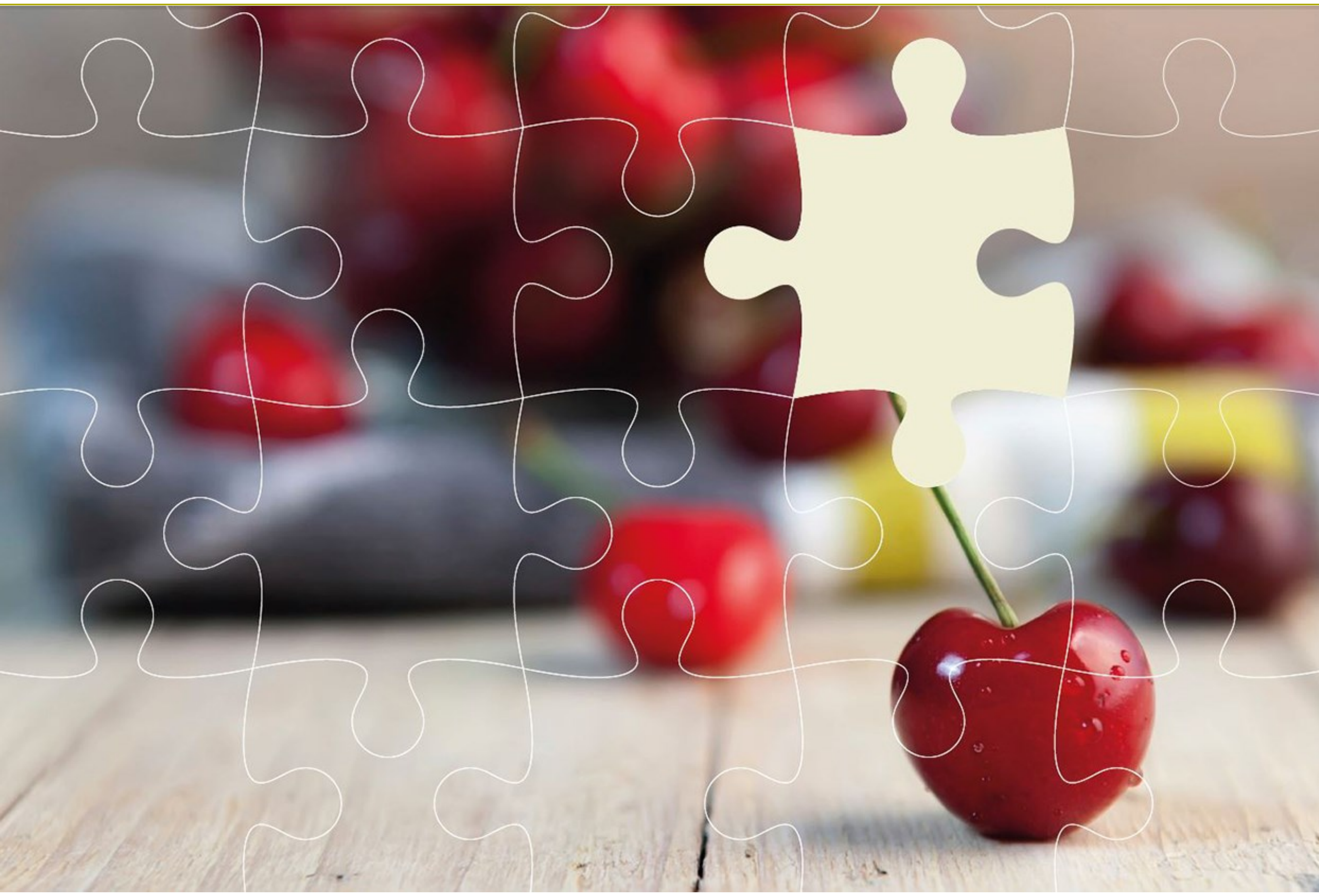
Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety



VKM Report 2016: 48

Research needs and data gaps of importance for food safety and protection of biodiversity

From VKM's scientific opinions in the period 2005 - 2015

The Scientific Steering Committee of the Norwegian Scientific Committee for Food Safety (VKM)

Research needs and data gaps of importance for food safety and protection of biodiversity. From VKM's scientific opinions in the period 2005 - 2015

Report from the Scientific Steering Committee of the Norwegian Scientific Committee for Food Safety (VKM) 2016: 48

ISBN: 978-82-8259-238-3
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Cover photo: iStock Photo

Suggested citation: VKM. (2016) Research needs and data gaps of importance for food safety and protection of biodiversity. From VKM's scientific opinions in the period 2005 - 2015. Report of the Scientific Steering Committee of the Norwegian Scientific Committee for Food Safety, ISBN: 978-82-8259-238-3, Oslo, Norway.

Research needs and data gaps of importance for food safety and protection of biodiversity

From VKM's scientific opinions in the period 2005 - 2015

Assessed and approved

The report has been assessed and approved by the Scientific Steering Committee. Members of the Scientific Steering Committee are: Jan Alexander (chair), Lene Frost Andersen, Åshild Andreassen, Edel Oddny Elvevoll, Gro-Ingunn Hemre (vice-chair), Brit Hjeltnes, Merete Hofshagen, Per Ole Iversen, Åshild Krogdahl, Torstein Källqvist, Trond Rafoss, Ida Skaar, Janneche Utne Skåre, Hilde-Gunn Opsahl Sorteberg, Inger-Lise Steffensen, Vigdis Vandvik, Yngvild Wasteson.

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Acknowledgment

All VKM Panel members that contributed to the present report are greatly acknowledged. The draft report was prepared by VKM staff (members of the project group were Angelika Agdestein, Gro Haarklou Mathisen (project leader), Danica Grahek-Ogden and Edgar Rivedal). Gro-Ingunn Hemre, Merete Hofshagen and Jan Alexander are acknowledged for their valuable comments and views on this report.

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 aim of the present report is to highlight research needs and data gaps that are of future importance for food safety and protection of biodiversity.

The Norwegian Scientific Committee for Food Safety (VKM) produces and communicates scientific opinions, i.e. risk- and risk-benefit assessments, with the main goal of securing food safety and protection of biodiversity.

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.

Biodiversity is the basis for ecosystem health and functioning, and thus for the provision of a range of ecosystem services essential for human well-being. The wide-ranging decline in biodiversity results largely from habitat loss and degradation, increased rates of invasions by deliberately or accidentally introduced non-native species, over-exploitation of natural resources and other human-caused disturbances. The impact of these processes may be further accelerated by climate changes.

Norwegian conditions may in many respects differ from other countries, e.g. dietary habits and climate. Therefore, research and surveillance data from other countries may be of less or no relevance for Norwegian conditions. This knowledge must therefore be obtained nationally by active research communities.

This report includes only research needs and/or data gaps identified in and related to VKM scientific opinions during the period 2005-2015.

VKM highlights the following research needs and data gaps as they are of great importance for our society:

- Knowledge on possible impacts of climate change and globalization on Norwegian food production and the food safety.
- Knowledge on possible impacts of climate change and globalization on Norwegian nature and biodiversity.
- Knowledge on what we eat, which substances the food contains, and the relationship between intake of various foods and health and disease.
- Knowledge on foodborne pathogens, food production and antibiotic resistance in Norway.
- Knowledge on how to assess simultaneous exposure to multiple chemicals.
- Knowledge on health and environmental effects of nanomaterials in food and cosmetics.

An overview of more specified reported research needs and data gaps follows below:

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

- Pesticide fate under Norwegian conditions; degradation, mobility, models for half-lives, and the impact of culture plants.
- Plant pests under Norwegian conditions; epidemiology and population dynamics, monitoring, models for behavior and development, and effects of climate changes and/or globalization.
- Non-traditional feed ingredients; impact on animal health and welfare, production efficiency, product quality, and contaminant and nutritional composition of the final food product.
- Data on content of nutrients, contaminants and pathogens in the food production chain (food ingredients and/or processed food), including knowledge on trends.
- Models predicting transfer of contaminants from animal feed to the food chain.
- Foodborne pathogens, antimicrobial resistance in these.

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

- Transmission of infectious fish diseases under Norwegian conditions.
- Parameters for fish welfare.
- Effects of water quality on fish health and/or welfare.
- Non-traditional feed ingredients; impact on animal health and welfare, production efficiency, product quality and contaminant and nutritional composition of the final food product.
- Data on nutrients, contaminants and pathogens in the food production chain (food ingredients and/or processed food), including knowledge on trends.

- Models predicting transfer of contaminants from animal feed to the food chain.

Human health

- Data on what we eat, how much, and how often.
- Relationships between food/food groups and the prevention or development of disease.
- Presence and concentration of pathogens in drinking water.
- Diseases caused by foodborne pathogens or contaminants in food and the disease burden (loss of health and mortality).
- The stability and solubility of nanomaterials in food, in the gastrointestinal tract and in biological tissues.
- Negative health effects of organic nanomaterials.
- Skin absorption and metabolism of cosmetic ingredients.
- Exposure and use of cosmetics.
- Toxicological data on nanomaterials in cosmetics.

Biodiversity

- Alien species under Norwegian conditions; epidemiology and population dynamics, surveillance, models for behavior and development, and models for effects of climate changes.
- Effects of pesticides on bees and other pollinating insects.

Combined exposures

- Methods for risk assessment of combined exposures of chemicals.

Surveillance data for food and diet

- A regularly updated food database with data on food intake in the Norwegian population and data on presence and concentrations of nutrients, contaminants and foodborne pathogens in food.

Sammendrag på norsk

Målet med denne rapporten er å synliggjøre kunnskapsbehov som er viktige for å sikre trygg mat og opprettholdelse av biologisk mangfold i årene som kommer.

Vitenskapskomiteen for mattrygghet (VKM) utarbeider og kommuniserer uavhengige, vitenskapelige uttalelser, blant annet risikovurderinger og nytte-risikovurderinger. Hovedmålet til VKM er å sikre trygg mat og opprettholdelse av biologisk mangfold.

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

Biologisk mangfold og velfungerende økosystemer bidrar til økosystemtjenester av avgjørende verdi for menneskers velferd. Det omfattende tapet av biologisk mangfold er i stor grad et resultat av tap og forringelse av leveområder, økende introduksjon av fremmede arter, overbeskatning av naturressurser og andre menneskeskapte aktiviteter. Klimaendringer kan akselerere disse prosessene ytterligere.

Norske forhold kan på flere måter skille seg fra andre lands, slik som kosthold og klima. Det gjør at forsknings- og overvåkingsdata fra andre land kan ha liten eller ingen relevans for Norge, og at kunnskap om særnorske forhold må genereres nasjonalt. Dette forutsetter at vi har aktive norske forskningsmiljøer innenfor fagområder hvor det er behov for kunnskap om særnorske forhold.

I arbeidet med risikovurderinger har VKM identifisert en rekke områder hvor det trengs mer og ny kunnskap for å sikre trygg mat og biologisk mangfold. Denne rapporten inkluderer kun kunnskapsbehov som er identifisert i og/eller relatert til VKM's vitenskapelige uttalelser i perioden 2005-2015.

VKM mener det er særlig viktig å dekke følgende kunnskapsbehov for å sikre trygg mat og biologisk mangfold:

- Kunnskap om hvilke virkninger klimaendringer og økt globalisering kan ha på norsk matproduksjon og mattrygghet.
- Kunnskap om hvilke virkninger klimaendringer og økt globalisering kan ha på norsk natur og det biologiske mangfoldet.
- Kunnskap om hva vi spiser, hva maten vår inneholder, og om helseeffekter av ulike typer mat.
- Kunnskap om matsmitte, matproduksjon og antibiotikaresistens i Norge.
- Kunnskap om hvordan vi skal vurdere samtidig eksponering for flere kjemikalier.
- Kunnskap om effekter nanomaterialer i mat og kosmetikk kan ha på helse og miljø.

Under følger en oversikt over mer spesifikke rapporterte kunnskapsbehov:

<u>Landbruk og matproduksjon</u>

- Hva som skjer med plantevernmidler i miljøet under norske forhold; hvordan de brytes ned, modeller for halveringstid og hvordan kulturplanter eventuelt påvirker dette.
- Planteskadegjørere under norske forhold; epidemiologi og populasjonsdynamikk, overvåking, modeller for atferd og utvikling og modeller for effekter av klimaendringer og/eller globalisering.
- Hvordan nye fôrråvarer kan påvirke husdyrs helse og/eller velferd, produksjonseffektiviteten, ernæringsmessig kvalitet og innhold av fremmedstoffer i matvaren.
- Analyser av innhold av næringsstoffer, fremmedstoffer og smittestoffer i matvarer(ingredienser og ferdig bearbeidet mat) og hvordan utviklingen er over tid.
- Modeller for overføring av fremmedstoffer fra fôr til mat.
- Smittestoffer og antibiotikaresistens i disse.

<u>Fiskeri, havbruk og sjømatproduksjon</u>

- Hvordan smittsomme fiskesykdommer overføres under norske forhold.
- Hvordan fiskevelferd kan måles.
- Hvordan vannkvalitet kan påvirke fiskens helse og/eller velferd.
- Hvordan nye fôrråvarer kan påvirke fiskens helse og/eller velferd, produksjonseffektiviteten, ernæringsmessig kvalitet og innhold av fremmedstoffer i matvaren.
- Analyser av innhold av næringsstoffer, fremmedstoffer og smittestoffer i matvarer (ingredienser og ferdig bearbeidet mat) og hvordan utviklingen er over tid.
- Modeller for overføring av fremmedstoffer fra fôr til mat.

Human helse

- Hva vi spiser, hvor mye vi spiser og hvor ofte.
- Sammenhenger mellom mat/matvaregrupper og forebygging og utvikling av sykdom.
- Forekomst og konsentrasjon av smittestoffer i drikkevannet.
- Sykdommer som er forårsaket av matsmitte eller kontaminanter og hvordan befolkningen rammes i form av helsetap og dødelighet.
- Hvor stabile og hvor løselige nanomaterialer er i mat,i magen og tarmkanalen og i kroppsvev.
- Organiske nanomaterialer og mulige negative helseeffekter.
- Ulike ingredienser i kosmetikk og opptak over hud og metabolisme.
- Hvor mye som brukes av ulike typer kosmetiske produkter.
- Potensielle negative helseeffekter av nanomaterialer i kosmetikk.

Biologisk mangfold

- Hvordan nye fremmede arter vil kunne klare seg under norske forhold; epidemiologi og populasjonsdynamikk, overvåking, modeller for atferd og utvikling og modeller for effekter av klimaendringer.
- Hvilke effekter plantevernmidler har på bier og andre pollinerende innsekter.

Kombinasjonseffekter

- Metoder for risikovurdering av kombinasjonseffekter av kjemiske stoffer.

Overvåkning av mat og kosthold

- Databaser med informasjon om hva vi spiser og hva maten vår inneholder (næringsstoffer, fremmedstoffer og smittestoffer). Slike databaser må oppdateres jevnlig.

1 Introduction

The Norwegian Scientific Committee for Food Safety (VKM) produces and communicates scientific opinions, mainly risk assessments, with the main goal of securing food safety and protection of biodiversity.

The aim of the present report is to highlight research needs and data gaps that are of future importance for food safety and protection of biodiversity.

VKM highlights the following research needs and data gaps as they are of great importance for our society:

- Knowledge on possible impacts of climate change and globalization on Norwegian food production and the food safety.
- Knowledge on possible impacts of climate change and globalization on Norwegian nature and biodiversity.
- Knowledge on what we eat, which substances the food contains, and the relationship between intake of various foods and health and disease.
- Knowledge on foodborne pathogens, food production and antibiotic resistance in Norway.
- Knowledge on how to assess simultaneous exposure to multiple chemicals.
- Knowledge on health and environmental effects of nanomaterials in food and cosmetics.

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.

Biodiversity is the basis for ecosystem health and functioning, and thus for the provision of a range of ecosystem services essential for human well-being. The wide-ranging decline in biodiversity results largely from habitat loss and degradation, increased rates of invasions by deliberately or accidentally introduced non-native species, over-exploitation of natural resources and other human-caused disturbances. The impact of these processes may be further accelerated by climate changes.

This report includes only research needs and data gaps identified in and related to VKM scientific opinions during the period 2005-2015.

1.1 Risk assessment

A risk assessment consists of three key elements: hazard assessment, exposure assessment and risk characterisation. The risk characterisation integrates knowledge on hazard and exposure. The assessment is based on the scientific documentation available, including e.g. peer reviewed articles, previous risk assessments from national and international institutions, data from national and international surveillance and monitoring – in particular exposure data, and studies and data provided by the industry.

