional vaccines by GM-VV in Norway in the future.

Information naturally circulating virus-relatives in Norway of the vaccine-relevant virus species will provide baseline data on the potential off-target virus species in different locations in Norway, which will help to map strategies for prevention of spread of transgenes in the environment in the event that GM-VV products are applied in Norway.

For additional information, see «Knowledge base for the assessment of environmental risks by the use of genetically modified virus-vectored vaccines for domesticated animals» (2016) produced by the Panel on Microbial Ecology.

2.3.3 Association between bumblebee mortality and lime (*Tilia*) trees

There is a need for more knowledge related to mortality of bumblebees in general and in the presence of *Tilia* trees in particular. Tailored monitoring and research should focus on the temporal and spatial dynamics of bumblebee mortality, with emphasis on different species and casts, in relation to both *Tilia* trees and other floral resource hotspots.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- There is need for monitoring also of other insect species found dead under *Tilia* trees.
- The reasons for the accumulation of dead bumblebees under *Tilia* trees are still unknown. There is need for research aiming to test the different hypothesis listed in the related report.

Expected effects/impact:

Filling the above-mentioned research gaps will reveal whether *Tilia* trees are the cause of extensive bumblebee mortality, or not. Irrespective of the nature of the research findings, this will enable landscape planners and managers to make informed decisions regarding planting or removing *Tilia* trees in parks and other public places.

For additional information, see « Assessment of the potential connection between *Tilia* trees and bumblebee death » (2017) produced by the Panel on Alien Organisms and trade in Endangered Species (CITES).

2.4 Food products

2.4.1 Analytical data for nutrients

Changes in the food production may cause changes in the in the nutrient content in food products.

A periodical update of nutrient content in raw and processed foods is needed. New and modified food products are introduced to the Norwegian food market and there is need for regular surveillance of the nutrient content in the food products.

In order to estimate intake of nutrients, the concentration of nutrients in both raw and processed foods must be analysed.

Nutrient content in fruits, vegetables, legumes and meat, and processed food products of these foods, constitute essential background data in several assessments of nutrient intakes in relation to tolerable upper intake levels.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- In order to estimate intake of nutrients, the concentration of nutrients in both raw and processed foods must be analysed.

Expected effects/impacts:

Nutrient content in fruits, vegetables, legumes and meat, and processed food products of these foods, constitute essential background data in several assessments of nutrient intakes in relation to tolerable upper intake levels. Better analytical data on the different nutrients will reduce the uncertainty in exposure assessment of the nutrients.

For additional information, see Data gap chapters in the 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium (2017 and 2016) produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy.

2.4.2 Presence and concentration of pathogens in food and drinking water

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. The main sources of knowledge on presence and concentration of pathogens in primary production and food processing are annual national Zoonosis Reports and surveillance programs (by the Norwegian Veterinary Institute), but not all pathogens of interest are included.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

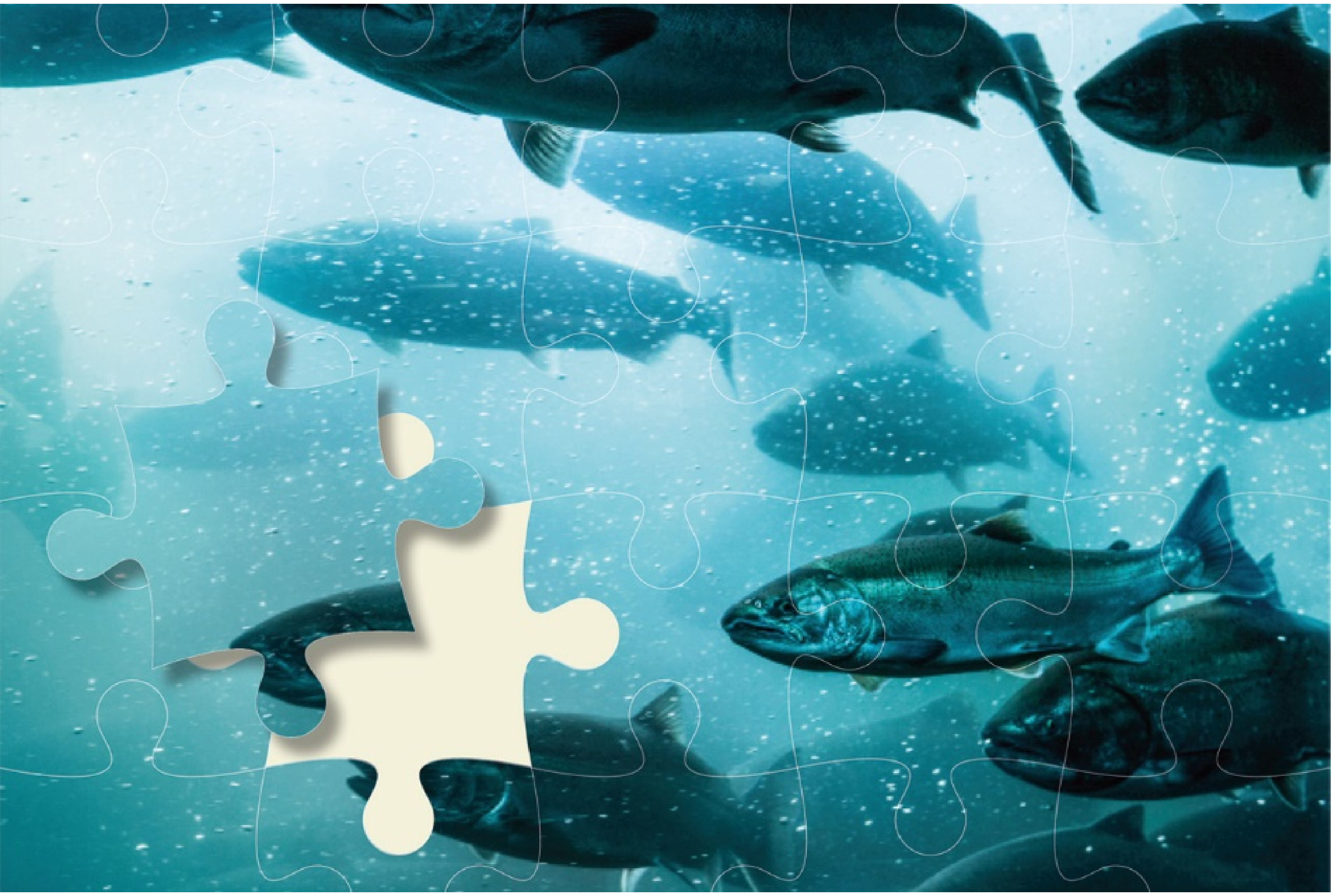
- Data on trends in the presence and concentration of pathogens in animal populations, food and drinking water are needed.
- Knowledge on presence and concentration of e.g. parasites like Toxoplasma (very few data available), *Cryptosporidium* and *Giardia* (no data available) are needed.

