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# Dietary exposure to inorganic arsenic in the Norwegian population

Assessment of the Panel on Contaminants of the Norwegian Scientific Committee for Food Safety

Report from the Norwegian Scientific Committee for Food Safety (VKM) 2016: 11 Dietary exposure to inorganic arsenic in the Norwegian population

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# Dietary exposure to inorganic arsenic in the Norwegian population.

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#### Assessed and approved

The opinion has been assessed and approved by Panel on Contaminants. Members of the panel are: Janneche Utne Skåre (chair), Heidi Amlund, Anne Lise Brantsæter, Gunnar Sundstøl Eriksen, Christiane Kruse Fæste, Helle K. Knutsen, Helen Engelstad Kvalem, Christopher Owen Miles, Anders Ruus, and Cathrine Thomsen.

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The Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) has appointed a working group consisting of VKM members and VKM staff to answer the request from the Norwegian Food Safety Authority. Project leaders from the VKM secretariat has been Edel Holene and Inger Therese L. Lillegaard. Heidi Amlund and Inger Therese L. Lillegaard are acknowledged for their valuable work on this opinion. The Panel on Contaminants is acknowledged for comments and views on this opinion.

#### **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

#### **Request from the Norwegian Food Safety Authority**

The Norwegian Food Safety Authority (NFSA) requested a statement from the Norwegian Scientific Committee for Food Safety (VKM) on the dietary exposure to inorganic arsenic in the Norwegian population. VKM was asked to comment on the following; 1.) Why the European Food Safety Authority (EFSA) assessment from 2009 found that the Norwegian population had higher dietary exposure to total arsenic than other European populations, 2.) Whether the Norwegian population or special groups of the population have food consumption patterns which could lead to a different dietary exposure to inorganic arsenic than what is reported for the European population, and 3.) Whether the consumption rice and rice products, such as rice cakes, and in Hijiki seaweed could pose additional health risks for children and adults.

#### How VKM has addressed the request

VKM has appointed a working group consisting of members of the Panel on Contaminants and from the VKM secretariat to answer the request. The Panel on Contaminants has reviewed and revised the draft prepared by the working group and finally approved the assessment on dietary exposure to inorganic arsenic in the Norwegian population.

#### What arsenic is and its toxicity to humans

Arsenic is a metalloid occurring in many different chemical forms in the environment. In the terrestrial environment, arsenic is mainly found as inorganic arsenic, i.e. arsenite and arsenate. In the aquatic environment, more than a 100 arsenic species have been identified. The organic form arsenobetaine is the major form in fish and other seafood.

Humans are mainly exposed to arsenic through food and drinking water. Food is the major source for most people, but for people living in regions with naturally elevated concentrations of arsenic in groundwater, drinking water is the major source.

The toxicity of arsenic species depends on the chemical form, with inorganic arsenic (arsenite and arsenate) being more toxic than organic arsenic compounds. Inorganic arsenic is carcinogenic, but not genotoxic, and is classified as a human carcinogen.

#### Dietary total arsenic exposure in Europe and Norway

The dietary exposure to total arsenic for the Norwegian population was estimated by EFSA (2009). The Norwegian exposure levels were the highest among the European populations. A high exposure to total arsenic for Norwegian adults was also estimated in the Norwegian Fish and Game study (Birgisdottir et al., 2013). Fish and seafood is the main contributor to the

dietary exposure to total arsenic, and a high consumption of fish and seafood leads to a high dietary exposure to total arsenic.

#### Dietary inorganic arsenic exposure in Europe and Norway

There was little variation in the estimated dietary exposures to inorganic arsenic for the European populations (EFSA, 2014). The dietary exposure to inorganic arsenic has earlier been estimated for the Norwegian adult population based on a study including participants with high consumption of fish and other seafood and game meat, and participants representing the general population (Birgisdottir et al., 2013). The estimates for inorganic arsenic exposure were within the ranges reported by EFSA (2014), suggesting that Norwegian adults do not have specific eating patterns leading to a different dietary exposure to inorganic arsenic than other European adult populations.