During the process of performing a risk assessment, data gaps and research needs are identified. Lack of knowledge may be an important source of uncertainty in the outcome of the assessment, and may result in uncertainties in the conclusions. These uncertainties could be reduced provided that the missing information is made available through research, surveillance and/or monitoring. In order to be open and transparent, needs for research, surveillance and/or monitoring are expressed in the assessments.

Factors critical for risk assessments include

- High quality research and/or data that are common and can be applied generally. Such knowledge is generated by the international scientific community or by surveillance or monitoring organized by international organizations.
- High quality research and/or data that are country specific. Since Norwegian conditions may differ from other countries (e.g. the Norwegian dietary habits and the Norwegian climate), research and surveillance data from other countries may be of minor or no relevance for risk assessments related to Norwegian conditions. This knowledge must therefore be obtained nationally.
- Highly competent experts within all areas of VKM's mandate are essential. The recruiting basis are from active research groups at universities, research institutes etc.

1.2 About VKM

VKM produces and communicates scientific opinions, i.e. risk- and risk-benefit assessments, with the main goal of securing food safety and protection of biodiversity. VKM assess risks within the following areas:

Food safety	Biodiversity
• Biological Hazards • Plant Protection Products • Genetically Modified Organisms • Food Additives • Flavourings • 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	• Plant Protection Products • Genetically Modified Organisms • Alien Organisms • Trade in Endangered Species (CITES) • Microbial Ecology

VKM's risk assessments are performed at the request of the Norwegian Food Safety Authority and the Norwegian Environment Agency, which use the assessments when managing risks, in giving advice to the relevant ministries, choosing measures to take and developing new laws and regulations.

1.3 How to use this report

VKM has identified research needs and data gaps related to specific topics. Therefore, the report is 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.

The aspects of food safety throughout the production chain show a complex pattern of connections between human health, plant health, animal health and welfare, and biodiversity. Knowledge needs or data gaps might be of significance at several steps in the production chain and in several areas. Therefore, some research needs and data gaps will be 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, nanomaterials and cosmetics (Chapter 4)
- Biodiversity (Chapter 5)
- Combined exposures (Chapter 6)
- Surveillance data for food and diet (Chapter 7)

2 Agriculture, terrestrial food production and terrestrial animals

Summary

Knowledge within the area of agriculture, terrestrial food production and terrestrial animals must cover Norwegian conditions and changes in the food production, and in addition emphasize the effect of climate change and increased globalization. The research needs and data gaps include:

- Pesticide fate under Norwegian conditions; degradation, mobility, models for half-lives, and the impact of culture plants.
- Plant pests under Norwegian conditions; epidemiology and population dynamics, monitoring, models for behavior and development, and effects of climate changes and/or globalization.
- Non-traditional feed ingredients; impact on animal health and welfare, production efficiency, product quality, and contaminant and nutritional composition of the final food product.

- Data on content of nutrients, contaminants and pathogens in the food production chain (food ingredients and/or processed food), including knowledge on trends.
- Models predicting transfer of contaminants from animal feed to the food chain.
- Foodborne pathogens, antimicrobial resistance in these.

Only research needs and data gaps related to VKM risk assessments are included. A detailed presentation is given in this chapter.

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2.1 Environment

2.1.1 Pesticide fate under Norwegian conditions

2.1.1.1 Degradation and mobility of pesticides under Norwegian conditions

Accumulation of pesticides in the environment is considered undesirable. Standardized laboratory data on degradation and mobility of pesticides are available (European data), however, data from the Norwegian Agricultural Environmental Monitoring Programme (JOVA) suggests that some types of pesticides behave differently under Norwegian conditions. Degradation studies from various localities in Norway show a large variation in the estimated half-life for pesticides.

- Knowledge on the fate (degradation and transport) of pesticides under Norwegian conditions is needed. Factors that should be considered are covering of snow and freeze-thaw processes, combined with rainfall episodes, topography and soil type.

This knowledge will clarify the usefulness of European data for Norwegian conditions, and is therefore essential when approving new pesticides.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011) and «Degradation and mobility of pesticides in Norwegian soils» (2015).

2.1.1.2 Models for half-lives of (persistent) pesticides

The half-life values for the commonly used pesticide propiconazole recommended by the EU are from 29 to 70 days. However, degradation experiments performed in laboratories at 20° showed half-lives ranging from 45 days to more than 1000 days for different Norwegian soil types. Laboratory data for persistent chemical compounds are particularly difficult to use, since the half-life usually goes far beyond the duration of the experiment, and therefore requires extrapolation.

- Field tests with repetitive spraying using some of the most persistent pesticides are needed.

This knowledge will clarify the usefulness of European data for Norwegian conditions. Further, such studies could also be used to validate models such as the Finnish PEC calculator (a calculator for predicted environmental concentration in soils). This knowledge is important when approving new pesticides.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011) and «Degradation and mobility of pesticieds in Norwegian soils» (2015).

2.1.1.3 Surface runoff of pesticides - effect of vegetation zones with different slopes, cultures and precipitation

Buffer strips (security zones with different vegetation) is a possible measure to reduce the impact of pesticide runoff. In the report FOCUS 2000 by FOCUS DG SANTE (the forum for co-ordination of pesticide fate models and their use, the European Commission) it is emphasized that the effectiveness of buffer zones should be assessed in each individual case. Whether data on surface runoff of pesticides generated in central Europe are representative for Norwegian conditions is often questioned when approving new pesticides. Particularly vulnerable are pesticides that bind strongly to soil particles which are transported to lakes and rivers in rainfall episodes due to erosion.

- Data on surface runoff of pesticides under Norwegian conditions are needed. Factors that should be considered are soil characteristics, width of buffer zones, density of plant growth and precipitation.

Knowledge on the faith of pesticides in the environment is an important part of the risk assessment performed when considering applications for use.

For additional information, see «Degradation and mobility of pesticides in Norwegian soils» (2015).

2.1.2 Biodiversity

2.1.2.1 Effects of pesticides on bees and other pollinating insects

There is international awareness of the issue of bees and pesticides. It is important to assess the situation for bees and other pollinating insects in Norway, and to evaluate the possible impact of neonicotinoid pesticides.

- A review of the existing literature and experience of relevance for Norwegian conditions is needed.

This knowledge will provide a basis for better understanding and thus relevant national measures.

2.1.3 Contaminants in fertilizers and soil conditioners

2.1.3.1 Contaminants in sewage sludge used as fertilizer and soil conditioner

The number of chemicals with potential entry to agricultural soil via sewage sludge is high. These chemicals, including e.g. biological active compounds such as pharmaceuticals, cover a broad range of physicochemical properties and many are pH-sensitive. This is in contrast to the regulated persistent organic pollutants which commonly are hydrophobic and seldom pH-sensitive.

- Data on presence and concentration of contaminants in sewage sludge used as fertilizers or soil conditioners are needed.
- Research on factors of importance for environmental fate of contaminants, such as degradation kinetics (rates, half-lives) under different environmental conditions, distribution- and partition coefficients (for example between soil/sediment, octanol/water) and bioaccumulation is needed.
- Toxicity values for contaminants (described as Predicted No Effect Concentration (PNEC)) in soil and aquatic environment are needed.

This knowledge is essential for risk assessments of sewage sludge as fertilizer and soil conditioner.

For additional information, see «Risk assessment of contaminants in sewage sludge applied on Norwegian soils» (2009).

2.1.3.2 Establishing a guideline for food safety risk assessments of contaminants in organic fertilizers and soil conditioner

Sewage sludge, allowed used as fertilizer and soil conditioner, may contain contaminants. For example, a long list of persistent and hydrophobic halogenated flame retardants is detected in sewage sludge. It is also recognized that highly persistent and water soluble positively charged contaminants are transferred and found in mg/kg levels in sewage sludge. The uptake and metabolism kinetics for the contaminants varies, and hydrophobic contaminants accumulate in root vegetables whereas water soluble contaminants accumulate in root, leaves and even in seeds. It is known that uptake and further translocation/distribution vary between different plants species and different chemicals. For plants used as forage, the bioaccumulation factor for one specific chemical was e.g. reported to be 40 in grasses and 70 in cereals.

- Knowledge on contaminant transfer from fertilizers and soil conditioners to food is needed. This includes knowledge on environmental fate quantity and quality of input data, available databases for input data and knowledge on which models that are

most suitable and for different contaminants. The models should be tested for selected emerging contaminants where sufficient information is available.
- For risk assessments of contaminants in fertilizers and soil conditioners, data/knowledge about environmental fate kinetics, including uptake models, is needed.
- For organic contaminants, which vary highly in physicochemical properties, improved models for estimating environmental fate and uptake in plants are needed.

This knowledge is essential for risk assessment of sewage sludge as fertilizers and soil conditioners in food production. With enhanced focus at circular economy, the use of sewage sludge as fertilizers and/or soil conditioners may increase. To ensure the safety of the food, improved risk assessment tools are important.

For additional information, see «Risk assessment of contaminants in sewage sludge applied on Norwegian soils» (2009).

2.2 Plant health

2.2.1 Plant pests

2.2.1.1 Epidemiology and population dynamics of plant pests (including possible new pests) under Norwegian conditions

A continuous increase in import of fruits, vegetables and ornamental plants has the potential to increase the risk/increase the pressure of new plant pests entering the country

- Research on epidemiology and population dynamics for new plant pests under Norwegian conditions is needed.
- Research on epidemiology and population dynamics for plants pest already present in Norway is needed. As an example: the plant pest pinewood nematode (PWN) might be imported to Norway. The nematode is vectored, or carried, by a number of bark beetles and wood borers. Potential beetle vectors are present in Norway, but more research is needed to verify the suitability and distribution of these vector beetles.
- The efficacy of eradication of plant pests using updated methods of trapping technology based on attractants must be tested.

Changes in the plant pest status in Norway may lead to higher production costs and increased use of pesticides. Knowledge on epidemiology and population dynamics of plant pests under Norwegian conditions is essential when predicting the behaviour of specific pest, the potential for establishment, spread and damage to natural and cultivated plants in Norway, and possibilities for pest eradication.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

2.2.1.2 Development of a reliable contingency plan for the pinewood nematode

Several countries in Europe aim at avoiding the introduction of the pinewood nematode (a forest pest) by e.g. developing contingency plans. Also in Norway a contingency plan against the pinewood nematode has been developed. However, in two VKM risk assessments serious weaknesses have been pinpointed. The case of contingency planning for pinewood nematode is also interesting in general for contingency planning under Norwegian conditions.

- Research needs to improve the basis for the contingency plan:
    - Taxonomic research is needed to clearly distinguish the exact distribution of the longhorn beetles *Monochamus galloprovincialis* and *Monochamus sutor* in Norway. The first specie is a verified vector of the pinewood nematode and may be more widely distributed in Norway than previously assumed. The latter specie is believed to be a suitable vector and is widely distributed in Norway. However, it remains to perform experiments to verify its suitability as vector for the pinewood nematode.
    - Mark-recapture studies are necessary to determine the dispersal capabilities of *Monochamus galloprovincialis* and *Monochamus sutor.*

The pinewood nematode can cause enormous costs due to damage and control measures. This knowledge is important for the development of a reliable contingency plan. If trapping with attractants is to be used as a part of a strategy for early detection of the pinewood nematode, data from mark-recapture experiments can be used to estimate the efficiency of the traps and how wide surrounding circle is included by the trapping. Based on these results, simulation models may be used to estimate the likelihood of success in eradication at different levels of effort.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

2.2.1.3 Models for behaviour and development of plant pests under Norwegian conditions

Growth, survival and spread of plant pests are to a great extent dependent on climatic factors such as temperature, humidity, precipitation and radiation. Changes in climate will influence the speed of the development of a plant pest, the speed of defense responses of the host plants, and the interactions between the host and the pest. Quantitative models estimate how the development of the pest changes during time and space, in relation to changes in climate and susceptibility of the host plant. Quantitative models give a causal connection between variables of the weather and development of the pest. Models based on weather have been used in plant pest management in several countries, are based on regional weather conditions, and are specific for the region or the country.

- Models to predict the behaviour and development of plant pests under Norwegian conditions are needed. In such models, weather data should be correlated with knowledge on the life cycle of the plant pest and its hosts.
    - A specific model is required for a specific pest or group of pests.
    - Data on epidemiology and population dynamics for the pest is important input to the model.
    - Other organisms that might carry the pest (vectors) must be quantified in the model.

Quantitative models are important to reduce uncertainties in risk assessment and risk management of plant pests. Models for behavior and development of plant pests based on agro-climatic conditions in Norway are required to estimate development of plant pests under Norwegian conditions. Using models based on agro-climatic conditions in other countries, the uncertainties related to the relevance of the results for Norwegian conditions will be high.

Such models should be used together with climate models for the next ten years. The empirical basis for the models, the input data, should be transparent and visible to ensure that the reliability and uncertainties of the model predictions can be evaluated before any management decisions are made. It is important that the Norwegian research community knows and masters the latest within model methodology and techniques

For additional information, see «Forskningsbehov påpekt av VKM 2012» (2012).

2.2.1.4 Monitoring new and potentially harmful pests

New and harmful plant pests, including quarantine pests, are repeatedly detected in imported plants. Since plant propagation is labour intensive, European companies have moved parts of their propagation to countries with low production costs (in Eastern Europe, Asia, and Africa). Production for export to Europe, e.g. African rose production and fruit and vegetable production in Latin America, is rapidly increasing. Raw materials for Norwegian wood-processing industry arrive mostly from overseas countries. The commodities are distributed so quickly and efficiently, that the risk is high that plant pests follow undetected, and that symptoms of infections do not develop before the commodities have arrived at Norwegian nurseries, stores and industrial plants.

- Sensitive and reliable methods for diagnostics of plant pests (specific plant pests) must be developed and/or established. Such methods can be based on techniques like DNA barcoding and real time PCR.

The methods are to be used in analyses of import consignments, and for monitoring of the plant health situation in Norway. A well-functioning system for quick and reliable detection and identification of plant pests is mandatory to prevent establishment and spread of organisms harmful to plants in Norway. In addition, such a system forms the basis for necessary eradication or regulation measures. A proactive effort to increase our knowledge on the biology of plant pests, and to develop the best methods for diagnostics, will help both scientists and risk managers to react quickly and efficiently concerning new or already established pests. Good methods for diagnostics will contribute to more reliable information on emerging plant health risks and on the actual plant health situation in Norway.

For additional information, see «Forskningsbehov påpekt av VKM 2012» (2012).

2.2.1.5 Retrospective studies on effects of climate changes on plant pests

It is highly/most certain that the expected climate changes will affect the plant health situation in Norway. On the other hand, it is highly uncertain how the plant pest will be affected by changes in climate. Together with the presence of host plants, temperature and precipitation are the most important factors affecting establishment of a plant pest, plant pathogens and weeds. An increase in the temperature may affect harmful organisms that are already present in the country, and exotic harmful organisms might be able to survive and cause damage to both natural vegetation and cultivated plants. A longer growth season may increase the generation number of plant pests and prolong epidemics caused by plant pathogens. It is commonly mistaken that experiences with a pest in southern latitudes can be transferred directly to future conditions in Norway. Especially light conditions, such as day length that is independent of climate changes, together with winter conditions, such as covering of snow and freeze-thaw processes, makes it impossible to automatically conclude that the future plant health situation in Norway will be the same as seen further south in today’s climate. Also, climate and topography in Norway differs from the other Nordic countries, thus, an extrapolation of experiences in those countries might also be difficult in many cases.

- Analysis of experienced climate changes versus experienced changes in behaviour of plant pests in Norway is needed. An in-depth evaluation of the climate changes observed in recent decades should be made together with changes in behaviour and spread of the plant pest seen during the same period. Such retrospective studies require monitoring/survey data of the plant pest, and studies on behaviour/population dynamics would also be useful. These studies may utilize data

from monitoring programmes, such as the Norwegian monitoring of the European spruce bark beetle with yearly data from more than 100 municipalities back to 1979.
- Models to estimate changes in temperature and precipitation are needed. Different models for different organisms should be developed. Retrospective studies will be a very useful input to such models. In many cases such studies will be a more reliable basis than the use of climate scenarios.

This knowledge is needed to predict the future situation for plant health in Norway.

For additional information, see «Forskningsbehov påpekt av VKM 2012» (2012).

2.2.2 Plant production

2.2.2.1 Field experiments comparing plant health in different production systems

Norway is on the northern frontier for commercial plant production with short growing season, low summer temperature and in some districts precipitation above the optimum for crops. Very few Norwegian or Nordic studies have compared the harvested crop of organic, integrated and conventional plant production.