Expected effects/impact:

Data on presence and concentration of pathogens in animal populations, in food and in the drinking water will provide a better basis for prioritisation of measures reducing the risk levels for the human population. Knowledge on trends in the presence and concentration of pathogens in food and drinking water is also essential to capture emerging pathogens as early as possible.

For additional information, see «Research needs and data gaps of importance for food safety and protection of biodiversity from VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Biological hazards since then.

3 Fisheries, aquaculture, seafood production and aquatic animals



Summary

Significant research needs and data gaps regarding fisheries, aquaculture, seafood production and aquatic animals identified in VKMs assessments are mainly:

- Animal health and welfare regarding introduction of novel pathogens in aquaculture through cleaner fish and marking of farmed fish.
- Nutrients in fish and other seafoods.

Detailed descriptions follow in this chapter.

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3.1 Animal health and welfare

3.1.1 Spread of novel pathogens in aquaculture through cleaner fish

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 pathogenic agents.

Being a relatively new species in aquaculture, knowledge on transmission of pathogens from cleaner fish to farmed salmonids is currently poor. In particular, data on the disease-status in wild-caught cleaner fish is scarce.

Knowledge on pathogenic agents relevant in salmonid farming, like for example *lumpfish flavivirus*, *lumpfish ranavirus*, *Piscirickettsia salmonis* and *Vibrio* spp, is limited or lacking. Unknown viral agents 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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Quarantine stocking of wild-caught cleaner fish and screening for pathogens prior to mixing with salmon.
- Access to cell lines for cultivation of viruses and development of more reliable methods for screening and detection of viral infections.
- Optimization on vaccination regimes (both bacterial and viral).
- More studies on cleaner fish biology and physiology.

Expected effects/impacts:

- Contribute to better diagnosis of disease status in clinically and sub-clinically ill cleaner fish.
- More knowledge on cleaner fish biology will result in a better overview of health status and facilitate identification of novel, potentially serious diseases.
- Access to cell lines will improve our understanding of viral diseases and the pathogenic potential for salmonid fish (including those specific for cleaner fish).

For additional information, see « Research needs and data gaps of importance for food safety and protection of biodiversity From VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Animal Health and Welfare since then.

3.1.2 Marking of farmed salmonid fish

Escaped farmed salmon represents an environmental problem, potentially threatening genetic integrity in wild populations as well as transmission of diseases. There is a need of a marking system that makes it easy to separate farmed fish from wild and trace escaped fish back to its origin. Current tagging methods usually comprise a combination of an external mark, such as removal of adipose fin, with a tracing method that has sufficient number of codes or IDs. Administration of anaesthesia is used in order to immobilize fish and reduce stress during the marking procedure. However, data is scarce with regards to what extent fish experiences pain post-marking.

The functional role of the adipose fin is not well understood.

With regards to external marking (i.e. freeze branding and visible tags attached to the body) or visible internal tags, data on how fish are affected in different environmental contexts or different life stages is either scarce or non-existent. For example, whether different ontogenetic stages or fish sizes affects how fish respond to tagging can only be speculated upon.

Publications on interference with behaviour or infection risks/diseases due to visible external tags post marking are few.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- More behavioural studies focusing on nociception/pain responses following marking is needed.
- The adipose fin being innervated suggests that the fish may experience pain if clipped. More information on the functional role of the adipose fin is necessary; i.e. swimming behaviour or social behaviour during spawning season.
- Large scale studies monitoring behaviour and potential infections over time as well as survivability.
- Training of personnel handling the fish and carrying out the marking procedure.
- Development of non-invasive techniques for marking and tracing farmed fish, which takes fish welfare into account.

Expected effects/impact:

- More knowledge on the functional role of the adipose fin will contribute to our understanding of how fin clipping affects animal welfare.

- Better understanding of how marking affects fish welfare in the long term.
- Reliable and practical non-invasive marking and tracing methods will significantly improve fish welfare.

For additional information, see « Research needs and data gaps of importance for food safety and protection of biodiversity From VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Animal Health and Welfare since then.

3.2 Food products

3.2.1 Nutrients in fish and other seafood

In the Norwegian diet, fish is the major source of EPA (eicosapentaenoic acid), DPA docosapentaenoic acid) and DHA (docosahexaenoic acid). Fish is also an important source for vitamin D, iodine and selenium. Over the last years, there has been a change in raw materials used in fish feeds for farmed Atlantic salmon and 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. Data on the content of EPA, DPA and DHA in fish and fish products is needed. 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 of time makes it possible to show time-trends.

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.

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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

In order to estimate intake of nutrients, the concentration of nutrients in both raw and processed foods must be analysed.