In the European populations, the main contributors to dietary exposure of inorganic arsenic were the food groups "grain-based processed products (non rice-based)", "rice", "milk and dairy products" and "drinking water" (EFSA, 2014). There is no information regarding specific dietary patterns of Norwegian sub-populations possibly leading to a higher exposure to inorganic arsenic. Fish and other seafood generally contain high levels of total arsenic, but the level of inorganic arsenic is very low.

### Exposure to inorganic arsenic through consumption of rice and rice products, and Hijiki seaweed

The dietary exposures to inorganic arsenic in the European populations are within the range of the  $BMDL_{01}$  values and therefore possible health risks cannot be excluded (EFSA, 2009; EFSA, 2014). The estimated dietary exposure to inorganic arsenic in the Norwegian adult population (Birgisdottir et al., 2013) is also within the range of the  $BMDL_{01}$  values.

Rice was identified as one of the main contributors to the dietary exposure to inorganic arsenic in Europe (EFSA, 2014). Rice and rice products contain higher levels of inorganic arsenic than other food groups and individuals with a high consumption of rice and rice products may have a higher exposure to inorganic arsenic than the rest of the population, resulting in an added health risk.

For infants and toddlers, rice and rice products are not an important source of inorganic arsenic (EFSA, 2014). According to EFSA (2014) the main contributor to exposure to inorganic arsenic in infants and toddlers was "milk and dairy products", then "drinking water", "grain-based processed products (non rice-based)" and "Foods for infants and young children".

However, the dietary exposure to inorganic arsenic in toddlers and children is higher than in adults because of their higher food consumption relative to body weight (EFSA, 2014). Rice cakes are a product, which may contain particularly high levels of inorganic arsenic, and consumption of rice cakes by children will increase their exposure to inorganic arsenic

(Livsmeddelsverket 2015, DTU Food 2013). Thus, Norwegian infants and toddlers with a high consumption of rice and rice products, such as rice cakes, may have a higher exposure to inorganic arsenic than other infants and toddlers, resulting in an added health risk.

The edible seaweed Hijiki generally contains high levels of inorganic arsenic, whereas other seaweeds contain low levels of inorganic arsenic. Any consumption of Hikiji seaweed will lead to an additional exposure of inorganic arsenic, resulting in an added health risk.

**Key words:** Arsenic, dietary exposure, Hijiki seaweed, inorganic arsenic, the Norwegian Scientific Committee for Food Safety, rice, rice products, risk assessment, seaweed, total arsenic, the VKM

# Sammendrag på norsk

#### **Oppdrag fra Mattilsynet**

Mattilsynet ba Vitenskapskomiteen for mattrygghet (VKM) om en vurdering av eksponeringen for uorganisk arsen fra kostholdet i den norske befolkningen. VKM ble bedt om å kommentere på følgende punkter: 1) Hvorfor fant European Food Safety Authority (EFSA) i sin vurdering fra 2009 at befolkningen i Norge hadde en høyere eksponeringen for total arsen fra kostholdet enn andre i Europa, 2) Har nordmenn generelt eller grupper av befolkningen et kosthold som gir forskjellig eksponering for uorganisk arsen sammenlignet med hva som er rapportert for andre i Europa, og 3) Kan inntaket av uorganisk arsen i ris og risprodukter, som riskaker, og Hijiki tang medføre en tilleggsrisiko for barn og voksne.

#### Slik har VKM besvart bestillingen

VKM nedsatte en arbeidsgruppe som bestod av medlemmer av Faggruppen for forurensninger, naturlige toksiner og medisinrester og sekretariatet i VKM for å svare på bestillingen. Faggruppen har gjennomgått og revidert utkastet utarbeidet av arbeidsgruppen, og har godkjent vurderingen av uorganisk arsen i den norske befolkningen.

#### Hva er arsen og hvor farlig er det for mennesker

Arsen er et metalloid som forekommer i mange forskjellige kjemiske former i miljøet. I landmiljø opptrer arsen i hovedsak i form av uorganisk arsen som arsenitt og arsenat. I det marine miljøet er det indentifisert mer enn 100 forskjellige former for arsen. Den organiske formen for arsen, arsenobetain, er hovedformen i fisk og annen sjømat.