- There is a need for Norwegian field experiments comparing plant health in different production systems. The field experiments should investigate whether there are differences in the presence and concentration of nutrients or contaminants, or in the susceptibility to plant pests and weeds.

Such field experiments are necessary to elucidate possible yield and quality differences between the harvested crops from organic, integrated and conventional plant production. Today, conclusions on possible differences have been based on studies from other parts of the world, if available. The uncertainties behind these conclusions might be significant, due to other countries' requirements to the different production regimes, use of other crops and plant varieties, and particularly due to differences in growth conditions. Norwegian field experiments would reduce these uncertainties.

For additional information, see «Comparison of organic and conventional food and food production. Part I: Plant health and plant production» (2014).

2.2.3 Pesticides

2.2.3.1 Prevention of pesticide resistance in Norway

Pesticide resistance describes decreased susceptibility of a pest population to a previously effective pesticide. Development of resistance is often a result of the repeated use of the same chemical agent for many years in row. Pests, weeds and fungi that have developed resistance to pesticides are a growing challenge and create problems for important agricultural and horticultural crops, and possibilities for eradication of quarantine pests. In many cultures, there are currently fewer approved pesticides than is prudent in order to prevent development of resistance. One problem is that alternative pesticides to be used to break resistance may belong to groups considered to have higher environmental or health risk.

- Knowledge on the current resistance situation and future risk of developing resistance is needed.
- Long-term monitoring of the effectiveness of available pesticides is needed.

The lack of knowledge and understanding of effective measures means that farmers must try out different procedures which may lead to unnecessary chemical treatments. The requested knowledge is essential for development of preventive measures to avoid/reduce the resistance problem.

2.2.3.2 The impact of culture plants on the fate of pesticides in the environment

The significance of the plant cover for pesticide fate in the environment is uncertain. Uptake and deposit of pesticides are affected by e.g. distribution of leaf mass, culture type, growth stage, germination and maturation. In addition, spraying equipment and the chemical-physical properties of the pesticides will influence the outcome. Plant uptake also affects leaching to groundwater, which is shown to be reduced by 20-40% depending on the plant cover. Row crops also affect the risk of leaching into groundwater. In EU there are no general guidelines for how such investigations should be conducted, and knowledge is sparse.

- Research on the role and impact of culture plants on the fate of pesticides in the environment, including leaching to the groundwater, is needed. Factors to be investigated are:
    - the role of the distribution of leaf mass, culture type, growth stage, germination and maturation.
    - the effect of different spraying equipment and the chemical-physical properties of the pesticides.

This knowledge is an important basis for making a satisfactory risk assessment. Today the modeling of plant uptake is based on values for inherent chemical properties of the pesticide, which in many cases is not sufficient.

For additional information, see «Degradation and mobility of pesticides in Norwegian soils» (2015).

2.3 Animal health and welfare

2.3.1 Feed

Raw materials for feed for Norwegian livestock are changing, and the use of new, non-traditional ingredients may affect the health and/or welfare of the animals.

2.3.1.1 Contaminants

Presence and concentration of mycotoxins in feed, including feed raw materials and stored feed

Mycotoxins are a diverse group of potentially toxic metabolites produced by a variety of fungal species that often contaminate feedstuffs. Fungal growth can occur in the field, at harvest, during storage, transport or processing of feedstuffs. Fungal contamination and growth are primarily related to environmental conditions such as temperature and moisture. In addition, inappropriate processing and storage conditions increase the risk of mycotoxin contamination. The most important mycotoxin-producing fungi infecting cereals during the growing season in Norway belong to the genus *Fusarium*. The most important storage fungi are species of *Aspergillus* and *Penicillium*. All three genera contain several species with different potential for mycotoxin production. Due to lack of data and large year-to-year variation, EU member states are encouraged to increase the monitoring of mycotoxins in feed and feed ingredients in order to assess the need for further legislative measures. In Norway, the surveillance of mycotoxins is limited and sporadic for both agriculture and aquaculture feed.

- Data on presence and concentration of mycotoxins (aflatoxins, ochratoxins, fumonisins, trichothecenes, zearalenone, fusaproliferin, beauvericin, enniatins and moniliformin) in feed, feed ingredients and stored feed is needed.

This knowledge is important to ensure animal health and welfare and to ensure safe food.

For additional information, see «Risk assessment of mycotoxins in cereal grain in Norway» (2013).

Effect of mycotoxin binders and inactivators in contaminated feed

Cereal grain is one of the main components of food and feed, and mycotoxins in cereal grain can pose a risk to both human and animal health. Mycotoxin contamination is expected to increase in Norway due to higher temperatures and moisture in the field and under storage.

- Research on effects of mycotoxin binders and inactivators for contaminated feed is needed.

For contaminated feed, mycotoxin binders and inactivators may be useful, but present knowledge is insufficient for effective use. This knowledge is also important to ensure animal health and welfare and to ensure safe food.

For additional information, see «Risk assessment of mycotoxins in cereal grain in Norway» (2013).

Effect of mycotoxins on domesticated animals

In animals, symptoms of mycotoxicosis include reduced feed intake, digestive disturbances, endocrine effects, immunological effects, neurological effects, various types of cancer and death. Sensitivity to mycotoxins varies greatly, both among and within species, and depends on life stage, nutritional and health status, and environmental conditions.

Pigs are, in comparison to other domestic animals, particularly sensitive to the mycotoxin DON (deoxynivalenol).

For intensively fed ruminants, there are indications of increased susceptibility to DON,T-2 ((2α,3α,4β,8α)-4,15-bis(acetyloxy)-3-hydroxy-12,13-epoxytrichothec-9-en-8-yl 3-methylbutanoate) and HT-2 (15-Acetoxy-3α,4β-dihydroxy-8α-(3-methylbutyryloxy)-12,13-epoxytrichothec-9-ene) and possibly also other mycotoxins. Feed for horses may include considerable amounts of oat, which may contain abundant amounts of T-2 and HT-2 toxins. Feed for dogs may contain considerable amounts of maize, a feed ingredient of particular mycotoxin concern with regard to fumonisin.

- Research on effects of mycotoxins in domesticated animals is needed, in particular interaction effects when several mycotoxins are present in one product.
- Research on critical factors related to effects of DON and zearalenone in feed on growing pigs (during gestation and lactation) is needed.
- Research on critical effects of mycotoxins, both effects of single mycotoxins and combinations of mycotoxins, is needed.
- Dose-response relationships of mycotoxins are needed, and the resulting NOAEL/LOAEL values can be used to establish tolerance values for domesticated animals.

In order to ensure good animal health and welfare and safe food, this knowledge is important.

For additional information, see «Risk assessment of mycotoxins in cereal grain in Norway» (2013).

2.3.1.2 Pathogens

<u>Presence and concentration of pathogens in raw materials for animal feed</u>

Microbial contamination from bacteria and viruses may enter the feed production chain and pose a risk for both animal and human health.

- Data on presence and concentration of pathogens in feed and feed ingredients is needed.

This knowledge is important to ensure animal health and welfare and to ensure safe food.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

<u>Feed production and pathogens; disinfection and survival mechanisms</u>

Feed ingredients may contain pathogens that pose a risk for both domestic animals and humans. Pathogens entering the production environment may survive there and cross-contaminate subsequent feed batches. Research on *Salmonella* in feed factories suggests that these bacteria may survive in biofilms. Heat treatment is a measure to reduce the presence and concentration of pathogens during feed production.

- Research on the effect of heat treatment on presence and concentration of pathogens in feed is needed, including studies on effects of heat treatment alone and in combination with acid treatment, and various combinations of treatment duration and temperature levels.
- Research on the effect of disinfectants on biofilms is needed, including studies on how pathogens survive and how they can be eliminated.

This knowledge is important to ensure animal health and welfare and to ensure safe food.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

2.3.1.3 Genetically modified (GM) feed

2.3.1.3.1 Herbicide residues in herbicide tolerant (HT) crops

Several crops have been genetically modified to be tolerant to broad spectrum or non-selective herbicides, such as glyphosate. This permits the use of the herbicides to control a wide range of weeds without sustaining crop injury. Farmers thereby get more flexibility in choosing times for spraying as well as reducing the use of other herbicides.

- Field trials with herbicide tolerant plants sprayed with the intended herbicide (e.g. glyphosate) and detailed measurements of herbicide residues and metabolite levels in the plant before and after processing to feed products are needed.

This knowledge will give us a more solid basis to prepare risk assessments.

For additional information, see « Scientific opinion on glyphosate-tolerant, genetically modified cotton GHB614 from Bayer CropScience for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (Application EFSA/GMO/NL/2008/51)» (2009).

2.3.1.3.2 Safety assessments of genetically modified crops

<u>Evaluation of unintended effects caused by genetic modification</u>

Future advances in omics technologies (e.g. genomics, transcriptomics, proteomics or metabolomics) may be used to distinguish between unintended effects caused by genetic modifications and compositional differences caused by natural variability between GM crops and their non-GM counterparts. This could help facilitate specific hypothesis-driven investigations by first identifying the new unintended components in the GM plant as a basis to decide whether or not further studies, e.g. animal testing, are needed.

- The potential of omics techniques in risk assessment of GM crops should be further investigated.

Although modern *in vitro* methods may not fully replace animal testing, they might significantly reduce the number of animal studies needed in the safety evaluation of GMOs. They could also indicate whether relevant production animals should be tested instead of or in addition to rodents, due to biological differences.

Genetically modified plants with deliberately altered composition

Input traits such as insect resistance and herbicide tolerance are the modifications used in the first generation of genetically modified plants. These traits affect the agronomic performance of the plant with the aim to enhance or stabilise crop yield.

The second generation GM crops include GM plants with deliberately altered composition or so-called output traits. These modifications are introduced in order to achieve a nutritionally improved food or feed. Examples are soybeans, maize and oilseed rape with modified fatty acid profile and composition, potatoes with modified starch metabolism and composition, grains enriched in vitamin E, vegetables with enhanced folate levels and crops with higher content of protein or amino acids, or modified amino acid composition for enhanced nutritional value. Genetic modification is also used to eliminate or reduce the level of undesirable substances in food. Other second generation GM crops with novel output traits are in the pipeline.

The development of GM crop varieties in which the composition of the final product has been deliberately altered, poses a challenge to the existing risk assessment methodology. The assessment is based on the concept of substantial equivalence, which implies a systematic comparison of phenotypic traits with a conventional, non-GM comparator. The question is whether safety and nutritive value of these products can be properly assessed with the existing comparative safety assessment methodology.

- Further development of evaluation standards and methodology for products with deliberately altered composition are needed.

The development of GM crop varieties in which the composition of the final product has been deliberately altered, poses a challenge to the existing risk assessment methodology. The assessment is based on the concept of substantial equivalence, which implies a systematic comparison of phenotypic traits with a conventional, non-GM comparator. The question is whether safety and nutritive value of these products can be properly assessed with the existing comparative safety assessment methodology; therefore, this knowledge is essential.

For additional information, see «Foreløpig helse- og miljørisikovurdering av genmodifisert soyalinje MON 87769 fra Monsanto Company (EFSA/GMO/UK/2009/76)» (2011).

Feed containing genetically modified plants

As previously mentioned, hypothesis driven animal feeding studies could be initiated based on the results of preceding investigations with the omics technologies. These results could possibly also indicate whether relevant production animals should be tested in addition to, or rather than, rodents.

- Feeding studies with relevant production animals such as farmed fish, pigs, and cattle given feed containing genetically modified plants are needed.

More data from safety studies with relevant production animals such as farmed fish, pigs, and cattle would add valuable information to the risk assessments of GM-plants meant for animal feeds and should be included when appropriate, to reduce the uncertainties of extrapolating results across species, e.g. rats to salmon.

For additional information, see «Uttalelse fra Hovedkomiteen i Vitenskapskomiteen for mattrygghet 27.10.05. Helse- og miljøvurdering knyttet til antibiotikaresistensmarkørgener i genmodifiserte planter» (2005).

2.3.1.3.3 Genetically modified organisms and antibiotic resistance genes

Monitoring of antibiotic resistance situation in Norway (NORM, NORM-VET) indicates that the presence of aminoglycoside resistance, and consequently presence of neomycin phosphotransferase genes (primarily *nptII*), is low in pathogenic bacteria. Kanamycin/neomycin resistance has been found in *Escherichia coli*, *Enterococcus faecalis*, *E. faecium* og *Staphylococcus intermedius* from pig, pig faeces, faeces of turkey, cattle meat, dog and dog faeces in Norway. Frequency of the resistant isolates varied between 1 and 10 % (NORM-VET reports 2004-2007).

The neomycin phosphotransferase genes, primarily *nptII*, are used as selection markers for transformation of plants. Data on the prevalence of the *nptII* gene in Norway are scarce. Given the current pattern of aminoglycoside use in Norway and the low level of phenotypic resistance to aminoglycosides in pathogenic bacteria in Norway, a large scale introduction of the *nptII* gene in food and feed could pose a risk to animal health if horizontally transferred and further disseminated. However, as long as it is unlawful with antibiotic resistance genes in GMOs in Norway this is not a national risk.

- More information on *nptII* gene copy number in relevant Norwegian environments and information on the distribution and ecology of the *nptII* gene are needed.
- The type of genes responsible for the resistance in the isolates of pathogenic bacteria in Norwegian environments needs to be characterized.

This knowledge will give us a more solid basis to prepare health and environmental risk assessment of GMOs with *nptII* genes in Norway.

For additional information, see «Uttalelse fra Hovedkomiteen i Vitenskapskomiteen for mattrygghet 27.10.05. Helse- og miljøvurdering knyttet til antibiotikaresistensmarkørgener i genmodifiserte planter» (2005).

2.3.2 Diseases

2.3.2.1 Presence and concentration of agents pathogenic to terrestrial animals

Agents pathogenic to terrestrial animals pose a risk for animal health.

- The presence and concentration of e.g. Methicillin-resistant *Staphylococcus aureus* (MRSA) in Norwegian livestock, as well as *paratuberculosis*, *leptospirosis*, *mycoplasmosis* and *Streptococcus agalactiae* in the cattle population should be monitored.
- In horses, data on presence and concentration of strangles, salmonellosis and equine infectious anemia is needed.

Knowledge on presence and concentration of agents pathogenic to animals aids the prevention of transmission and facilitates appropriate interventions with regard to animal health and also human health.

For additional information, see «Risk assessment of governmental responsibility for combating diseases in terrestrial animals» (2011).

2.3.2.2 Colony collapse disorder

Colony collapse disorder (CCD) is a disorder that destroys entire bee communities in North America and Europe. It has yet not been observed in Norway.

- General knowledge on CCD in bees is needed.

The causality of the disorder has not yet been established, and it is imperative to keep up to date on new research and on measures of prevention and control to prepare for possible introduction to Norway.

For additional information, see «Risk assessment of governmental responsibility for combating diseases in terrestrial animals» (2011).

2.3.2.3 Risk of introduction of new diseases through import of camelids (lamas and alpacas) to Norway

There is a need for more knowledge on the risk of introducing pathogens through the import of exotic and alien animal species to Norway. The mycobacterial infections tuberculosis and paratuberculosis, as well as exotic parasites, are currently considered the highest concern in this regard.

- Data on the introduction of new diseases through import of camelids (lamas and alpacas) and potential effects on Norwegian livestock is needed.

Increased knowledge on this subject would allow a better and safer administration of import of camelids and thereby help prevent the spread of diseases hazardous to Norwegian livestock.

For additional information, see «Risk assessment of governmental responsibility for combating diseases in terrestrial animals» (2011).

2.4 The food products

Climate change, changes in the agricultural food production methods and the continually development of new food products results in a constant need for new knowledge to ensure food safety. In general, these research needs and data gaps are related to nutrients, contaminants and pathogens. Knowledge on trends by regular updating of the knowledge (time series; the same type of knowledge is gathered regularly over a longer period) is essential.

2.4.1 Nutrients

2.4.1.1 Analytical data for nutrients

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

- A periodical update of nutrient content in raw food and commercial food products 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.

In order to estimate intake of nutrients, the concentration of nutrients in commercial food must be analysed.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

2.4.2 Contaminants

2.4.2.1 Presence and concentration of contaminants

<u>Presence and concentration of mycotoxins and toxic metabolites</u>

An increase of mycotoxins in grains and grain-based products is expected due to milder springs and wetter summers in Norway. The consumption of maize-based products and rice in Norway has increased in recent years.

- For grain and grain-based products:
    - Data on presence and concentration of the mycotoxins DON, T-2 and HT-2 in Norwegian food are needed. A more systematic surveillance should be performed, especially focusing on products with high wheat and oat contents.
    - Data on presence and concentration of the emerging mycotoxins enniatins, beauvericin and moniliformin are needed.
- For maize-based products:
    - Data on presence and concentration of mycotoxins such as aflatoxin, zearalenone, fuminosin, and DON are needed.