Expected effects/impact:

Nutrient content in fish and other seafood and food products in these food groups constitute essential background data in several assessments of nutrient intakes in relation to tolerable upper intake levels and maximum limits in food supplements (such as vitamin D in children and adolescents).

For additional information, see «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014) produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy.

4 Human health – diet, food, and microbiological products

Summary

Significant research needs and data gaps in food safety and environmental protection regarding human health identified in VKMs assessments are mainly:

- Norwegian occurrence/consumption data for inorganic arsenic.
- Occurrence of foodborne pathogens and disease incidence/foodborne diseases.

- Knowledge on the intake of food supplements.
- National dietary surveys as well as epidemiological studies and studies on mechanisms of beneficial or harmful effects of food/food groups or nutrients in food/food groups.
- Genetically modified (GM) food; herbicide residues in herbicide tolerant (HT) crops as well as safety assessments of genetically modified crops.
- The health effects of microorganisms used in bioremediation/cleaning products.

Detailed descriptions follow in this chapter.

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4.1 Diet and food

4.1.1 Dietary exposure to inorganic arsenic in the Norwegian population

Occurrence data and updated food consumption data of inorganic arsenic in different age groups are lacking.

Norwegian occurrence data of inorganic arsenic are limited to fish and seafood. There are only few data points for rice and none for rice products.

There is lack of information on the consumption of foods with elevated levels of inorganic arsenic, such as rice and rice products and seaweed.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Systematic surveillance of the levels of inorganic arsenic in food, an update of food consumption data and a Total Diet Study are needed.
- Combined, the data would provide a good scientific basis for the population's dietary exposure to inorganic arsenic.

Expected effects/impact:

More occurrence data and updated dietary exposure assessment in different sub-groups of the Norwegian population will give a more realistic exposure assessment of inorganic arsenic. This will provide better basis for prioritisation of measures to reduce the human health risk from arsenic.

For additional information, see «Dietary exposure to inorganic arsenic in the Norwegian population» (2016) and assessments produced by the Panel on Contaminants since then.

4.1.2 Disease incidence/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 relative and the absolute disease rate based on the MSIS data.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Knowledge on the relative and the absolute disease incidence 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.

- Knowledge on the burden of foodborne diseases is needed.

Expected effects/impacts:

Knowledge on the actual disease incidence in a population and the burden of disease will provide a better basis for prioritisation of measures and thereby also reduce the risk level.

For additional information, see «Research needs and data gaps of importance for food safety and protection of biodiversity From VKM's scientific opinions in the period 2005 - 2015» (2016) and assessments produced by the Panel on Biological hazards since then.

4.1.3 Foodborne pathogens - presence and concentration

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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- 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.

Expected effects/impacts:

Data on presence and concentration of zoonotic pathogens in the animal population and in food processing will provide a better basis for prioritisation of measures, reduce the risk levels for the human population and ensure compliance with EU principles of modern risk-based audit for the Norwegian Food Safety Authority.

For additional information, see «Research needs and data gaps of importance for food safety and protection of biodiversity from VKM's scientific opinions in the period 2005 - 2015» (2016) and assessments produced by the Panel on Biological hazards since then.

4.1.4 Knowledge on the intake of food supplements

Knowledge on the intake of food supplements in Norwegians, for both genders, all age groups and population groups with different eating habits, is needed.

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

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

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

Expected effects/impact:

This knowledge is important to estimate the exposure to specific substances in food supplements for various population groups and evaluate potential negative health effects.

For additional information, see « Research needs and data gaps of importance for food safety and protection of biodiversity from VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics since then.

4.1.5 Dietary surveys

Changes in eating habits/diets, food production methods and the continually development of new food products 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. Biomarkers, biobanks and health registers linked to dietary surveys will provide better knowledge about the relationship between food, the diet and health.

4.1.5.1 National dietary surveys

National dietary surveys are lacking.

National dietary surveys provide information on dietary habits (what is eaten and how much).

The national dietary surveys cover three different age groups. «Sped- and 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, both at mean level and for the lower and the higher end intakes like the 5th- and 95th-percentiles.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- A continuous rolling programme for national dietary surveys for all age groups is needed (every 5-10 years).
    - The surveys should be designed to capture variations in intake of substances, foods/food groups, and include high consumers of the specific substance or foods/food groups.
    - A sufficient number of participants must be recruited, to allow for exposure calculations of the outer limits of the intake (5th- and 95th percentiles).
    - Conducting regular dietary surveys which give comparable results from survey to survey enable us to follow trends in dietary habits.

Expected effects/impact:

National dietary surveys will provide information on dietary habits (what is eaten and how much) in the Norwegian population in future assessments.

For additional information, see the 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy.

4.1.5.2 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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- 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, wild mushrooms, game etc.) are needed.

- Data on population groups that follow special diets (e.g. vegetarian and vegan) and ethnic food patterns are needed.

- Data on food packaging materials, product name/brand, production method and country of origin are needed.

Expected effects/impact:

Knowledge and data on consumption of foods and food groups with particularly high concentrations and highly exposed population groups will be available for future assessments.

4.1.5.3 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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- TDS, including analyses on levels of selected pesticide residues, contaminants, toxins, radionuclides, nutrient and non-nutrient elements, is needed. Updated food lists from the national dietary surveys in different population groups are used to collect and analyse the food that consumers eat.

- To investigate time trends (change over time), a continuous data collection program with yearly or cyclic data collections is required.

Expected effects/impact:

The results from a TDS would provide a basis for detecting possible chronic risks from contaminated food. A TDS will be used to calculate the intake and exposure from the diet in the different population groups in Norway. A TDS would be a useful tool in addition to surveillance programs. A TDS will not make other surveillance programs on foods/contaminants/pesticides redundant, but would be a valuable addition to establish levels of exposure of the average Norwegian population.