Mennesker er i hovedsak eksponert for arsen fra mat og drikke. Mat er hovedkilden til arsen for de fleste, men for personer som bor i regioner med naturlig høye arsenverdier i grunnvannet, vil drikkevannet være hovedkilden.

Hvor helseskadelig de forskjellige formene for arsen er, er avhengig av den kjemiske formen. Uorganisk arsen (arsenitt og arsenat) er mer skadelig enn organiske arsenformer. Uorganisk arsen er kreftfremkallende, men ikke gentoksisk, og er klassifisert som et kreftfremkallende stoff for mennesker.

#### Eksponering for total arsen i Europa og Norge

Eksponering for total arsen fra kostholdet i den norske befolkning er blitt estimert av EFSA (2009). Det norske eksponeringsnivået var det høyeste i Europa. Det norske eksponeringsnivået for total arsen blant voksne, ble også estimert i den norske «Fisk og vilt studien» (Birgisdottir et al., 2013). Fisk og sjømat er hovedkilden til eksponering for total arsen, og et høyt inntak av fisk og sjømat fører til en høy eksponering for total arsen.

#### Eksponering for uorganisk arsen i Europa og Norge

Det var lite variasjon i den estimerte eksponeringen for uorganisk arsen fra kosten mellom forskjellige grupper i Europa (EFSA, 2014). Eksponeringen fra kostholdet for uorganisk arsen er tidligere blitt estimert i den voksne norske befolkningen basert på en studie som inkluderte deltagere med et høyt inntak av fisk og annen sjømat og vilt, og deltagere som representerte den generelle befolkningen (Birgisdottir et al., 2013). Eksponeringen for uorganisk arsen var innenfor samme området som rapportert av EFSA (2014). Det tyder på at voksne i Norge ikke har et kosthold som gir forskjellig eksponering for uorganisk arsen sammenlignet med andre voksne i Europa.

Hovedkildene til uorganisk arsen fra kosten i den europeiske befolkningen var matvaregruppene: «kornbaserte produkter (ikke risbaserte)», «ris», «melk og melkeproduktere» og «drikkevann» (EFSA, 2014). Det er ingen informasjon om spesielle grupper som har et kosthold som fører til et høyere inntak av disse matvarene. Fisk og annen sjømat inneholder vanligvis høye nivåer av total arsen, men nivået av uorganisk arsen er svært lavt.

#### Eksponering for uorganisk arsen ved inntak av ris og risprodukter og hijiki tang

Eksponeringen for uorganisk arsen fra kostholdet i Europa er innen BMDL<sub>01</sub> området og mulig helserisiko kan ikke utelukkes (EFSA, 2009; EFSA, 2014). Den estimerte eksponeringen for uorganisk arsen blant voksne i Norge (Birgisdottir et al., 2013) er også innen BMDL<sub>01</sub> området.

Ris ble identifisert som en av hovedkildene til eksponering for uorganisk arsen i Europa (EFSA, 2014). Ris og risprodukter inneholder høyere nivå av uorganisk arsen enn andre matvaregrupper, og personer med et høyt inntak av ris og risprodukter kan ha en høyere eksponering for uorganisk arsen enn resten av befolkningen, noe som fører til en økt helserisiko.

Ris og risprodukter er ikke en viktig kilde til uorganisk arsen blant spedbarn og småbarn (EFSA, 2014). I følge EFSA (2014) var hovedkilden til uorganisk arsen for aldersgruppene sped- og småbarn: «melk og melkeprodukter», deretter «drikkevann», «prosesserte kornprodukter (ikke risbaserte)» og «Mat for spedbarn og småbarn».

Eksponeringen for uorganisk arsen fra kostholdet til småbarn og barn er høyere enn hos voksne fordi barn spiser mer mat i forhold til sin kroppsvekt (EFSA, 2014). Riskaker er et produkt som inneholder særlig høye verdier av uorganisk arsen, og ved å spise riskaker vil barn øke eksponeringen av uorganisk arsen (Livsmeddelsverket 2015, DTU Food 2013). Slik at norske sped- og småbarn med et høyt inntak av ris og risprodukter som riskaker, kan få en høyere eksponering for uorganisk arsen enn andre sped- og småbarn, noe som fører til en økt helserisiko.