This knowledge is critical to estimate the exposure to mycotoxins and to assess potential negative health effects.

For additional information, see «Risk assessment of mycotoxins in cereal grain in Norway» (2013).

<u>Presence and concentration of (heavy) metals / minerals</u>

Only a small number of samples and food types has been analysed for aluminium and cadmium concentrations.

- Presence and concentration data on aluminium in more food samples are needed.
- Presence and concentration on cadmium in commonly consumed food items as well as in specific food items containing higher levels of cadmium is needed.
- Data on cadmium levels in organically produced vegetables, particularly if grown in alum shale areas, is lacking.

In order to estimate the exposure to contaminants, the presence and concentration in different food and food groups must be known.

For additional information, see «Risk assessment of the exposure to aluminium through food and the use of cosmetic products in the Norwegian population» (2013) and «Risk assessment of dietary cadmium exposure in the Norwegian population» (2015).

2.4.2.2 Toxicity of mycotoxins

Grain may contain contaminants both biological and chemical origin, such as mycotoxins, bacteria, residues of pesticides etc.

- Since potential interactions between contaminants and mycotoxins are currently unknown, research is needed.
- Studies on toxicity of mycotoxins, including enniatins, beauvericin and moniliformin, are needed.
- Studies of mycotoxins and their mechanisms of action are required to derive toxicological reference values for humans.

This knowledge is the basis for judging the likelihood of adverse health effects of mycotoxins in humans.

For additional information, see «Risk assessment of mycotoxins in cereal grain in Norway» (2013).

2.4.2.3 Factors that enhance toxicity and add to the toxic effects

Fusarium-infected grain is more toxic than grain with the corresponding amount of pure toxin added. It is therefore likely that some unknown factors in the naturally infected grain considerably enhance and add to the toxic effects.

- Research on factors in naturally infected grain that enhance and add to the toxic effects is needed.
- Data on presence and concentration and toxicological significance of so-called masked mycotoxins (modified forms of the mycotoxins), such as modified forms of DON and T-2 toxins, is needed.

This knowledge is essential to enable an improved and more accurate risk assessment of mycotoxins in grain and grain products and the potential impact for human health.

For additional information, see «Risk assessment of mycotoxins in cereal grain in Norway» (2013).

2.4.2.4 Models for predicting environmental fate and transfer of chemicals from sewage sludge to the food chain

The number of chemicals with potential entry to agricultural soil via sewage sludge is high. It is therefore important to use models for predicting their environmental fate and eventual transfer to the food chain. Uptake models for plant and fish have during recent years been improved to include ionized chemicals. However, the models are not adjusted for all chemical properties. Technical Guidance Documents (TGD version 2003, the European Comission, Institute for Health and Consumer Protection) still contain models for uptake of nonionized and not ionized chemical.

- Experimental data for chemicals which today are not predictable by models (e.g. perfluorinated compounds, siloxanes) is needed.

These data is needed to improve existing models for uptake and environmental fate.

For additional information, see «Risk assessment of contaminants in sewage sludge applied on Norwegian soils» (2009).

2.4.2.5 Analytical methods for contaminants

- More sensitive analytical methods for T-2 and HT-2 toxins and nivalenol should be established ascertaining that the levels of detection (LODs) are low enough to measure low toxin concentrations.

This will generate better data sets and improve the exposure estimation.

For additional information, see «Risk assessment of mycotoxins in cereal grain in Norway» (2013).

2.4.2.6 Fragmentation pattern of lead bullets

- Knowledge on the fragmentation pattern of lead bullets in moose is needed.

Data on the fragmentation pattern of lead bullets in moose is needed in order to provide better advice on the amount of meat around the bullet wound channel that needs to be removed in order to avoid lead exposure from moose meat.

For additional information, see «Risk assessment of lead exposure from cervid meat in Norwegian consumers and in hunting dogs» (2013).

2.4.3 Foodborne pathogens

2.4.3.1 Presence and concentration of foodborne pathogens

Levels of contamination of many agents in food processing can vary significantly between different areas and one cannot simply transfer international data to Norwegian conditions. Our main sources of knowledge on presence and concentration of zoonotic agents in primary production and food processing are annual Zoonosis Reports and surveillance programs (by the Norwegian Veterinary Institute), but not all agents of interest are included.

- Systematic monitoring data on presence and concentration of pathogens in the food chain (primary production and processing), including the pathogens *Toxoplasma, Cryptosporidium* and *Giardia*, is needed.

Knowledge on presence and concentration of pathogens in the food chain is essential to capture emerging pathogens as early as possible. Knowledge on trends in the presence and concentration of pathogens in the food will provide a better basis for prioritisation of measures to reduce the human health risk.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011) and assessments produced by the Panel on Biological hazards since then.

2.4.3.2 Foodborne pathogens and antimicrobial resistance

Foodborne pathogens may be a source for spreading of pathogens carrying genes introducing antimicrobial resistance.

- Research on non-animal sources of antimicrobial resistant pathogens (e. g. vegetables/fruit, wastewater) is needed.
- Research on transmission of antimicrobial resistant bacteria from human to food-producing animal and vice versa is needed.
- Systematic monitoring of antimicrobial resistant pathogens in imported food is needed.
- Research on the possibility for spreading of resistant bacteria/resistance genes with food after antimicrobial treatment of animals under Norwegian conditions is needed.

To provide a better basis for prioritisation of measures to prevent spreading of antibiotic resistance in primary production and to humans, this knowledge is essential.

For additional information, see «Assessment of antimicrobial resistance in the food chains in Norway» (2015) and «Assessment of the transfer of antimicrobial resistance between pets and humans in Norway» (2015).

2.4.3.3 Development of antibiotic resistance subsequent to development of zinc/copper resistance

Feed for food producing animals (e.g. fish, sheep, poultry, pigs and ruminants) may contain high levels of zinc (Zn) and copper (Cu), both essential trace elements. Farmed animals such as pig and poultry receive additional Zn and Cu in their diets due to supplementation of the compound to the feed as well as the use of Zn as medical remedy. This use results in a considerable content of Zn and Cu in the animal manure. Animal manure is a valuable source for fertilisation of agricultural soil. Exposure of bacteria in livestock and the environment may lead to development of resistance to Zn and Cu and subsequently antibiotic resistance. The resistance genes to Zn and Cu have been identified in some bacterial species and are often located on plasmids. Resistance to Cu is often linked to resistance to macrolides (e.g. erythromycin) or glycopeptides (e. g. vancomycin) in *enterococci*. Zn supplementation to animal feed may increase the proportion of multi-resistant *E. coli* in gut microbiota.

- Research on mechanisms of development of Zn/Cu resistance in bacteria, including dose-response relationships, is needed. In addition, knowledge on the link to antibiotic resistance should also be studied.

This knowledge is necessary to avoid a trace element driven development of antibiotic resistance.

For additional information, see «Zinc and copper in pig and poultry production – fate and effects in the food chain and the environment» (2014).

2.5 References

- Assessment of antimicrobial resistance in the food chains in Norway (2015)
- Assessment of the transfer of antimicrobial resistance between pets and humans in Norway (2015)
- Comparison of organic and conventional food and food production. Part I: Plant health and plant production (2014)
- Degradation and mobility of pesticides in Norwegian soils (2015)
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- Forskningsbehov og kunnskapshull påpekt av VKM 2013 (2013)
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- Risk assessment of contaminants in sewage sludge applied on Norwegian soils (2009)
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- Scientific opinion on glyphosate-tolerant, genetically modified cotton GHB614 from Bayer CropScience for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (Application EFSA/GMO/NL/2008/51) (2009)
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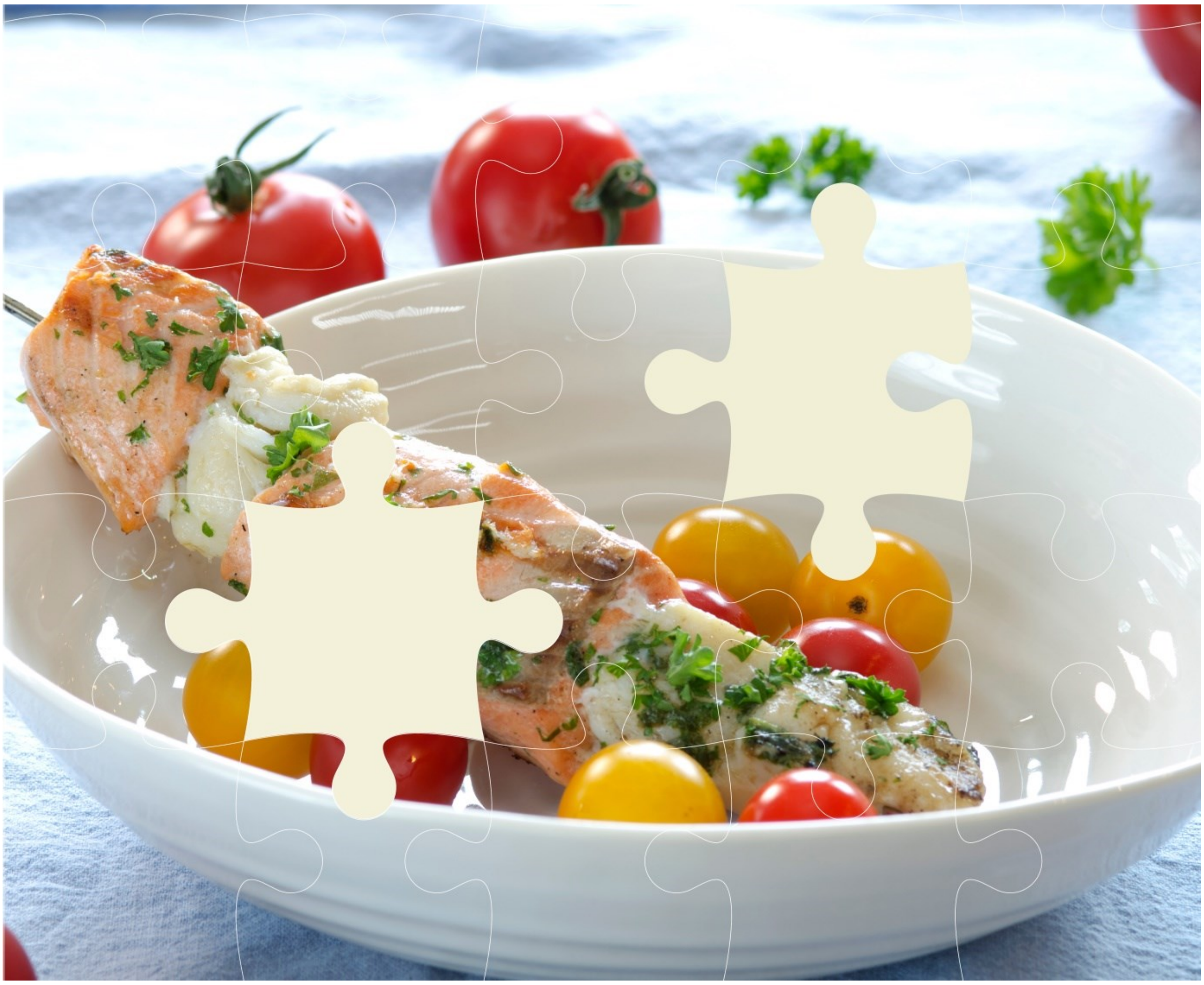
- Zinc and copper in pig and poultry production – fate and effects in the food chain and the environment (2014)

All references are published on www.vkm.no

3 Fisheries, aquaculture, seafood production and aquatic animals



Summary

Knowledge within the area of fisheries, aquaculture, seafood production and aquatic animals must cover Norwegian conditions and changes in the food production. The research needs and data gaps include:

- Transmission of infectious fish diseases under Norwegian conditions.
- Parameters for fish welfare.
- Effects of water quality on fish health and/or welfare.

- Non-traditional feed ingredients; impact on animal health and welfare, production efficiency, product quality and contaminant and nutritional composition of the final food product.
- Data on nutrients, contaminants and pathogens in the food production chain (food ingredients and/or processed food), including knowledge on trends.
- Models predicting transfer of contaminants from animal feed to the food chain.

Only research needs and data gaps related to VKM risk assessments are included. A detailed presentation is given in this chapter.

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3.1 Animal health and welfare

Fish welfare deals with more than survival and not being sick. It includes the ability to fulfil behavioural needs, to avoid distress and perhaps even to experience some positive emotions.

3.1.1 Welfare parameters for farmed fish

Today, the welfare of farmed fish is mainly assessed by mortality rates and production parameters.

- Methodology for welfare assessment for farmed fish is needed. It should include morphology and health conditions, measurements of physiological stress and behaviour, and, ideally, indicate the affective state of the fish.

With more knowledge within this field is important to secure welfare for farmed fish.

For additional information, see «Scientific Opinion on factors relevant for listing infectious diseases in aquatic animals» (2015).

3.1.1.1 Transmission of infectious diseases under Norwegian conditions

The transmission efficiency of an infectious disease is influenced by a multitude of factors, e.g. contagiousness, stability in the environment, host range, vectors and reservoirs.

- Research on the environmental (i.e. physical and chemical) stability, reservoirs and infection routes of pathogens in aquatic animals under Norwegian conditions is needed.

The above mentioned research need were specifically pointed out for the amoeba *Paramoeba perurans*, the causative agent of amoebic gill disease (AGD). The available information on the ecology of *P. perurans* in nature outside the fish farm cages is very limited. There is evidence suggesting the presence of an environmental reservoir, where the amoebae reside spring and summer. The reservoir could be constituted by biota, such as wild fish and invertebrates, or by water and sediments.

- Data on presence and concentration of *P. perurans* in deep water is needed. Analyses of water and sediment samples covering all depths should be included.
- Research on the impact of temperature and salinity on the infectivity and proliferation rate of *P. perurans* in Norway is needed.
- Since wild fish may represent natural hosts for the amoeba and may suffer due to an elevated infection pressure near AGD outbreaks, data on presence and concentration and potential impact of *P. perurans* on wild fish is needed.

Better knowledge on these factors is imperative to successfully interrupt the transmission of infectious agents in aquatic animals.

For additional information, see «Risk assessment of amoebic gill disease» (2014) and «Scientific Opinion on factors relevant for listing infectious diseases in aquatic animals» (2015).

3.1.2 Fish farming

Several factors in commercial fish farming may influence on health and welfare.

3.1.2.1 Water quality and other farming conditions

- Research on fish welfare under environmental conditions typically found in different fish farming systems (multi-factor studies) is needed.
- Research on water quality parameters preferred or actively avoided by fish are needed.
- Studies on the relationship between water quality, composition of microbial communities and fish health under commercial fish farming conditions are needed.
- For brown trout, data on tolerance levels for different water quality parameters and appropriate fish farming conditions are needed.
- Maximal and optimum stocking densities for adult charr in grow-out cages and tanks needs to be established.

More knowledge on these aspects is important for a better understanding of health and welfare in fish farming.

For additional information, see «Risk assessment of fish health and welfare in freshwater production systems for rainbow trout, brown trout and Arctic char» (2014), and «Risk assessment of recirculation systems in salmonid hatcheries» (2012).

3.1.2.2 Presence and concentration of pathogens in feed

Feed ingredients, including e.g. imported ingredients and byproducts from fish slaughter, may be contaminated with pathogens. Since pathogens not are equally distributed in every batch, it is difficult to detect the pathogens during routine controls.

- Data on presence and concentration of pathogens in raw materials for feed is needed.

Pathogens can be transferred from the feed to the animals and subsequently to the consumer. This knowledge is important to ensure animal health and welfare and to ensure safe food.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

3.1.2.3 Heat treatment of pathogens in fish feed production

In general, heat resistance of psychrotrophic bacterial fish pathogens has not been well examined.

- For several fish pathogens, research on the importance of the treatment time and/or temperature for elimination of the pathogens is needed. In particular, information on the effect of heat treatment of *Piscine Reovirus* (PRV), *Francisella noatunensis* subsp. *noatunensis* and *Moritella viscosa* are needed.
- Research on possible influences of the matrix in which the pathogen is located during the heat treatment is needed.

This knowledge is important to ensure animal health and welfare and to ensure safe food.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

3.1.2.4 Presence and concentration of mycotoxins in feed

Storage of feed may affect the presence and concentration of mycotoxins.