4.1.5.4 Regular submission of data to EFSA

In EU, the comprehensive food consumption database contains information on food consumption across Europe. Detailed data for a number of EU countries are included, and the database plays a key role in the evaluation of the risks and allows estimates of consumers' exposure. Norway has been invited to contribute with data from the national dietary surveys; and Norkost 3 will in 2018, be entered into the EFSA food database FoodEx2.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- All Norwegian food dietary surveys should be performed with a methodology that allow for submission of the data to the EU food consumption database.

Expected effects/impact:

The need for specific Norwegian risk assessments on substances/issues EFSA has assessed will be reduced, when Norwegian data is included in this database.

4.1.6 Nutrients

4.1.6.1 Analytical data for nutrients

Changes in food production may cause changes in the nutrient content in food products. Nutrient content in all food groups constitutes essential background data in several assessments of nutrient intakes in relation to tolerable upper intake levels. Norwegian food composition data for certain nutrients, e.g. vitamin K, is lacking.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- A periodical update of nutrient content in raw food and commercial food products, including food supplements is needed. New and modified food products are introduced to the Norwegian food market and there is special need for surveillance of the nutrient content in these food products.

Expected effects/impact:

Updated information on nutrient content in all food groups essential as background data in several assessments of nutrient intakes in relation to tolerable upper intake levels will improve the basis of future assessments.

For additional information, see the 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium (2016-2017) produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy.

4.1.6.2 Tolerable upper intake levels

The tolerable upper intake level (UL) is the maximum level of total chronic daily intake of a nutrient (from all sources) 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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

Updated systematic literature reviews of human and animal studies on high intakes of vitamins and minerals is vital for 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.

Expected effects/impact:

More evidence-based and updated risk assessment of vitamins and minerals.

For additional information, see the 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium (2016-2017) produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy.

4.1.7 Epidemiological studies and studies on mechanisms of beneficial or harmful effects of food/food groups or nutrients in food/food groups

4.1.7.1 Epidemiological studies

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

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

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. Ideally, to provide data to inform tolerable upper intake levels for nutrients, toxicity studies with graded oral supplement doses should be performed in humans. For ethical reasons, such data is scarce.

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 large age ranges.

Expected effects/impact:

The data collections described above may be combined with several biological measurements and linked with endpoints from registers. Examples of currently existing cohorts in Norway with repeated data collections in large samples over decades are the Tromsø study and the Nord-Trøndelag Health Study.

For additional information see:

- The 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium (2017 and 2016).
- The 20 opinions regarding doses of “other substances” in food supplements; alanine, arginine and arginine alpha ketoglutarate, aspartic acid, beta-alanine, branched chained amino acids (leucine, isoleucine and valine), creatine, cystin and cysteine, glutamine and glutamic acid, glycine, histidine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, conjugated linoleic acids (CLAs) and n-3 fatty acids; Eicosapentaenic acid (EPA), Docosapentaenic acid (DPA) and Docosahexaenic acid (DHA) produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy. The 15 opinions regarding doses of “other substances” in food supplements and/or energy drinks: l-Carnitine and l-Carnitine-L-tartrate, l-citrulline, coenzyme Q10, collagen from fish skin, d-Ribose, glucuronolactone, inositol, lecithin from sunflower, taurine, caffeine, curcumin, isoflavones from soy, lycopene, piperine from black pepper and inulin produced by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics.

4.1.7.2 Studies on mechanisms of beneficial or harmful effects

Mechanistic studies using animal models are lacking.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Animal studies are used e.g. to get more insight into mechanisms of actions regarding the development and progression of adverse health effects. In the absence of sufficient human data, knowledge on mechanisms of beneficial or harmful effects resulting from the intake of specific food/food groups from animal experiments is needed, e.g. to identify safe use in terms of negative effects and duration of exposure.

- Mechanistic studies using *in vitro* models are useful in the absence of adequate human and animal data.

Expected effects/impact:

- Knowledge on mechanisms of beneficial or harmful effects resulting from the intake of specific food/food groups from animal experiments can be employed in the absence of sufficient human data.

- In the absence of adequate human and animal data, information about mechanisms of action could be deduced from properly performed *in vitro* experiments using primary cells or cell lines, organ cultures etc.

For additional information, see:

- The 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium (2016 and 2017).

- The 20 opinions regarding doses of “other substances” in food supplements; alanine, arginine and arginine alpha ketoglutarate, aspartic acid, beta-alanine, branched chained amino acids (leucine, isoleucine and valine), creatine, cystin and cysteine, glutamine and glutamic acid, glycine, histidine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, conjugated linoleic acids (CLAs) and n-3 fatty acids (eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA) and docosahexaenoic acid (DHA) (2016 and 2017) produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy. The 15 opinions regarding doses of “other substances” in food supplements and/or energy drinks: l-Carnitine and l-Carnitine-L-tartrate, l-citrulline, coenzyme Q10, collagen from fish skin, d-Ribose, glucuronolactone, inositol, lecithin from sunflower, taurine, caffeine, curcumin, isoflavones from soy, lycopene, piperine from black pepper and inulin produced by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics.

4.2 Genetically modified (GM) food

4.2.1 Herbicide residues in herbicide tolerant (HT) crops

HT crops permits the use of broad-spectrum herbicides, as an in-crop selective herbicide to control a wide range of broadleaf and grass weeds without sustaining crop injury. The broad-spectrum herbicide(s) that are used with HT crops are sprayed directly on the plant canopy. The spraying often takes place later in the growing season than is the case with the selective herbicides that are associated with conventional crops. Levels of herbicide residues and their metabolites may therefore potentially be higher in plants with tolerance to herbicides, compared to that of plants produced by conventional farming practices. In addition, the genetic modifications used to make a plant tolerant against certain herbicide(s) may influence the metabolism of the intended herbicide.