Hijiki, som er en spiselig tangart, inneholder vanligvis høye nivåer av uorganisk arsen, mens andre tangarter inneholder lave nivåer av uorganisk arsen. Å spise Hijiki tang vil føre til en tilleggseksponering for uorganisk arsen, noe som fører til en økt helserisiko. **Nøkkelord:** arsen, kostholdseksponering, Hijiki tang, uorganisk arsen, Vitenskapskomiteen for mattrygghet, ris, risprodukter, risikovurdering, tang, total arsen, VKM

## Abbreviations and/or glossary

#### Abbreviations

ALARA As	as low as reasonably achievable arsenic
BfR	Bundesinstitut für Risikobewertung
BMDL <sub>01</sub>	Benchmark Dose Lower Confidence Limit (for 1% effect change)
bw	body weight
CI	confidence interval
CONTAM	The Scientific Panel on Contaminants in the Food Chain
EFSA	European Food Safety Authority
IARC	International Agency for Research on Cancer
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kg	kilogram
NFSA	Norwegian Food Safety Authority
MOE	Margin of Exposure
PTWI	provisional tolerable weekly intake
SAMOE	severity adjusted margin of exposure
TDI	tolerable daily intake
ToR	terms of reference
mg	milligram
μg	microgram
ww	wet weight

#### Glossary

Age groups as defined by EFSA for European countries are infants (<1 year old), toddlers ( $\geq$ 1 year to <3 years old), other children ( $\geq$ 3 years to <10 years old), adolescents ( $\geq$ 10 years to <18 years old), adults ( $\geq$ 18 years to <65 years old), elderly ( $\geq$ 65 years to <75 years old) and very elderly ( $\geq$ 75 years old).

**ALARA principle describes that** levels of an unwanted substance should be as low as reasonably achievable.

**Benchmark dose** is the minimum dose of a substance that produces a clear, low level health risk, usually in the range of a 1-10% change in a specific toxic effect such as cancer induction, e.g.  $BMDL_{01}$ .

**Carcinogenic substances may** cause development of cancer when an animal or human is exposed to it.

Genotoxic substance is capable of damaging the DNA in cells.

**Inorganic arsenic** is the sum of arsenite and arsenate.

**Lower bound** is when values below limit of quantification (LOQ), or in some cases limit of detection (LOD), are set to zero.

**Margin of exposure (MOE)** is a tool used in risk assessment to explore safety concerns arising from the presence of a potentially toxic substance in food. The MOE is a ratio of two factors assessed for a given population: the dose at which a small but measurable adverse effect is first observed and the level of exposure to the substance considered.

**Medium bound** is when values below limit of quantification (LOQ), or in some cases limit of detection (LOD), are set to half of the LOQ or LOD.

**P95-exposure** is the estimated exposure at the 95-percentile.

**Percentile** is a term for visualising the low, medium and high occurrences of a measurement (e.g. arsenic exposure) by splitting the whole distribution into one hundred equal parts. The 95-percentile is the value (or score) below which 95 percent of the observations are found.

**Total arsenic** is the sum off all arsenic species present in a given sample.

**Upper bound** is when values below limit of quantification (LOQ), or in some cases limit of detection (LOD), are set equal to the LOQ or LOD.

# Background as provided by the Norwegian Food Safety Authority

Arsenic is an element occurring both naturally in the environment and as a contaminant resulting from human activity. There are two main forms of arsenic, organic and inorganic. Long-term intake of inorganic arsenic has been associated with adverse health effects like cancer of the lungs, bladder, and skin.

Until recently, the available analytical methods have had difficulties in distinguishing between the different forms of arsenic. This is why most of the knowledge we have about the level of arsenic in food is expressed mostly as "arsenic", without specifying whether it is organic or inorganic.

According to a risk assessment EFSA published in 2009, Norway had the highest intake of arsenic in Europe, partly due to our high consumption of fish. Norwegian dietary data were included in the assessment. Studies show that although fish have high concentration of arsenic, 97-99% is the organic type that does not represent any health risks.