- Data on actual concentrations of mycotoxins in feed when fed to the fish is needed. Future surveillance should therefore include samples taken at the farm level.
- Presence and concentration data on mycotoxins in feed, e.g. alternaria toxins, ergot alkaloids and enniatins, are needed.
- Research on toxicity of enniatins, beauvericin and moniliformin to fish is needed. In order to establish mycotoxin tolerance values for fish, effect studies are needed and dose-response relationships should be established.

This knowledge is important to ensure animal health and welfare and to ensure safe food.

For additional information, see «Risk assessment of mycotoxins in cereal grain in Norway» (2013).

3.1.2.5 Non-traditional feed ingredients

The use of non-traditional feed ingredients may affect fish health and/or welfare. An example is replacement of bloodmeal with other ingredients. When use of bloodmeal in fish feed was abolished, cataract in salmon became a large problem due to histidine deficiency.

Apparently, the availability of histidine in the remaining feed ingredients was not sufficient to cover the requirement.

- Data on nutrient availability in non-traditional feed ingredients is needed.
- Research on the availability of macro- and micronutrients in new feed ingredients, as well as presence of contaminants or anti-nutrients (compounds that interfere with the absorption of nutrients), is needed.

This knowledge is required to assure the production of healthy fish and safe food.

3.1.2.6 Genetically modified (GM) fish

At the end of 2015, Environment Canada approved GM sterile all-female salmon eggs (by triploidisation) to be manufactured on a commercial scale in Canada (AquaBounty Technologies). According to Environment Canada, AquAdvantage® Salmon (AAS) are not harmful to the environment or human health when produced in land-based, contained facilities. Transgenic Atlantic salmon contain a gene construct (opAFP-GHc2; EO-1α) consisting of GH cDNA from *Chinook* salmon (*Oncorhynchus tshawytscha*) that is regulated with antifreeze protein gene sequences from an Ocean pout (*Zoarces americanus*). Introduction of triploidy is done by exposing salmon eggs to high pressure.

- It has been reported that there is a greater number of transcriptional changes overall in transgenic fish compared to domesticated fish. This may be due to dysregulation of metabolic pathways as a result of the dramatic metabolic change in a single generation. More knowledge on metabolism in GM fish is needed.
- In one study, it was reported that diet composition and rearing location had a much larger influence on the nutritional content of the fish muscle than did effects of the transgene. Studies on effects of dietary composition and rearing location and effects on the nutritional content of the fish muscle are needed.
- It is known that triploids have a higher phosphorous requirement than diploids in fresh water. Since triploid salmon may have other nutritional requirements than traditional salmon, knowledge on the nutritional needs for triploid salmon is needed.

This knowledge is important to secure the fish health, and is essential for assessment of GM fish health.

3.1.3 Genetically modified (GM) feed

3.1.3.1 Herbicide residues in herbicide tolerant (HT) crops

Several crops have been genetically modified to be tolerant to broad spectrum or non-selective herbicides, such as glyphosate. This permits the use of the herbicides to control a wide range of weeds without sustaining crop injury. Farmers thereby get more flexibility in choosing times for spraying as well as reducing the use of other herbicides.

- Field trials with herbicide tolerant plants sprayed with the intended herbicide (e.g. glyphosate) and detailed measurements of herbicide residues and metabolite levels in the plant before and after processing to feed products are needed.

This knowledge will give us a more solid basis to prepare risk assessments.

For additional information, see « Scientific opinion on glyphosate-tolerant, genetically modified cotton GHB614 from Bayer CropScience for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (Application EFSA/GMO/NL/2008/51)» (2009).

3.1.3.2 Safety assessments of genetically modified crops

Evaluation of unintended effects caused by genetic modification

Future advances in omics technologies (e.g. genomics, transcriptomics, proteomics or metabolomics) may be used to distinguish between unintended effects caused by genetic modifications and compositional differences caused by natural variability between GM crops and their non-GM counterparts. This could help facilitate specific hypothesis-driven investigations by first identifying the new unintended components in the GM plant as a basis to decide whether or not further studies, e.g. animal testing, are needed.

- The potential of omics techniques in risk assessment of GM crops should be further investigated.

Although modern *in vitro* methods may not fully replace animal testing, they might significantly reduce the number of animal studies needed in the safety evaluation of GMOs. They could also indicate whether relevant production animals should be tested instead of or in addition to rodents, due to biological differences.

Genetically modified plants with deliberately altered composition

Input traits such as insect resistance and herbicide tolerance are the modifications used in the first generation of genetically modified plants. These traits affect the agronomic performance of the plant with the aim to enhance or stabilise crop yield.

The second generation GM crops include GM plants with deliberately altered composition or so-called output traits. These modifications are introduced in order to achieve a nutritionally improved food or feed. Examples are soybeans, maize and oilseed rape with modified fatty acid profile and composition, potatoes with modified starch metabolism and composition, grains enriched in vitamin E, vegetables with enhanced folate levels and crops with higher content of protein or amino acids, or modified amino acid composition for enhanced nutritional value. Genetic modification is also used to eliminate or reduce the level of undesirable substances in food. Other second generation GM crops with novel output traits are in the pipeline.

The development of GM crop varieties in which the composition of the final product has been deliberately altered, poses a challenge to the existing risk assessment methodology. The assessment is based on the concept of substantial equivalence, which implies a systematic comparison of phenotypic traits with a conventional, non-GM comparator. The question is whether safety and nutritive value of these products can be properly assessed with the existing comparative safety assessment methodology.

- Further development of evaluation standards and methodology for products with deliberately altered composition are needed.

The development of GM crop varieties in which the composition of the final product has been deliberately altered, poses a challenge to the existing risk assessment methodology. The assessment is based on the concept of substantial equivalence, which implies a systematic comparison of phenotypic traits with a conventional, non-GM comparator. The question is whether safety and nutritive value of these products can be properly assessed with the existing comparative safety assessment methodology; therefore, this knowledge is essential.

For additional information, see «Foreløpig helse- og miljørisikovurdering av genmodifisert soyalinje MON 87769 fra Monsanto Company (EFSA/GMO/UK/2009/76)» (2011).

3.1.3.3 Feed containing genetically modified plants

As previously mentioned, hypothesis driven animal feeding studies could be initiated based on the results of preceding investigations with the omics technologies. These results could possibly also indicate whether relevant production animals should be tested in addition to, or rather than, rodents.

- Feeding studies with relevant production animals such as farmed fish, pigs, and cattle given feed containing genetically modified plants are needed.

More data from safety studies with relevant production animals such as farmed fish, pigs, and cattle would add valuable information to the risk assessments of GM-plants meant for animal feeds and should be included when appropriate, to reduce the uncertainties of extrapolating results across species, e.g. rats to salmon.

For additional information, see «Uttalelse fra Hovedkomiteen i Vitenskapskomiteen for mattrygghet 27.10.05. Helse- og miljøvurdering knyttet til antibiotikaresistensmarkørgener i genmodifiserte planter» (2005).

3.2 The food products

Climate change, changes in food production methods and the continually development of new food products results in a constant need for new knowledge to ensure food safety. In general, these research needs and data gaps are related to nutrients, contaminants and pathogens. Knowledge on trends by regular updating of the knowledge (time series; the same type of knowledge is gathered regularly over a longer period) is essential.

3.2.1 Nutrients in seafood

3.2.1.1 Analytical data on nutrients

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 10 years there has been a great change in raw materials used in fish feeds for farmed Atlantic salmon and trout. In 2013, terrestrial plant proteins and vegetable oils accounted for 70% of the feed. These changes in concentration of nutrients and in fish feed is reflected in changed concentrations and compositions of the same nutrients in the farmed fish fillet. Compared to 2006, the concentrations of EPA, DPA and DHA are about 50%, the concentration of selenium is about 40%, while the concentration of vitamin D appears unchanged. The level of iodine in farmed Atlantic salmon was low in 2006, and is still low compared to lean fish.

- Data on the content of EPA, DPA and DHA in commercial products containing seafood 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 periodical update of presence and concentration of nutrients in raw food and commercial food products 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.

This knowledge is essential for estimation of nutrient intake in the population.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011) and «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014).

3.2.2 Contaminants in seafood

3.2.2.1 Presence and concentration of contaminants

Methylmercury, dioxins and dioxin-like PCBs

Fish can contribute significantly to the dietary exposure to some contaminants, e.g. methylmercury, dioxins and dioxin-like PCBs.

- For wild caught fish, there is a need for knowledge on presence and concentration of methylmercury, dioxins and dioxin-like PCBs in commercially available fish species. In order to show time-trends of contaminant levels, regular sampling of the same species, e.g. cod liver and fillet, from the same area over a long period of time is needed.
- Data on contaminants in commercial products containing fish is needed.

Such data will refine the exposure calculations and reduce uncertainty in the exposure calculations.

For additional information, see «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014).

New contaminants

Future non-traditional feed ingredients for farmed fish may introduce new contaminants which may be recovered in the fish filet.

- Data on presence and concentration of new contaminants introduced by use of non-traditional ingredients in fish feed, such as PAHs, mycotoxins, brominated flame retardants, perfluorated compounds and pesticides, is needed.
- More knowledge on transfer of potential new contaminants from feed to fillet is needed. Therefore, for farmed fish, changes in fish feed recipe should be followed by continuing scientific research and monitoring to reveal its impact on fish as food.

Knowledge on the contaminant composition and concentrations in fish filet is essential for exposure estimation.

For additional information, see «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014).

3.2.2.2 Models for predicting transfer of contaminants from feed to food

For farmed fish, changes in fish feed recipe should be followed by continuing research and monitoring to reveal its impact on fish as food. Plant-based feed ingredients and other non-traditional feed ingredients can introduce e.g. food allergens and new contaminants such as PAHs, mycotoxins, brominated flame retardants, perfluorated compounds and pesticides. Knowledge on the composition and content of new and undesirable components in fish feed and their potential transfer from feed to fillet need to be established.

- Mathematical models for prediction of potential transfer of feed contaminants to fish fillet are needed.

Such models will make it possible to predict concentrations of specific contaminants in the fish filet based on the content in fish feed, and demonstrate the need for surveillance of new contaminants. For contaminants not transferred to the fillet, analyses of fillet are not necessary. Reduced need for frequent chemical analysis of the fillet would be cost effective in the long run.

For additional information, see «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014).

3.3 References

- Benefit-risk assessment of fish and fish products in the Norwegian diet – an update (2014)
- Foreløpig helse- og miljørisikovurdering av genmodifisert soyalinje MON 87769 fra Monsanto Company (EFSA/GMO/UK/2009/76)» (2011)
- Forskningsbehov og kunnskapshull påpekt av VKM 2013 (2013)
- Forskningsbehov påpekt av VKM 2012 (2012)
- Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010 (2011)
- Risk assessment of amoebic gill disease (2014)
- Risk assessment of fish health and welfare in freshwater production systems for rainbow trout, brown trout and Arctic char (2014)
- Risk assessment of recirculation systems in salmonid hatcheries (2012)
- Risk assessment of mycotoxins in cereal grain in Norway (2013)
- Scientific Opinion on factors relevant for listing infectious diseases in aquatic animals (2015)
- Scientific opinion on glyphosate-tolerant, genetically modified cotton GHB614 from Bayer CropScience for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (Application EFSA/GMO/NL/2008/51) (2009)
- Trygg mat og kosmetikk, friske dyr og planter forutsetter forskning, kartlegging og overvåkning (2014)
- Uttalelse fra Hovedkomiteen i Vitenskapskomiteen for mattrygghet 27.10.05. Helse- og miljøvurdering knyttet til antibiotikaresistensmarkørgener i genmodifiserte planter» (2005)

All references are published on www.vkm.no

4 Human health – diet, food, nanomaterials and cosmetics

Summary

Food safety is in addition to a healthy diet one of the prerequisites for good health. To evaluate possible health effects from different foods and diets, knowledge on dietary intake, food composition and possible relationships between different foods and health effects is essential. In addition, effects of nanomaterials should be in focus, both in food and cosmetics.

Research needs and data gaps of importance for human health include:

- Data on what we eat, how much, and how often.
- Relationships between food/food groups and the prevention or development of disease.
- Presence and concentration of pathogens in drinking water.

- Diseases caused by foodborne pathogens or contaminants in food and the disease burden (loss of health and mortality).
- The stability and solubility of nanomaterials in food, in the gastrointestinal tract and in biological tissues.
- Negative health effects of organic nanomaterials.
- Skin absorption and metabolism of cosmetic ingredients.
- Exposure and use of cosmetics.
- Toxicological data on nanomaterials in cosmetics.

Only research needs and data gaps related to VKM risk assessments are included. A detailed presentation is given in this chapter.

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4.1 Diet and food

Changes in eating habits/diets, food production methods and the continually development of new food products result in a constant need for new knowledge to ensure food safety.

4.1.1 Dietary surveys

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

4.1.1.1 National dietary surveys

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 based on a pre-coded 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.

- Regular performance of the national dietary surveys for all age groups is needed (every 5-10 years).
  - The surveys should be designed to capture variations in intake of foods/food groups, and include high consumers of specific foods/food groups.
  - A sufficient number of participants must be recruited.
- Comparable methodology across the age groups should be used.

This knowledge is critical for exposure estimation, and to relate food intake to health effects. Performing regular dietary surveys which give comparable results from survey to survey enable us to follow trends in dietary habits.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

4.1.1.2 Other dietary surveys

More specialized dietary surveys captures data on e.g. specific food/food groups and specific population groups.

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

This knowledge is critical for exposure estimation, and to relate food intake to health effects.

4.1.1.3 Dietary assessment methodology

Some factors are of particular importance when designing dietary surveys.

- Presence and concentration of nutrients, contaminants and foodborne pathogens should be linked to specific food/food groups in one database.
- The impact of the number of registration days or the number of recall days on the results (e.g. 5th and 95th percentile) should be evaluated.
- The impact on the results of the number of food items included and/or the methods for portion size estimation should be evaluated.
- Only validated dietary assessment methods should be used.

This is critical for exposure estimation and evaluation of impact of food/food groups on human health.

For additional information, see «Forskningsbehov påpekt av VKM 2012» (2012).

4.1.1.4 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; however, the most recent surveys have not been submitted to the EU.

- All Norwegian food consumption data should be submitted to the EU food consumption database.

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

4.1.2 Nutrients

4.1.2.1 Analytical data for nutrients

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

- A periodical update of nutrient content in raw food and commercial food products 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.

In order to estimate intake of nutrients, the concentration of nutrients in commercial food must be analysed.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011) and «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014).

4.1.2.2 Safe upper limits

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.

To establish ULs for dietary intake of vitamin D for children and adolescents, studies on these age groups are needed.

For additional information, see «Evaluation of tolerable upper intake levels for vitamin D in children and adolescents» (2014).

4.1.3 Contaminants

4.1.3.1 Presence and concentration in food

Different types of contaminants are present in different food/food groups.

Presence and concentration of contaminants in commercial products

- Data on contaminants in commercial products is needed.

For additional information, see «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014).

Presence and concentration of mycotoxins

An increase of mycotoxins in grains and grain-based products is expected due to milder springs and wetter summers in Norway. The consumption of maize-based products and rice in Norway has increased in recent years.

- Grain and grain-based products
    - Data on presence and concentration of the mycotoxins DON, T-2 and HT-2 in Norwegian food are needed. A more systematic surveillance should be performed, especially focusing on products with high wheat and oat contents.
    - Data on presence and concentration of the emerging mycotoxins enniatins, beauvericin and moniliformin are needed.
- Maize-based products
    - Data on presence and concentration of mycotoxins such as aflatoxin, zearalenone, fuminosin, and DON are needed.

This knowledge is critical to estimate the exposure to mycotoxins and to assess potential negative health effects.

For additional information, see «Risk assessment of mycotoxins in cereal grain in Norway» (2013).

<u>Presence and concentration of metals</u>

- Analyses of aluminium in more food samples are needed.
- More data on presence and concentration of cadmium in both commonly consumed food items as well as in food items considered to contain higher levels of cadmium is needed.
- Data on cadmium levels in organically produced vegetables, particularly if grown in alum shale areas, is needed.

This knowledge is critical to estimate the exposure to aluminium and cadmium for various population groups and evaluate potential negative health effects.

For additional information, see «Risk assessment of the exposure to aluminium through food and the use of cosmetic products in the Norwegian population» (2013) or «Risk assessment of dietary cadmium exposure in the Norwegian population» (2015).

<u>Presence and concentration of process induced contaminants</u>

Furan is a volatile and lipophilic compound formed in a variety of heat-treated commercial food. Furan has been found in a number of food products, including jarred baby food and infant formulae, and high concentrations in coffee were reported. The presence and concentration of furan in a variety of food suggests that there are multiple routes of furan formation rather than one single mechanism.

- Data on furan in food is needed, both in processed and heated food.