More research is needed to elucidate whether the genetic modifications used to make a plant tolerant against certain herbicide(s) may influence the metabolism of this or other plant protection products (PPPs), and whether possible changes in the spectrum of metabolites may result in altered toxicological properties.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Data on residue levels of the target herbicide in HT-crops is needed, as well as data on their metabolites.
- To evaluate the question whether the genetic modifications used to make a plant tolerant against certain herbicide(s) may influence the metabolism of this/these herbicide(s), or other PPPs, theoretical considerations based on known modifications and relevant herbicides and PPPs must be done. In cases where it is deemed necessary, further studies on the nature, levels and toxicity of residues should be performed based on the theoretical considerations.

Expected effects/impact:

Data on residue levels and knowledge on new metabolites in HT crops will contribute to better risk assessments of the herbicides, their active ingredients and metabolites, more precise residue definitions and MRLs (maximum residue levels), as well as better risk assessments of herbicide tolerant GM-plants.

For additional information, see « Research needs and data gaps of importance for food safety and protection of biodiversity From VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Genetically Modified Organisms since then.

4.2.2 Safety assessments of genetically modified crops (evaluation of unintended effects caused by genetic modification)

RNA interference (RNAi) is an emerging technology that offers new opportunities for the generation of novel traits in GM plants. The technique is used to produce GM plants with altered agronomic, nutritional, industrial and food-processing traits. However, there are uncertainties concerning the mode of action and the effect of application of RNAi in GMOs. RNAi raises new questions for risk assessment of GMOs.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

More research on the exact rules for small RNA-target matches is required in order to design efficient algorithms, and to make predictions regarding the effect of small RNAs in GMOs more consistent. Advancements in “omics” technologies (e.g. genomics, transcriptomics, proteomics and metabolomics) could further strengthen these predictions.

Expected effects/impact:

Future advances in omics may be used to distinguish between unintended effects caused by RNAi modifications and compositional differences caused by natural variability between GM plants and their non-GM counterparts.

Omics and bioinformatics could play a significant role in the risk assessment of RNAi-based GM plants by detecting off-target genes that require further characterisation.

For additional information, see «Research needs and data gaps of importance for food safety and protection of biodiversity from VKM’s scientific opinions in the period 2005 - 2015» (2016) and assessments produced by the Panel on Genetically Modified Organisms since then.

4.3 Microorganisms used in bioremediation and cleaning products

The products

- There is limited knowledge on specific products on the Norwegian market and the extent of usage.
- Poor characterization of the microorganisms used in bioremediation and cleaning products, and the lack of knowledge on the risks linked to the use of strains which belong to species known to include opportunistic pathogens, makes it difficult to assess the risks related to their use and potential risks to vulnerable

groups like pregnant women, children, elderly, immunocompromised persons, and people with respiratory ailments.

- The shelf life or the viability of the microorganisms used in microbiological bioremediation and cleaning products are unknown.
- The effectiveness of microbial cleaning products in relation to chemical-based cleaning products is not known.
- The available information on the mechanisms of action for microorganisms in microbial cleaning products are considered inadequate.

Environmental aspects

- There is no information on the ecological impact of products produced by microbial degradation of PAH.
- The long-term effects of microbial bioremediation in halo-organic (organic compounds that contains at least one halogen such as chlorine and fluorine) mixtures is unknown.

Most of the work on bioremediation are laboratory experiments or *in situ* pilot trials. Data is missing from full-scale field experiments.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

The Products

- Higher requirements on the characterization of the microbial species utilized in products

Research on:

- The shelf life, viability and mechanisms of action of microorganisms employed in microbial products.
- The effectiveness of microbial cleaning products in relation to chemical based cleaning products.

Environmental aspects

Research on:

- the long-term ecological impact of the various intermediate products of degradation
- full-scale field experiments on bioremediation

Expected effects/impact:

Filing the above-mentioned knowledge gaps will enable risk assessors to perform semi-quantitative/quantitative assessments that will better inform regulators in decision-making and setting appropriate standards.

For additional information, see «Health and environmental risk evaluation of microorganisms used in bioremediation» (2016) and «Health and environmental risk assessment of microbial cleaning products» (2016) produced by the Panel on Microbial Ecology.

5 Biodiversity

Summary

Significant research needs and data gaps in food safety and environmental protection regarding biodiversity identified in VKMs assessments are mainly:

- Spread, climate tolerance, as well as ecological impact of alien organisms in Norway
- Ecological impacts of genetically modified crops, and genetically modified virus vaccines (GM-VV) in domestic animals

Detailed descriptions follow in this chapter.

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5.1 Alien organisms

Major research gaps related to species rich groups such as those assessed in VKMs reports on arachnids, insects, gastropods and aquatic plants, are related to taxonomic uncertainties, in particular taxa in need of revision and unsettled nomenclature.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

There is a need for better knowledge on species-specific native distribution and climate tolerance, mechanisms for-, and extent of dispersal as well as ecological impact, including spread and impact of accompanying pathogens.

Expected effects/impact:

Filling the above-mentioned research gaps will enable VKM to make better risk assessments and consequently the Environmental agency to make better-informed decisions regarding import of exotic animals and plants for private keeping (alien organisms in general).

For additional information, see « Research needs and data gaps of importance for food safety and protection of biodiversity From VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Alien Organisms and trade in Endangered Species (CITES) since then.

5.2 Hand-reared mallards

Data on both short-term and long-term survival as well as the breeding success of released mallards are required.

Studies on the effects caused by hand-reared mallards on the nutrient status of freshwaters are largely lacking.

Data on causes of mortality, and the rate of crippling and wounding during the hunting season are lacking.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

Close surveillance of the released ducks before, through and after the hunting season as well as monitoring of any impact on the environment the ducks are released into will be required.