- Coffee is a major source of furan exposure in adults. However, data on presence and concentration of furan in Norwegian coffee is very limited. Therefore, data on presence and concentration of furan in Norwegian coffee is needed.
- No information on the furan concentration in home-cooked food are available, thus, data on furan in home-cooked food are needed.
- A comprehensive and continually updated national furan database is necessary for estimating the overall exposure to furan through diet.

This knowledge is critical to estimate the exposure to furan for various population groups and evaluate potential negative health effects

For additional information, see «Risk assessment of furan exposure in the Norwegian population» (2012).

Presence and concentration of contaminants from food contact materials

The regulation of plastics food contact materials in EU is extensive and harmonized. The regulation of other food contact materials than plastics is not yet harmonized in EU. National regulations are therefore used, and in most countries, including Norway, it is much less comprehensive than the regulation of plastics.

- Better data on consumers' exposure to contaminants in food contact materials from food, included imported food, is needed.
- Data on the percentage of various food types that are packaged, the area of the packaging materials that is in contact with the food, and how many times the food have been packaged in how many different packaging materials from raw material to the consumers' table, is needed.
- Data on realistic use of packaging materials and other food contact materials in Norway is needed. In order to obtain these data, surveys specifically aimed at answering these questions are necessary. Consumers participating in such surveys may report information on the food and submit all packaging materials from all food they have eaten during a certain time period, for measurement of area in contact with food and identification of the type of material in each packaging.
- Analytical methods for detection of the migrated chemicals into food or food simulants will need continuous development.

Better data on presence and concentration of chemical contaminants in the food as a result of migration from the food packaging materials, both plastic and non-plastics, will give better risk assessments and safer food. Including information on food contact materials in the dietary surveys will give knowledge on realistic use of packaging materials and other food contact materials in Norway.

4.1.4 Toxicological data on contaminants

Toxicological data on substances used in food contact materials

- Knowledge chemical contaminants that migrate from food packaging materials to the food is needed. This includes knowledge on contaminants migrating from plastics materials but especially from non-plastics materials such as paper and board, printing inks and adhesives.
- For many of the chemicals found to migrate from food packaging materials into food, toxicological data on several end points are needed. This may be the situation for some of the chemicals intended to be used in the packaging materials, but even more so for the non-intentionally-added substances (NIAS), which are degradation products, reaction products or other impurities in the materials.

In order to perform risk assessments of human exposure to chemical contaminants in food migrating from the packaging material, knowledge on the toxicological properties of these substances is necessary. Such knowledge is most often obtained from animal experiments, and *in vitro* and *in silico* studies, but are often lacking.

Recirculated packaging materials may represent an elevated risk for compromised food safety.

Toxicological data on furan

Only one 2-year carcinogenicity study of furan in rats was available in 2012. In this study, the incidence of cholangiocarcinomas was already 100 % at the lowest tested dose. VKM is aware of an on-going 2-year carcinogenicity study in rats with exposure to low doses of furan performed by FDA (the U.S. Food and Drug Administration).

- To derive a reference point for carcinogenicity for furan, long-term studies including lower doses are needed.
- Genotoxic properties of the main metabolite of furan, BDA (cis-2-butene-1,4-dial), have been found in several *in vitro* tests. *In vivo* studies on genotoxicity of BDA are needed. *In vivo* studies may also contribute to elucidate mechanisms for the genotoxicity.

In order to perform risk assessments of furan and BDA, this knowledge is necessary.

For additional information, see «Risk assessment of furan exposure in the Norwegian population» (2012).

4.1.5 Absorption of contaminants

- Data on *in vivo* absorption of metallic lead are needed.

In order to reduce uncertainty related to bioavailability of metallic lead in food, this knowledge is necessary.

For additional information, see «Risk assessment of lead exposure from cervid meat in Norwegian consumers and in hunting dogs» (2013).

4.1.6 Foodborne pathogens

4.1.6.1 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.

- Data on trends in the presence and concentration of pathogens in animal populations, in 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.

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 «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

4.1.6.2 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 Public Health Institute. 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.

- 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.

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 «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011) and assessments produced by the Panel on Biological hazards since then.

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

Knowledge on relationships between various food/food groups and the prevention or development of disease is scarce. Studies may indicate that consumption of certain food reduces or increases the risk of diseases. However, there is lack of comparable epidemiological studies and mechanistic studies

4.1.7.1 Epidemiological studies

Randomized controlled trials (RCTs)

RCTs are considered the «gold-standard» for evaluation of health effects, both positive and negative effects, of an intervention (e.g. food, food groups or single nutrients).

- RCTs with sufficient participant numbers are needed to allow robust statistical analyses and to increase the generalizability of the obtained results.
- RCTs of sufficient duration are needed since intake of food/food groups gives life-long exposures and side-effects (e.g. development of cancer) may become evident only after several years.
- RCTs with adverse health effects as the primary end-point are needed.
- Given that certain health-risks are not identified until years after start of exposure, knowledge on validated biomarkers for risks is needed.
- In addition to the general population, there is a need to know more about health risks among segments of the population believed to be particularly vulnerable, e.g.

pregnant women and the fetus, lactating women and the breastfed infant, children and elderly.
- To identify specific hazardous compounds, RCTs testing single and well-defined compounds are needed.

Prospective observational studies

Performing long-lasting RCTs are often costly and sometimes impossible.
- Long-term studies (years) on defined cohorts that is followed for years is needed to identify risks associated with chronic exposure to food and nutrients.

This knowledge is important to establish relationships between food/food groups and the prevention or development of disease. Although RCTs in general give information about associations and not causality, data from properly designed RCTs can give important clues to mechanisms of action.

For additional information, see «Comparison of organic and conventional food and food production Part III: Human health – an evaluation of human studies, animal models studies and biomarker studies» (2014) and «Benefit and risk assessment of breastmilk for infant health in Norway» (2013).

4.1.7.2 Studies on mechanisms of beneficial or harmful effects

Mechanistic studies using animal models

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.

Mechanistic studies using *in vitro* models

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

For additional information, see «Comparison of organic and conventional food and food production Part III: Human health – an evaluation of human studies, animal models studies and biomarker studies» (2014).

4.2 Genetically modified (GM) food

4.2.1 Herbicide residues in herbicide tolerant (HT) crops

Several crops have been genetically modified to be tolerant to broad spectrum or non-selective herbicides, such as glyphosate. This permits the use of the herbicides to control a wide range of weeds without sustaining crop injury. Farmers thereby get more flexibility in choosing times for spraying as well as reducing the use of other herbicides.

- Field trials with herbicide tolerant plants sprayed with the intended herbicide (e.g. glyphosate) and detailed measurements of herbicide residues and metabolite levels in the plant before and after processing to feed products are needed.

This knowledge will give us a more solid basis to prepare risk assessments.

For additional information, see « Scientific opinion on glyphosate-tolerant, genetically modified cotton GHB614 from Bayer CropScience for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (Application EFSA/GMO/NL/2008/51)» (2009).

4.2.2 Adjuvants / immunological effects of different Cry-proteins in various biological systems

Development of food allergies and intolerances involves the interplay of various factors such as genetic predisposition, the composition of the mucosa as well as infection status of the gastrointestinal tract, age, and the nutritional state of an individual. Although there is limited knowledge regarding Cry proteins as immune-modulating substances, a study with mice revealed that Bacillus thuringiensis Cry1Ac protoxin activated macrophages by up-regulation of cell surface molecules and induction of proinflammatory cytokines. Previous studies have shown that Cry1Ac protein has a immunogenic potential to elicit strong IgG-response and to induce formation of IgG antibodies to food antigens. Even cross-priming against a bystander antigen may be of biological significance. Experimental studies both in vitro and in vivo have demonstrated that IgG antibodies that are not balanced by a mucosal IgA response can enhance the epithelial penetration of bystander proteins. Following knowledge gaps are identified:

- Validated methods for measuring adjuvant effects are needed.
- The extent to which Cry1Ac and other Cry proteins contribute to the development of allergies is largely unknown. Most of the immunologic adjuvant experiments have been performed using Cry1Ac and more research with other Cry proteins is needed.

- The possibility that Cry proteins might increase the permeability of the intestinal epithelium and thereby lead to "bystander" sensitization to strong allergens in the diet of genetically susceptible individuals cannot be completely excluded. This possibility could be explored in a relevant animal model.
- Knowledge on exposure via the respiratory tract and the skin, and also the lack of quantitative understanding of the relationship between the extent of exposure to an adjuvant and its effects in terms of development of allergies, are needed.
- Sensitive methods and models for investigating immune-modulating effects of Cry-proteins and the health implications these may have are needed..

This knowledge will provide a better basis for risk assessment of food and feed products containing Cry proteins, and will provide greater certainty when communicating conclusions regarding the safety of the GM products.

For more information, see "Summary of the health risk assessment of the adjuvant effects of Cry proteins from genetically modified plants used in food and fodder" (2012).

4.2.3 Safety assessments of GM crops

4.2.3.1 Evaluation of unintended effects caused by genetic modification

Future advances in omics technologies (e.g. genomics, transcriptomics, proteomics or metabolomics) may be used to distinguish between unintended effects caused by genetic modifications and compositional differences caused by natural variability between GM crops and their non-GM counterparts. This could help facilitate specific hypothesis-driven investigations by first identifying the new unintended components in the GM plant as a basis to decide whether or further studies, e.g. animal testing are needed.

- The potential of omics techniques in risk assessment of GM crops should be further investigated.

Although modern in vitro methods may not fully replace animal testing, they might significantly reduce the number of animal studies needed in the safety evaluation of GMOs. They could also indicate whether relevant production animals should be tested instead of or in addition to rodents, due to biological differences.

4.2.3.2 Genetically modified (GM) plants with deliberately altered composition

Input traits such as insect resistance and herbicide tolerance are the modifications used in the first generation of genetically modified plants. These traits affect the agronomic performance of the plant with the aim to enhance or stabilise crop yield.

The second generation GM crops include GM plants with deliberately altered composition or so-called output traits. These modifications are introduced in order to achieve a nutritionally improved food or feed. Examples are soybeans, maize and oilseed rape with modified fatty acid profile and composition, potatoes with modified starch metabolism and composition, grains enriched in vitamin E, vegetables with enhanced folate levels and crops with higher content of protein or amino acids, or modified amino acid composition for enhanced nutritional value. Genetic modification is also used to eliminate or reduce the level of undesirable substances in food. Other second generation GM crops with novel output traits are in the pipeline.

- Further development of evaluation standards and methodology for products with deliberately altered composition are needed.

The development of GM crop varieties in which the composition of the final product has been deliberately altered, poses a challenge to the existing risk assessment methodology. The assessment is based on the concept of substantial equivalence, which implies a systematic comparison of phenotypic traits with a conventional, non-GM comparator. The question is whether safety and nutritive value of these products can be properly assessed with the existing comparative safety assessment methodology; therefore, this knowledge is essential.

For additional information, see «Foreløpig helse- og miljørisikovurdering av genmodifisert soyalinje MON 87769 fra Monsanto Company (EFSA/GMO/UK/2009/76)» (2011)

4.3 Nanomaterials

4.3.1 Nanomaterials in food

4.3.1.1 Stability of nanomaterials

The non-degradable and insoluble nanomaterials are those who have the potential for leading to material-induced harmful effects.

- Knowledge about the stability and solubility of nanomaterials in food, in the gastrointestinal tract and in biological tissues is needed.
- Appropriate and reliable methods for testing stability/solubility of nanomaterials in various matrixes are needed.

Knowledge about the stability of nanomaterials is of fundamental importance for risk assessment.

For additional information, see «Annual report of the EFSA Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed for 2015» (2016; http://www.efsa.europa.eu/en/supporting/pub/939e).

4.3.1.2 Detection, characterisation and quantification of nanomaterials

Nanomaterials include both insoluble and persistent nanomaterials as well as soft nanomaterials (nanosized ingredients/additives made from natural sources, e.g. liposomes, nanoemulsions and biopolymer-based nanoencapsulates).The types of nanomaterials that are now occurring in the food/feed chain are mainly titanium dioxide and synthetic amorphous silica. Food additives and food contact materials are the most indicated current applications in Europe. Potential future developments are expected in the field of organic materials like nanoencapsulates and nanocomposites in applications such as novel food, food/feed additives, biocides, pesticides and food contact materials.

- An overview of existing and future nanomaterial applications in the food, feed and cosmetic sector, both on the international and on the Norwegian market, are needed.
- General knowledge about which nanotechnology applications the consumers are exposed to, and to what degree, is needed.
- Validated routine analysis for the detection, characterisation and quantification of nanomaterials in food, feed and food contact materials needs to be established.
- Knowledge on characteristics of nanomaterials affecting absorption into the body is needed.
- Knowledge on intestinal absorption and tissue distribution of nanomaterials after oral exposure is needed.
- Since there is a potential for slow elimination and accumulation of nanomaterials absorbed and distributed to various organs, as well as accumulation of materials that remain in the surface layer of the intestines, knowledge on possible effects of long-term exposure to nanomaterials is needed.
- More studies designed to examine potential hazards of well characterized nanosized materials at relevant doses are needed.
- For soft nanomaterials, criteria for identification of potentially harmful applications are needed.
- Soft nanomaterials, including liposomes, nanoemulsions, biopolymer-based nanoencapsulates, etc., are generally regarded as degradable. Recent literature indicates that nanoencapsulation increases uptake and bioavailability of the encapsulated substances in the body. Examples of such substances are antioxidants, some vitamins, certain minerals and also catechin flavonoids (from green tea). This may raise a concern since basically useful substances may cause harmful effects when taken/delivered at high doses. Therefore, knowledge on

uptake and bioavailability of nanoencapsulated substances in the body are needed.

Nanotechnology products could have a substantial impact on the food and feed sector in the future, with potential benefits for industry and the consumer. However, the specific properties and characteristics of nanomaterials need to be considered for any potential health risks. Such risk assessment has to be based on relevant and high quality knowledge about the hazard of the nanomaterials and, equally important, information and methods to estimate the exposure. Furthermore, such knowledge would enable all parties involved to prioritise and promote extensive research on effects of applications with the greatest implication for human health, an effort that would be appropriate regarding consumer safety.

For additional information, see «Annual report of the EFSA Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed for 2015» (2016; http://www.efsa.europa.eu/en/supporting/pub/939e) and «Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain» (2011; http://www.efsa.europa.eu/en/efsajournal/pub/2140).

4.4 Cosmetics

In 2014 about 10.5 billion NOK were spent on cosmetics like body lotions, deodorants, toothpaste and soap in Norway (www.klf.no). The widespread use of cosmetics among all age groups and both genders points to a need for surveillance of the ingredients used in cosmetics. In addition, identification and quantification of dermal absorption of cosmetic ingredients are needed in order to provide information concerning consumer safety.

All human tissues contain metabolising enzymes, but their expression level is organ specific. In the skin, both phase I and phase II enzymes are present. The cell type most relevant for enzymatic metabolism of chemicals in skin is keratinocytes. The degree of metabolism of chemical compounds in the skin during the penetration process will influence the nature of the chemical entering the vascular system and may also influence the rate of systemic distribution.

4.4.1 Cosmetics and human health effects

4.4.1.1 Skin absorption and metabolism

The human skin represents an important route of exposure to cosmetic ingredients, but data on skin absorption and metabolism is often very limited or are lacking entirely. Testing of chemical ingredients in live animals are banned in the EU, thus the producers are required to test new ingredients using e.g. *in vitro* systems. However, if the data generated by the producers is not published, it will be unavailable for risk assessors.

- Quantitative data on skin absorption and metabolism of cosmetic ingredients is very often needed. Skin absorption can be measured using *in vivo* and *in vitro* methods.
    - *In vivo* methods on skin absorption in laboratory animals (e.g. rats, mice) are well established. However, human skin is considered to be less permeable than that of laboratory animals. Thus the absorption values found in animal *in vivo* studies may be too high compared to the absorption into human skin.
    - In the *in vitro* methods, skin from either humans or pigs, are mounted in a diffusion cell, where the diffusion of cosmetic ingredients into and across skin to a fluid reservoir is measured. Non-viable skin can be utilized to measure diffusion only, whereas fresh and metabolically active skin can be used to study skin metabolism.
- *In vitro* studies on skin absorption and metabolism of cosmetic ingredients are needed. The results should be published in scientific papers and thus be available to risk assessors.

According to «The SCCS's Notes of Guidance for the testing of cosmetic substances and their safety evaluation»(2012), in case where skin absorption values are derived from an inadequate in vitro study, or no skin absorption data is available, a 100% skin absorption should be used when calculating the margin of safety. Using a 100% skin absorption value are in most cases too conservative and will overestimate the skin absorption of cosmetic ingredients. Therefore, risk assessors often conclude that the safety of cosmetic ingredients cannot be drawn due to inadequate data or lack of data. Increased knowledge of skin absorption and metabolism will contribute to a better scientific understanding of human exposure to cosmetic ingredients. Furthermore, this increased knowledge will enable risk assessors to perform better and more well-founded risk assessment on cosmetic ingredients.

For additional information, see «Risk assessment of the exposure to aluminium through food and the use of cosmetic products in the Norwegian population» (2013) and «Risk assessment of vitamin A (retinol and retinyl esters) in cosmetics» (2012).

4.4.1.2 Exposure and use

In «The SCCS's Notes of Guidance for the testing of cosmetic substances and their safety evaluation» (2012), default values based on European surveys are given for the daily exposure levels to different types of cosmetic products. These default values correspond, however, to the 90th percentile value from these studies. Thus, for a large group of consumers, smaller amounts of the cosmetic products may be applied on a daily basis. This may lead to an overestimation of the systemic exposure doses. Since the 50th percentile values are available in the original scientific papers, these daily exposure values should considered being used when doing risk assessment of cosmetic ingredients.

For some cosmetics, the frequency of use and amount of product applied may differ between countries (e.g. the cold and dry winter climate in Norway may cause a higher daily exposure level of body lotions compared to other European countries). The SCCS default values on daily exposure levels are based on European studies, not including Norway.

- Norwegian data on daily exposure levels of cosmetics is needed. To VKM's knowledge, there are no Norwegian surveys on the exposure and use of cosmetics. Thus, when estimating exposure levels in risks assessments on cosmetic ingredients, there will be a greater uncertainty when using the SCCS's default compared to values based on a national survey.

These data would be valuable when performing risk assessments on cosmetic ingredients.

For additional information, see «Risk assessment of the exposure to aluminium through food and the use of cosmetic products in the Norwegian population» (2013) and «Risk assessment of vitamin A (retinol and retinyl esters) in cosmetics» (2012).

4.4.1.3 Nanomaterials in cosmetics

Nanomaterials in cosmetics can be divided into soft and rigid particles, where soft particles are made of organic materials (e.g. lipids, proteins, polymers) and rigid particles are made of inorganic materials (e.g. metals, metal oxides, silica). Often, there is a low penetration rate of rigid particles such as titanium and zink oxide through intact skin.

- Data on penetration of rigid particles through damaged skin is needed.
- For nanoparticles made of silica, hydrated silica and silica modified with alkyl silylates, data on skin absorption is needed.
- Knowledge on the toxicity of different nanoparticles is needed.

Cosmetic ingredients are incorporated into soft particles or vesicles. Soft particles may act very differently from rigid particles. The total amount of cosmetic ingredients that are deposited is dependent on both the chemical and the material of the soft particle. Studies have shown that incorporation of cosmetic ingredients into soft particles not necessarily affect the skin permeability of the chemical. However, incorporation of chemicals into soft particles may increase the amount of chemical deposited on the skin in addition to an increase of the deposition time. Incorporation into soft particles may also affect the penetration pathway in that particles penetrate preferentially into the hair follicle canal, thus enabling high concentrations within the reservoir of the follicular infundibulum.

- Knowledge on how incorporation of cosmetic ingredients into soft vehicles affects the toxicokinetic and the toxicological profile of an ingredient is needed.
- Data on skin absorption and toxicological data for rigid nanoparticles is needed.

Since the use of nanoparticles can change both the penetration pathway and the amount of cosmetic ingredients deposited in the skin, ingredients in nanoform can act toxicologically different than the cosmetic ingredients in non-nano form. Thus, data on toxicokinetics and toxicity studies on cosmetic ingredients in non-nano form may not be relevant when evaluating the same ingredients as nanoparticles. This data will be valuable when performing risk assessment of nanomaterials in cosmetics.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

4.5 References

- Benefit and risk assessment of breastmilk for infant health in Norway (2013)
- Benefit-risk assessment of fish and fish products in the Norwegian diet – an update (2014)
- Comparison of organic and conventional food and food production Part III: Human health – an evaluation of human studies, animal models studies and biomarker studies (2014)
- Evaluation of tolerable upper intake levels for vitamin D in children and adolescents (2014)
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- Risk assessment of dietary cadmium exposure in the Norwegian population (2015)
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- Risk assessment of the exposure to aluminium through food and the use of cosmetic products in the Norwegian population (2013)
- Risk assessment of lead exposure from cervid meat in Norwegian consumers and in hunting dogs (2013)
- Risk assessment of mycotoxins in cereal grain in Norway (2013)
- Risk assessment of vitamin A (retinol and retinyl esters) in cosmetics (2012)
- Scientific opinion on glyphosate-tolerant, genetically modified cotton GHB614 from Bayer CropScience for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (Application EFSA/GMO/NL/2008/51) (2009)
- Summary of the health risk assessment of the adjuvant effects of Cry proteins from genetically modified plants used in food and fodder (2012)
- Trygg mat og kosmetikk, friske dyr og planter forutsetter forskning, kartlegging og overvåkning (2014)

All references above are published on www.vkm.no

Other references:

- Annual report of the EFSA Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed for 2015 (EFSA, 2016) http://www.efsa.europa.eu/en/supporting/pub/939e

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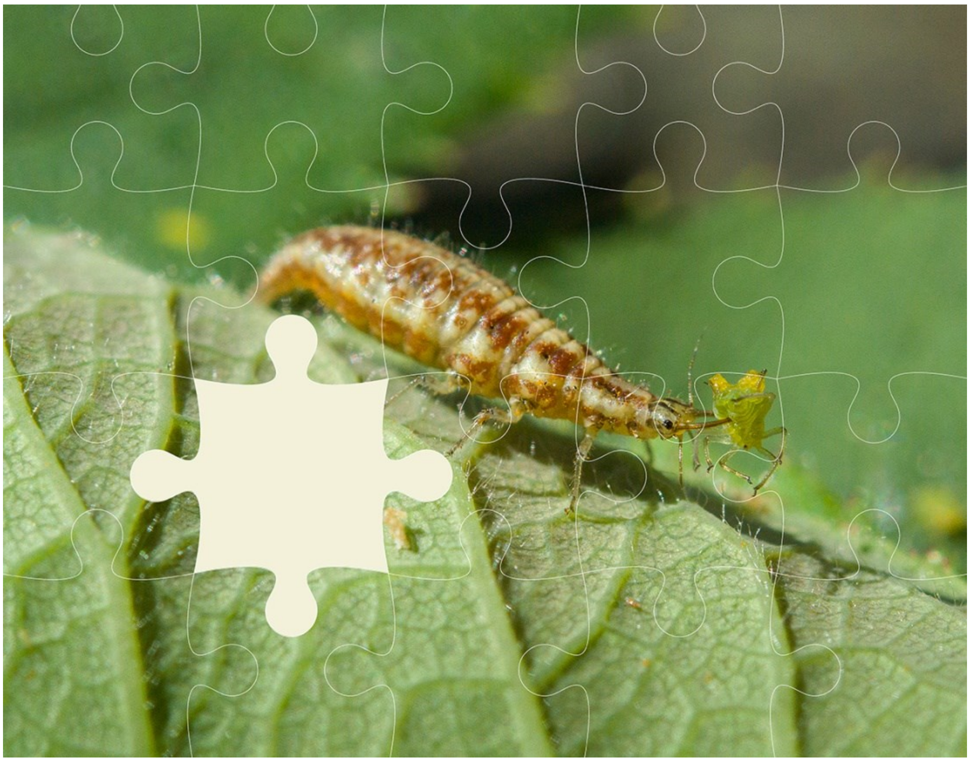
5 Biodiversity



Summary

Research needs and data gaps of importance for protection of biodiversity include:

- Alien species under Norwegian conditions; epidemiology and population dynamics, surveillance, models for behavior and development, and models for effects of climate changes.
- Effects of pesticides on bees and other pollinating insects.

Only research needs and data gaps related to VKM risk assessments are included.

In 2015, VKMs mandate was expanded by the Norwegian Environment Agency to encompass environmental risk assessments and other scientific considerations related to alien organisms, trade in endangered species (CITES – the Convention on International Trade in Endangered Species of Wild Fauna and Flora) and microbiological products. Research needs and data gaps within these areas are not included in the present report, since no risk assessments were published when this report was prepared.

A detailed presentation is given in this chapter.

Table of Contents

5.1 Alien organisms

Alien organisms are organisms that have been spread, intentionally or unintentionally, outside their natural ecological range (past or present) as a result of human action.

5.1.1 Epidemiology and population dynamics of new pests (alien species) under Norwegian conditions

A continuous increase in import of fruits, vegetables and ornamental plants may increase the risk/increase the pressure of new plant pests entering the country.

- Research on epidemiology and population dynamics for new plant pests under Norwegian conditions is needed.
- Research on epidemiology and population dynamics for plants pest already present in Norway is needed. As an example: the plant pest pinewood nematode (PWN) might be imported to Norway. The nematode is vectored, or carried, by a number of bark beetles and wood borers. Potential beetle vectors are present in Norway, but more research is needed to verify the suitability and distribution of these vector beetles.
- The efficacy of eradication of plant pests using updated methods of trapping technology based on attractants must be tested.

Changes in the plant pest status in Norway might lead to higher production costs and increased needs for using chemical plant production products. Knowledge on epidemiology and population dynamics of plant pests under Norwegian conditions is essential when predicting the behaviour of specific pest, the potential for establishment, spread and damage to natural and cultivated plants in Norway, and possibilities for pest eradication.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

5.1.2 Models for behaviour and development of new plant pests (alien species) under Norwegian conditions

Growth, survival and spread of new plant pests (alien species) are to a great extent dependent on climatic factors such as temperature, humidity, precipitation and radiation. Changes in climate may influence not only the speed of the development of a plant pest but also the speed of defense responses of the host plants of the pests. In addition, it may influence on the interactions between the host and the pest. Quantitative models can be used to estimate how the development of a pest changes during time and space, in relation to changes in climate and susceptibility of the host plant. Quantitative models present a causal connection between variables of the weather and development of the pest. Models based on weather have been used in plant pest management in several countries. Such models are based on regional weather conditions, and are specific for the region or the country.

- Models to predict the behaviour and development of plant pests under Norwegian conditions are needed. To reduce the uncertainties, it is important to develop models that can predict outbreaks under Norwegian conditions by correlating weather data with life cycle of the plant pest and its hosts. A specific model is required for a specific pest or group of pests. Data on epidemiology and population dynamics for the pest is important input to the model. Other organisms that might carry the pest (vectors) must be quantified in the model. The models should be used together with climate models for the next ten years. The empirical basis for the models, the input data, should be transparent and visible to ensure that the reliability and uncertainties of the model predictions can be evaluated before any management decisions are made. It is important that the Norwegian research community knows and masters the latest within model methodology and techniques.

Quantitative models are important to reduce uncertainties in risk assessment and risk management of plant pests. Models for behavior and development of plant pests based on agro-climatic conditions in Norway are required to estimate development of plant pests under Norwegian conditions. Using models based on agro-climatic conditions in other countries, the uncertainties related to the relevance of the results for Norwegian conditions will be high.

For additional information, see «Forskningsbehov påpekt av VKM 2012» (2012).

5.1.3 Monitoring new and potentially harmful pests (alien species)

New and harmful plant pests (alien species), including quarantine pests, are repeatedly detected in imported plants. Since plant propagation is labour intensive, European companies have moved parts of their propagation to countries with low production costs (in Eastern Europe, Asia, and Africa). African rose production and fruit and vegetable production in Latin America for export to Europe is rapidly increasing. Raw materials for Norwegian wood-processing industry arrive mostly from overseas countries. The commodities are distributed so quickly and efficiently that the risk is high that plant pests follow undetected, and that symptoms of infections do not develop before the commodities have arrived at Norwegian nurseries, stores and industrial plants.

- Sensitive and reliable methods for diagnostics of plant pests (specific plant pests) must be developed and/or established. The methods can be based on techniques like DNA barcoding and real time PCR.

The methods are to be used in analyses of import consignments, and for monitoring of the plant health situation in Norway. A well-functioning system for quick and reliable detection and identification of plant pests is mandatory to prevent establishment and spread of organisms harmful to plants in Norway. In addition, such a system forms the basis for necessary eradication or regulation measures. A proactive effort to increase our knowledge on the biology of plant pests, and to develop the best methods for diagnostics, will help both scientists and risk managers to react quickly and efficiently to different occurrences concerning new or already established pests. Good methods for diagnostics will contribute to more reliable information on emerging plant health risks and on the actual plant health situation in Norway.

For additional information, see «Forskningsbehov påpekt av VKM 2012» (2012).

5.1.4 Retrospective studies on effects of climate changes on plant pests

It is highly/most certain that the expected climate changes will affect the plant health situation in Norway. On the other hand, it is highly uncertain how the plant pest will be affected by changes in climate. Together with the presence of host plants, temperature and precipitation are the most important factors affecting establishment of a plant pest, plant pathogens and weeds. An increase in temperature may affect harmful organisms already present in the country, and exotic harmful organisms might be able to survive and cause damage to both natural vegetation and cultivated plants. A longer growth season may increase the generation number of plant pests and prolong epidemics caused by plant pathogens. It is commonly mistaken that experiences with a pest in southern latitudes can be transferred directly to future conditions in Norway. Especially light conditions, such as day length that is independent of climate changes, together with winter conditions, such as covering of snow and freeze-thaw processes, makes it impossible to automatically conclude that the future plant health situation in Norway will be the same as seen further south in today's climate. Also, climate and topography in Norway differs from the other Nordic countries, thus, an extrapolation of experiences in those countries might also be difficult in many cases.

- Analysis of experienced climate changes versus experienced changes in behaviour of plant pests in Norway is needed. An in-depth evaluation of the climate changes observed in recent decades should be made together with changes in behaviour and spread of the plant pest seen during the same period. Such retrospective studies require monitoring/survey data of the plant pest, and studies of its behaviour/population dynamics would also be useful. These studies may utilize data from monitoring programmes, such as the Norwegian monitoring of the European spruce bark beetle with yearly data from more than 100 municipalities back to 1979.

Models to estimate changes in temperature and precipitation are needed. Different models for different organisms should be developed. Retrospective studies will be a very useful input to such models. In many cases such studies will be a more reliable basis than the use of climate scenarios.

For additional information, see «Forskningsbehov påpekt av VKM 2012» (2012).

5.2 Pesticides

Pesticides may affect biological diversity by direct toxicity to organisms or by causing changes to their habitat and food chain. During the last decades, intensified agriculture has resulted in the loss of many wild plant and animal species, which has profoundly changed the agro-ecosystems. The cause of these changes has many components, such as loss of landscape elements, enlarged farm and field sizes and more intense use of fertilizer and pesticides. Little is however known about the relative contribution of the individual components such as pesticides to the large-scale negative effects on biodiversity.

The use of insecticides and fungicides may obviously induce negative effects on biodiversity. The possible influence of neonicotinoid pesticides on pollinating bees is just one of many examples where pesticide may have significant impacts on biodiversity.

5.2.1 Effects of pesticides on bees and other pollinating insects

- A review of the existing literature and experience of relevance for Norwegian conditions is needed.

This knowledge will provide a basis for better understanding and thus relevant national measures.

5.3 Genetically modified organisms (GMOs)

5.3.1 Genetically modified (GM) fish

At the end of 2015, Environment Canada approved GM sterile all-female salmon eggs (by triploidisation) to be manufactured on a commercial scale in Canada (AquaBounty Technologies). According to Environment Canada, AquAdvantage® Salmon (AAS) are not harmful to the environment or human health when produced in contained, land-based facilities. Transgenic Atlantic salmon contain a gene construct (opAFP-GHc2; EO-1α) consisting of GH cDNA from *Chinook* salmon (*Oncorhynchus tshawytscha*) that is regulated with antifreeze protein gene sequences from an Ocean pout (*Zoarces americanus*).

- To understand the effects of GM fishes on wild fish populations and overall on aquatic ecosystem function, knowledge on environmental effects of the transcriptional pattern of the inserted gene in the wild is needed.

5.3.2 Effects of Bt-toxins on ecosystems in soil and in aquatic environments

GMOs modified to be insect-resistant by the insertion of cry-genes, may allow for reduced use of insecticides because the crop expresses insecticidal Cry proteins. These Cry proteins may have fairly restricted, species-specific toxic properties for important insect pests. This has the advantage of reducing the need for farmers to handle and spray conventional insecticides onto crops.