Expected effects/impact:

The data gaps described above will need to be filled in order to conduct a full quantitative risk assessment of the impact of release of mallards on the environment, animal health, and animal welfare.

For additional information, see « Research needs and data gaps of importance for food safety and protection of biodiversity From VKM's scientific opinions in the period 2005 - 2015 » (2016) and assessments produced by the Panel on Alien Organisms and trade in Endangered Species (CITES) since then.

5.3 Mortality of bumblebees

There is a need for more knowledge related to mortality of bumblebees in general and in the presence of lime (*Tilia*) trees in particular. Tailored monitoring and research should focus on the temporal and spatial dynamics of bumblebee mortality, with emphasis on different species and casts, in relation to both *Tilia* trees and other floral resource hotspots.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- There is need for monitoring also of other insect species found dead under *Tilia* trees.
- The reasons for the accumulation of dead bumblebees under *Tilia* trees is still unknown. There is need for research aiming to test the different hypothesis listed in our report.

Expected effects/impact:

Filling the above-mentioned research gaps will reveal whether *Tilia* trees are the cause of extensive bumblebee mortality, or not. Irrespective of the nature of the research findings, this will enable landscape planners and managers to make informed decisions regarding planting or removing *Tilia* trees in parks and other public places.

For additional information, see « Assessment of the potential connection between *Tilia* trees and bumblebee death » (2017) and assessments produced by the Panel on Alien Organisms and trade in Endangered Species (CITES).

5.4 Genetically modified virus vaccines (GM-VV) in domestic animals

Currently, no experience exists on the use of GM-VV in animal domestication in Norway, thus, there exists knowledge-gap on field, post-field and post-marketing of such products in Norway.

Climate change will impact some factors relevant for ERA of GM-VV, especially within the Norwegian context. These factors are currently unknown and the extent of such impact cannot be deduced.

Information on the effectiveness of conventional vaccines in disease management of domesticated animals (especially of companion animals), in Norway was not available at the time of preparing this Report. Thus, no knowledge on vaccine type, dose requirement and potential spread should current conventional vaccines be replaced by GM-VVs in the future.

Baseline information on naturally circulating virus-relatives of the commonly used GM-VV strains in the Norwegian environment is lacking. It was not possible to map the occurrence, nature and geographic distribution of these virus-relatives in Norway.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Permission from relevant institutes/departments e.g. the Norwegian Institute of Public Health, to access data on the vaccination status of domestic animals. If the data is not available, steps should be taken to extract such information through retrospective study;
- Research to document circulating virus-relatives in Norway of the commonly used vectors is required. A starting point can be to document the relatives of the commonly used strains of Poxvirus, Adenovirus and Herpesvirus around established farm areas in Norway.

Expected effects/impact:

- Availability of post-release data in countries with experience in the use of GM-VV would allow for extrapolation/modelling of events scenario, such as spread to non-targets, in the event of use of GM-VV in Norway;
- data on the vaccination status of domestic animals in Norway will provide an indication of vaccine need, dose and potential spread, in the case of replacement of conventional vaccines by GM-VV in Norway in the future;
- Information naturally circulating relatives in Norway of the vaccine-relevant virus species will provide baseline data on the potential off-target virus species in different locations in Norway, which will help to map strategies for prevention of spread of transgenes in the environment in the event that GM-VV products are applied in Norway.

For additional information, see «Knowledge base for the assessment of environmental risks by the use of genetically modified virus-vectored vaccines for domesticated animals» (2016) produced by the Panel on Microbial Ecology.

5.5 Genetically modified crops

5.5.1 Safety assessments of genetically modified crops (evaluation of unintended effects caused by genetic modification)

RNA interference (RNAi) is an emerging technology that offers new opportunities for the generation of novel traits in GM plants. The technique is used to produce GM plants with altered agronomic, nutritional, industrial and food-processing traits. However, there are uncertainties concerning the mode of action and the effect of application of RNAi in GMOs. RNAi raises new questions for risk assessment of GMOs.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

More research on the exact rules for small RNA-target matches is required in order to design efficient algorithms, and to make predictions regarding the effect of small RNAs in GMOs more consistent. Advancements in "omics" technologies (e.g. genomics, transcriptomics, proteomics and metabolomics) could further strengthen these predictions.