Use of insect resistant crops could contribute to the presence of plant-produced Cry proteins in soil from root exudates and crop residues remaining in fields after harvesting. The persistence of the Cry proteins in soil depends, among others, on soil type and climatic conditions, and can be different for different Cry proteins. Although most Cry proteins are degraded or inactivated in soil within weeks, a small fraction can persist far longer under certain conditions. Cry proteins may also reach aquatic environments via run-off from soil as well as from Cry-containing feed ingredients in aquaculture feeds if and when these are authorized for use.

However, much of the available data is from short-term experiments and predictions of potential long-term effects are difficult to deduce.

- Knowledge on accumulation of Cry proteins and their long-term effects on terrestrial and aquatic environments in Norway are needed.

This knowledge is important for environmental risk assessment of GMOs expressing Bt-genes.

5.3.3 Feral populations of genetically modified (GM) oilseed rape

Import, transportation, handling, processing and use of oilseed rape commodities can easily result in accidental release of viable seeds into the environment. Demographic studies of feral oilseed rape have shown the ability of oilseed rape to establish self-perpetuating populations outside agricultural areas, mainly in semi-natural and ruderal habitats, and escaped populations of herbicide-tolerant oilseed rape have been reported along transportation routes, ports and close to processing plants in Japan, Canada and USA. Germination and establishment of volunteer oilseed rape plants may result in gene flow into cultivated varieties and feral populations of *Brassica napus*, as well as into closely related wild relatives. Furthermore GM-oilseed plants may cause potential problems for co-existence with conventional cultivars in case of admixture.

- Routes of import, transport and processing of oilseed rape seeds and quantitative considerations of the potential of spillage in Norwegian environments should be investigated.
- Knowledge on whether feral populations of oilseed rape are short-lived or have a more permanent nature is needed. Particularly the places where most substantial losses occur should be identified and studied.

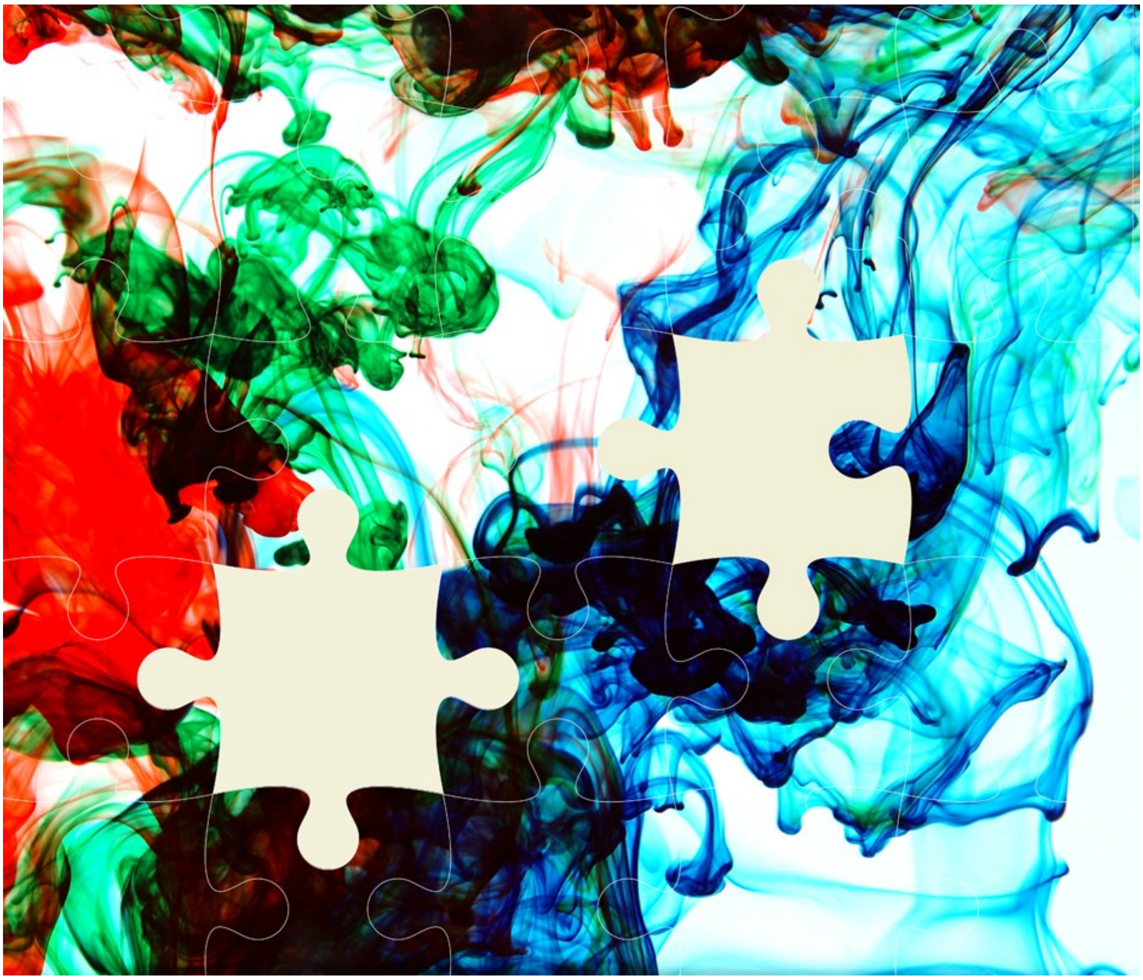
This information is important for environmental risk assessment of import and cultivation of transgenic oil seed rape in Norway.

5.4 References

- Forskningsbehov og kunnskapshull påpekt av VKM 2013 (2013)
- Forskningsbehov påpekt av VKM 2012 (2012)
- Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010 (2011)
- Trygg mat og kosmetikk, friske dyr og planter forutsetter forskning, kartlegging og overvåkning (2014)

All references are published on www.vkm.no

6 Combined exposures



Summary

Risk-benefit assessments within the food area, will highly benefit upon updated data and research on how to evaluate combined exposures to multiple contaminants ("cocktail effects") and contaminants and nutrients. Research needs and data gaps of importance for combined exposures include:

- Methods for risk assessment of combined exposures of chemicals.

Only research needs and data gaps related to VKM risk assessments are included.

A detailed presentation is given in this chapter.

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6.1 Risk assessment of combined exposures

6.1.1 Methods for risk assessment of combined exposures

Risk assessment is mainly performed on individual substances. However, a lot of work is in progress internationally, e.g. in EFSA and WHO, in order to develop more precise methods to assess the risks related to the exposure to several substances in combination.

- Robust and validated methods for assessment of combined exposures should be established.

The knowledge is considered important for risk assessments.

For additional information, see «Combined toxic effects of multiple chemical exposures» (2008) and «Statement on the applicability of the 2008 VKM report "Combined toxic effects of multiple chemical exposures" after consideration of more recently published reports on risk assessment of combined exposures» (2013).

6.2 References

- Combined toxic effects of multiple chemical exposures (2008)
- Forskningsbehov og kunnskapshull påpekt av VKM 2013 (2013)
- Forskningsbehov påpekt av VKM 2012 (2012)
- Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010 (2011)
- Statement on the applicability of the 2008 VKM report "Combined toxic effects of multiple chemical exposures" after consideration of more recently published reports on risk assessment of combined exposures (2013)
- Trygg mat og kosmetikk, friske dyr og planter forutsetter forskning, kartlegging og overvåkning (2014)

All references are published on www.vkm.no

7 Surveillance data for food and diet

Summary

Knowledge on what we eat and which substances the food contains are critical for risk assessments. Needs for surveillance data for food and diet includes:

- A regularly updated food database with data on food intake in the Norwegian population and data on presence and concentrations of nutrients, contaminants and foodborne pathogens in food.

Only data gaps related to VKM risk assessments are included.

A detailed presentation is given in this chapter.

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7.1 Food database

An infrastructure that combines data on food intake, nutrients, contaminants and foodborne pathogens will enable VKM to carry out more precise assessments with less uncertainty. Today, no such infrastructure exists.

7.1.1 Food database - infrastructure

Today, it is difficult to get an overview of potentially available data (since the data are spread in different institutions and files), and also to use the data (not on comparable format).

- A food database including presence and concentration of nutrients, contaminants and pathogens is needed. The data should be easy accessible, and in a format that are comprehensible and suitable for both intake and exposure calculations.
- For foodborne pathogens, an anonymised overall database on presence and concentration for zoonotic agents collated from both surveillance programs conducted by Norwegian Food Safety Authority and internal control conducted by food producers is needed.

To estimate intake of nutrients and exposure to contaminants and foodborne pathogens through diet there is need for a common food database.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

7.1.2 Food database – nutrients, contaminants and foodborne pathogens

A more systematic surveillance of contaminants in food/food groups is needed, including e.g. mycotoxins, metals, dioxins and dioxin-like PCBs, PAHs, pesticides, brominated flame retardants, perfluorated compounds, and process induced contaminants such as e.g. furan.

7.1.2.1 Nutrients – content in food

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 10 years there has been a great change in raw materials used in fish feeds for farmed Atlantic salmon and trout. In 2013, terrestrial plant proteins and vegetable oils accounted for 70% of the feed. These changes in concentration of nutrients and in fish feed is reflected in changed concentrations and compositions of the same nutrients in the farmed fish fillet. Compared to 2006, the concentrations of EPA, DPA and DHA are about 50%, the concentration of selenium is about

40%, while the concentration of vitamin D appears unchanged. The level of iodine in farmed Atlantic salmon was low in 2006, and is still low compared to lean fish.

- Data on EPA, DPA, DHA, vitamin D, iodine and selenium in wild caught fish is needed. With regular sampling of the same species from the same area over a long period of time makes, it possible to follow trends.
- For farmed fish, there is a need for knowledge about how new changes in the feed recipe affects the content on EPA, DPA, DHA, vitamin D, iodine and selenium in the fish fillet.
- For commercial products containing seafood, like fish cakes and fish soup, there is a need for knowledge about the content of EPA, DPA, DHA, vitamin D, iodine and selenium.
- A periodical update of nutrient content in raw food and commercial food products 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.

In order to estimate intake of nutrients, the concentration of nutrients in commercial food must be analysed. To estimate the intake of EPA, DPA, DHA, vitamin D, iodine and selenium, data on the content in fish are essential since fish is an important source for these nutrients in the Norwegian diet.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011) and «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014).

7.1.2.2 Contaminants - presence and concentration of mycotoxins and toxic metabolites

An increase of mycotoxins in grains and grain-based products is expected due to milder springs and wetter summers in Norway. The consumption of maize-based products and rice in Norway has increased in recent years.

- For grain and grain-based products:
    - Data on presence and concentration of the mycotoxins DON, T-2 and HT-2 in Norwegian food are needed. A more systematic surveillance should be performed, especially focusing on products with high wheat and oat contents.
    - Data on presence and concentration of the emerging mycotoxins enniatins, beauvericin and moniliformin are needed.
- For maize-based products:
    - Data on presence and concentration of mycotoxins such as aflatoxin, zearalenone, fuminosin, and DON are needed.

This knowledge is critical to estimate the exposure to mycotoxins and to assess potential negative health effects.

For additional information, see «Risk assessment of mycotoxins in cereal grain in Norway» (2013).

7.1.2.3 Contaminants - presence and concentration of metals

Aluminium

- A small number of samples and food types has been analysed for aluminium concentrations. Analyses of more food samples are warranted.

To estimate the exposure to aluminium through diet, this knowledge is essential.

For additional information, see «Risk assessment of the exposure to aluminium through food and the use of cosmetic products in the Norwegian population» (2013).

Cadmium

- There is a need for more data on presence and concentration both in commonly consumed food items as well as in food items considered as risk food for cadmium.
- Data on cadmium levels in organically produced vegetables, particularly if grown in alum shale areas, is needed.

To estimate the exposure to cadmium through diet, this knowledge is essential.

For additional information, see «Risk assessment of dietary cadmium exposure in the Norwegian population» (2015).

Lead

- Data on fragmentation pattern of bullets in moose is needed.

To provide better advice on the amount of meat around the bullet wound channel that needs to be removed in order to avoid lead-exposure from moose meat, data on fragmentation pattern of bullets in moose is essential.

For additional information, see «Risk assessment of lead exposure from cervid meat in Norwegian consumers and in hunting dogs» (2013).

7.1.2.4 Contaminants - presence and concentration of mercury, dioxins and dioxin-like PCBs

Fish can contribute significantly to the dietary exposure to some contaminants, of which the most important are methylmercury and the dioxins and dioxin-like PCBs.

- For wild caught fish, there is a need for knowledge about the concentration of methylmercury, dioxins and dioxin-like PCBs in commercially available fish species.
- In order to show time-trends of contaminant levels, regular sampling of the same species, e.g. cod liver and fillet, from the same area over a long period of time is needed.
- Data on contaminants in commercial products containing fish like fish cakes, bread spreads, and ready to eat meals (fish soup and fish au gratin) is needed.

To estimate the exposure to mercury, dioxins and dioxin-like PCBs through diet, this knowledge is essential.

For additional information, see «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014).

7.1.2.5 Contaminants - presence and concentration of new contaminants

Future new feed ingredients in fish feed for farmed fish, including GM-oils, other novel oils and protein sources, may introduce new contaminants which may be recovered in the fish filet. In farmed fish fillet for human consumption, the possible content of new contaminants introduced by use of plant ingredients in fish feed is unknown.

- Knowledge about the transfer of e.g. PAHs, mycotoxins, pesticides, brominated flame retardants and perfluorated compounds from feed to fish fillet is needed.

Knowledge on contaminants in fish filet, both composition and concentrations, is needed in order to ensure farmed fish as healthy food. Changes in fish feed recipe should be followed by continuing scientific research and monitoring to reveal its impact on fish as food.

For additional information, see «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014).

7.1.2.6 Contaminants – presence and concentration in commercial food products

- There is a general lack of analytical data on contaminants in commercial products containing fish like fish cakes and bread spreads, ready to eat meals (fish soup and fish au gratin).

To estimate the exposure to contaminants through commercial food products, data on presence and concentration of contaminants is needed.

For additional information, see «Benefit-risk assessment of fish and fish products in the Norwegian diet – an update» (2014).

7.1.2.7 Contaminants - presence and concentration of process induced contaminants

Furan is a volatile and lipophilic compound formed in a variety of heat-treated commercial food and contributes to the sensory properties of the product. The substance has been found in a number of foods such as e.g. coffee, canned and jarred food including baby food containing meat and various vegetables. High concentrations of furan have been found in coffee, and the presence of furan in jarred baby food and infant formulae has received much attention since such products may be the sole diet for many infants.

- Analyses of the furan concentration in both processed and heated food are warranted.
- Only a small number of samples and food types have been analysed for furan contents. In addition data on furan concentrations in Norwegian coffee do not exist. Since coffee is a major source of furan exposure in adults, this contributes to the uncertainties in the exposure calculations for furan. New data on the furan concentrations in Norwegian coffee would improve the exposure calculations of furan and reduce the uncertainty in the risk assessment for adults.
- A comprehensive and continually updated national furan database is necessary for estimating the overall exposure of furan through diet.
- No information on the furan concentration in home-cooked food are available, therefore presence and concentration data are needed on the presence of furan in home-cooked food are needed.

To estimate the overall exposure to furan through diet, this knowledge is needed.

For additional information, see «Risk assessment of furan exposure in the Norwegian population» (2012).

7.1.2.8 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.

- 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.

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 human population and ensure compliance with EU principles of modern risk-based audit for Norwegian Food Safety Authority.

7.2 Food intake/consumption

7.2.1 National dietary surveys

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 based on a pre-coded 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.

- Regular performance of the national dietary surveys for all age groups is needed (every 5-10 years).
    - The surveys should be designed to capture variations in intake of foods/food groups, and include high consumers of specific foods/food groups.
    - A sufficient number of participants must be recruited.
- Comparable methodology across the age groups should be used.

This knowledge is critical for exposure estimation, and to relate food intake to health effects. Performing regular dietary surveys which give comparable results from survey to survey enable us to follow trends in dietary habits.

For additional information, see «Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010» (2011).

7.2.2 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.

- 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.

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.

For additional information, see «Risk assessment of dietary cadmium exposure in the Norwegian population» (2015).

7.3 References

- Benefit-risk assessment of fish and fish products in the Norwegian diet – an update (2014)
- Forskningsbehov og kunnskapshull påpekt av VKM 2013 (2013)
- Forskningsbehov påpekt av VKM 2012 (2012)
- Kunnskapshull og forskningsbehov som VKM har avdekket i sitt arbeid med risikovurderinger 2009-2010 (2011)
- Risk assessment of dietary cadmium exposure in the Norwegian population (2015)
- Risk assessment of furan exposure in the Norwegian population (2012)
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