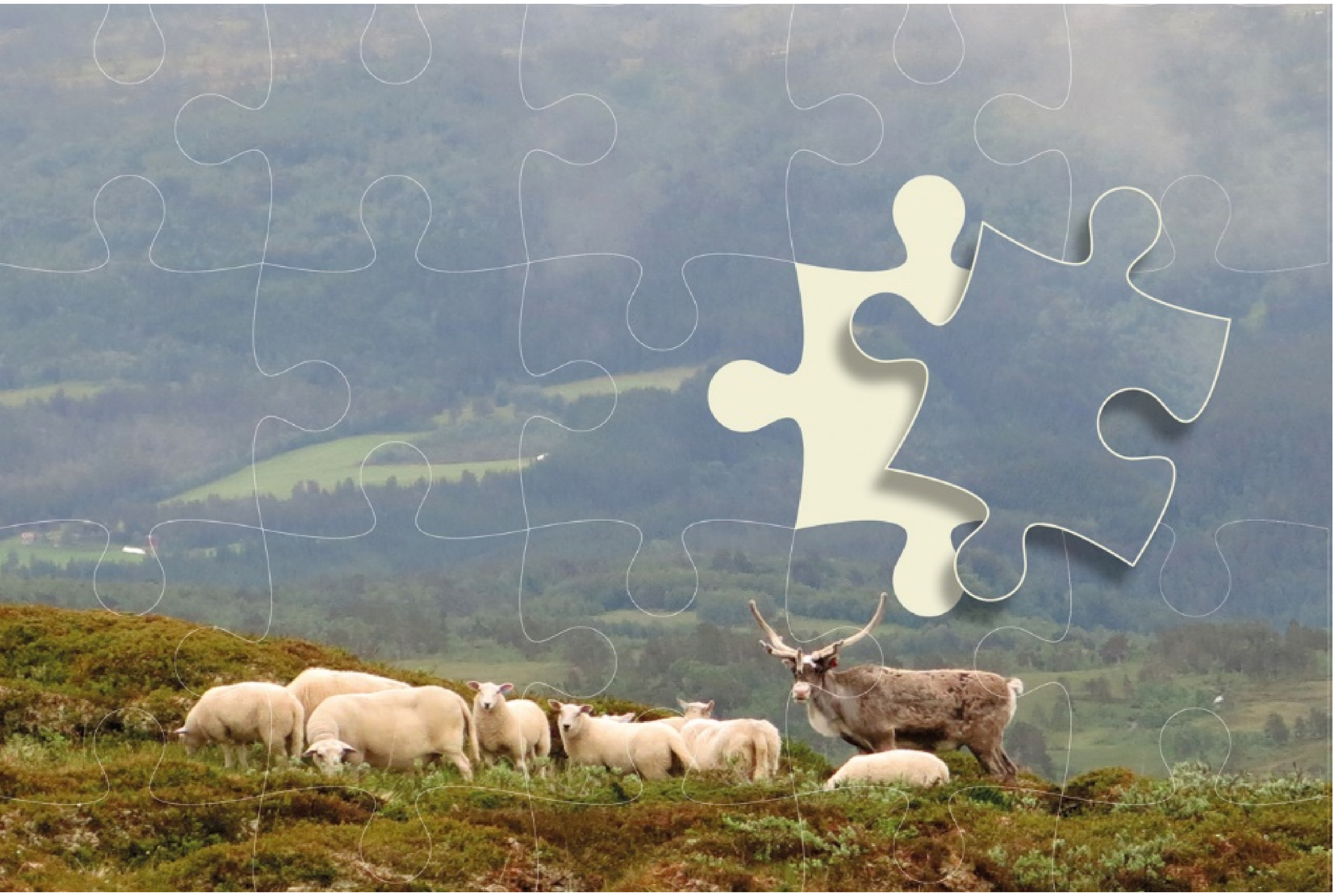
Expected effects/impact:

Future advances in omics may be used to distinguish between unintended effects caused by RNAi modifications and compositional differences caused by natural variability between GM plants and their non-GM counterparts.

Omics and bioinformatics could play a significant role in the risk assessment of RNAi-based GM plants by detecting off-target genes that require further characterisation.

For additional information, see «Research needs and data gaps of importance for food safety and protection of biodiversity from VKM's scientific opinions in the period 2005-2015» (2016) and assessments produced by the Panel on Genetically Modified Organisms since then.

6 Surveillance data for food and diet



Summary

Significant research needs and data gaps regarding surveillance data for food and diet identified in VKMs assessments follows:

- Monitoring data on occurrence of radioactivity in Norwegian food and water.
- National dietary surveys as well as epidemiological studies and studies on mechanisms of beneficial or harmful effects of food/food groups or nutrients in food/food groups

Detailed descriptions follow in this chapter.

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6.1 Radioactivity

6.1.1 Monitoring data on occurrence of radioactivity in Norwegian food

Monitoring data on occurrence of radioactivity in Norwegian food mainly reflect the most contaminated areas and food products. For food products with lower contamination levels, such as grains and vegetables, no recent Norwegian data are available. Furthermore, data on radon-222 in different types of drinking water including private supplies are lacking. Also, through food preparation and cooking some radioactivity are lost, for example caesium-137. No data exist on radioactivity in prepared food.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

More measurements of radioactivity in foodstuffs that are representative for the Norwegian diet, including natural radioactivity in seafood. For example, a Total Diet Study establishing the mean concentration of different substances, including radioactive elements, in selected prepared food would provide an improved scientific basis for estimating dietary exposure in food relevant for the Norwegian population.

Information about the number of people served by different types of drinking water supplies, including source and treatment, is necessary in order to estimate national mean levels of radon-222.

Expected effects/impact:

Improved reliability of radioactivity dose estimates in Norway.

For additional information, see «Risk assessment of radioactivity in food» (2017) produced by the Scientific Steering Committee.

6.1.2 Methodology for effective doses

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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

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

Expected effects/impact:

Improved reliability of radioactive doses to children.

For additional information, see «Risk assessment of radioactivity in food, 2017» published by the Scientific Steering Committee.

6.2 Dietary surveys

Changes in eating habits/diets, food production methods and the continually development of new food products 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. Biomarkers, biobanks and health registers linked to dietary surveys will provide better knowledge about the relationship between food, the diet and health.

6.2.1 National dietary surveys

National dietary surveys provide information on dietary habits (what is eaten and how much), and need to be conducted on a regular basis.

The national dietary surveys cover three different age groups. «Sped- and 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, both at mean level and for the lower and the higher end intakes like the 5th and 95th-percentile.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- A continuous rolling programme for national dietary surveys for all age groups is needed (every 5-10 years).

- The surveys should be designed to capture variations in intake of substances, foods/food groups, and include high consumers of the specific substance or foods/food groups.
- A sufficient number of participants must be recruited, to allow for exposure calculations of the outer limits of the intake (5th- and 95th percentiles).
- Conducting regular dietary surveys which give comparable results from survey to survey enable us to follow trends in dietary habits.

Expected effects/impact:

National dietary surveys will provide information on dietary habits (what is eaten and how much) in the Norwegian population.

For additional information, see the 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy.

6.2.2 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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- 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, wild mushrooms, game etc.) are needed.
- Data on population groups that follow special diets (e.g. vegetarian and vegan) and ethnic food patterns are needed.
- Data on food packaging materials, product name/brand, production method and country of origin are needed.

Expected effects/impact:

Knowledge and data on consumption of foods and food groups with particularly high concentrations and highly exposed population groups will be available for future assessments.

6.2.3 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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- TDS including analyses on levels of selected pesticide residues, contaminants, toxins, radionuclides, nutrient and non-nutrient elements is needed. Updated food lists from the national dietary surveys in different population groups are used to collect and analyse the food that consumers eat.

- To investigate time trends (change over time), a continuous data collection program with yearly or cyclic data collections is required.

Expected effects/impact:

The results from a TDS would provide a basis for detecting possible chronic risks from contaminated food. A TDS will be used to calculate the intake and exposure from the diet in the different population groups in Norway. A TDS would be a useful tool in addition to surveillance programs. A TDS will not make other surveillance programs on food/contaminants/pesticides redundant, but would be a valuable addition to establish levels of exposure of the average Norwegian population.

6.2.4 Regular submission of data to EFSA

In EU, the comprehensive food consumption database contains information on food consumption across Europe. Detailed data for a number of EU countries are included, and the database plays a key role in the evaluation of the risks and allows estimates of consumers' exposure. Norway has been invited to contribute with data from the national dietary surveys; and Norkost 3 will in 2018, be entered into the EFSA food database FoodEx2.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- All Norwegian food dietary surveys should be performed with a methodology that allow for submission of the data to the EU food consumption database.

Expected effects/impact:

The need for specific Norwegian risk assessments on substances/issues EFSA has assessed will be reduced, when Norwegian data is included in this database.

6.3 Nutrients

6.3.1 Analytical data for nutrients

Changes in the food production may cause changes in the nutrient content in food products. Nutrient content in all food groups constitutes essential background data in several assessments of nutrient intakes in relation to tolerable upper intake levels. Norwegian food composition data for certain nutrients, such as e.g. vitamin K, is lacking.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- A periodical update of nutrient content in raw food and commercial food products, including food supplements is needed. New and modified food products are introduced to the Norwegian food market and there is special need for surveillance of the nutrient content in these food products.

Expected effects/impact:

Updated information on nutrient content in all food groups essential as background data in several assessments of nutrient intakes in relation to tolerable upper intake levels will improve the basis of future assessments.

For additional information, see the 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium (2016-2017) produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy.

6.3.2 Tolerable upper intake levels

The tolerable upper intake level (UL) is the maximum level of total chronic daily intake of a nutrient (from all sources) 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.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Updated systematic literature reviews of human and animal studies on high intakes of vitamins and minerals. 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.

Expected effects/impact:

More evidence based and updated risk assessment of vitamins and minerals.

For additional information, see the 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium (2016-2017) produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy.

6.4 Epidemiological studies and studies on mechanisms of beneficial or harmful effects of food/food groups or nutrients in food/food groups

6.4.1 Epidemiological studies

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

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- 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. Ideally, to provide data to inform tolerable upper intake levels for nutrients, toxicity studies with graded oral supplement doses should be performed in humans. For ethical reasons, such data is scarce.
- 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 well-defined cohort studies covering large age ranges.

Expected effects/impact:

The data collections described above may be combined with several biological measurements and linked with endpoints from registers. Examples of currently existing cohorts in Norway with repeated data collections in large samples over decades are the Tromsø study and the Nord-Trøndelag Health Study.

For additional information see:

- the 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium (2017 and 2016);

- the 20 opinions regarding doses of “other substances” in food supplements; alanine, arginine and arginine alpha ketoglutarate, aspartic acid, betaalanine, branched chained amino acids (leucine, isoleucine and valine), creatine, cystin and cysteine, glutamine and glutamic acid, glycine, histidine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, conjugated linoleic acids (CLAs) and n-3 fatty acids; Eicosapentaenic acid (EPA), Docosapentaenic acid (DPA) og Docosahexaenic acid (DHA) produced by the Panel on Nutrition, Dietic Products, Novel Food and Allergy. The 15 opinions regarding doses of “other substances” in food supplements and/or energy drinks: l-Carnitine and l-Carnitine-L-tartrate, l-citrulline, coenzyme Q10, collagen from fish skin, d-Ribose, glucuronolactone, inositol, lecithin from sunflower, taurine, caffeine, curcumin, isoflavones from soy, lycopene, piperine from black pepper and inulin produced by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics.

6.4.2 Studies on mechanisms of beneficial or harmful effects

Mechanistic studies using animal models are lacking.

Suggestion(s) as to what research, surveillance and other forms of data collection can contribute follows:

- Animal studies are used e.g. to get more insight into mechanisms of actions regarding the development and progression of adverse health effects. In the absence of sufficient human data, knowledge on mechanisms of beneficial or harmful effects resulting from the intake of specific food/food groups from animal testing is needed, e.g. to identify safe use in terms of diseases and duration of exposure.

- Mechanistic studies using in vitro models are useful in the absence of adequate human and animal data.

Expected effects/impact:

- Knowledge on mechanisms of beneficial or harmful effects resulting from the intake of specific food/food groups from animal testing can be employed in the absence of sufficient human data, to identify safe use in terms of diseases and duration of exposure among others.
- In the absence of adequate human and animal data, information about mechanisms of action could be deduced from properly performed in vitro testing using primary cells or cell lines.

For additional information, see:

- the 15 opinions regarding tolerable upper intake levels and maximum limits for vitamins and minerals in food supplements; vitamin B6, nicotinic acid and nicotinamide, vitamin C, vitamin D in children and adolescents, vitamin E, beta-carotene, folic acid, calcium, magnesium, phosphorus, iron, zinc, selenium, copper and potassium (2016 and 2017);
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