In 2014 EFSA presented an updated exposure calculation for inorganic arsenic in the European population. It showed lower exposure to inorganic arsenic than the risk assessment of 2009. Neither the Norwegian consumer data nor data on occurrence in food were included in the report.

Foods with high concentration of inorganic arsenic are rice and rice products, supplements based on algae, and shellfish. Those who have a high intake of these specific foods, such as some parts of the ethnic minority population in both Norway and the EU, may be exposed to inorganic arsenic at levels of concern. For the majority of the Norwegian and European population there are, however, other foodstuffs (cereals and cereal products, vegetables, bottled water and coffee) that contribute most to the intake of arsenic. This is because these foodstuffs are consumed in higher amounts and more frequently. Several countries have dietary advices concerning the consumption of various foods on the basis of the content of inorganic arsenic. For instance, food safety authorities in Sweden, Denmark and Norway have issued advice on rice drink to children under 6 years, the Swedish National Food Agency has detailed advices on consumption of rice and rice cakes, while Denmark advices against everyone to eat Hijiki seaweed and discourages giving rice cakes to children.

# Terms of reference as provided by the Norwegian Food Safety Authority

The Food Safety Authority requests VKM for a statement on the following points:

- EFSA assessment from 2009
  - Comment on why EFSA identify Norwegians as a population with a high exposure to arsenic
- EFSA assessment 2014
  - Comment on whether the population in Norway or special groups of the population have different food consumption patterns, which could lead to different dietary exposure to inorganic arsenic than what is reported for the European population
- Comment on whether the inorganic arsenic in rice and rice products (for example rice cakes) and Hijiki seaweed could pose additional health risks for children and adults who eat such food.

### Assessment

### 1 Introduction

#### 1.1 Arsenic

Arsenic is ubiquitous metalloid in the environment originating from both natural and anthropogenic sources. Arsenic in the crust of the earth is released through volcanic activity and weathering of rock, while the anthropogenic sources are burning of fossil fuels, agriculture, mining, and smelting industries.

Arsenic occurs in many different chemical forms in the environment (EFSA, 2009). In the terrestrial environment, arsenic is mainly found as inorganic arsenic, i.e. arsenite and arsenate. In the marine environment, more than a 100 arsenic species have been identified. The major chemical forms are arsenate and arsenite (seawater), arsenosugars (algae) and arsenobetaine (molluscs, crustaceans and fish). Arsenolipids are a new group of arsenic compounds found in fish oil and fatty fish.

Humans are mainly exposed to arsenic through food and drinking water (EFSA, 2009). Food is the major source for most people, but for people living in regions with naturally elevated concentrations of arsenic in groundwater, drinking water is the major source.

Most occurrence data for food are for total arsenic, i.e. the sum of all arsenic species present in the analysed sample (EFSA, 2009; EFSA, 2014). There are some data available for the occurrence of inorganic arsenic, arsenobetaine and arsenosugars in foods. Food from the terrestrial environment generally contains low levels of total arsenic and inorganic arsenic, with the exception of rice, which may contain high levels of inorganic arsenic. Fish and other seafood generally contain high levels of total arsenic, mainly organic species, the major arsenical present is arsenobetaine, and the level of inorganic arsenic is very low. There are exceptions, e.g. blue mussels (Mytilus edulis) may contain high levels of inorganic arsenic. Algae also contain elevated levels of total arsenic, mainly organic arsenic, and in most species the major arsenic compounds are arsenosugars. However, the edible seaweed Hijiki (Hizikia fusiforme) generally contains high levels of inorganic arsenic, whereas other seaweeds contain low levels of inorganic arsenic.

Foods mainly contributing to exposure to inorganic arsenic in the general population are cereal grains and cereal based products, rice and rice products, milk and dairy products, and drinking water (EFSA, 2014).

#### 1.2 Toxicity

The toxicity of arsenic species depends on the chemical form, with inorganic arsenic (arsenite and arsenate) being more toxic than organic arsenic compounds. The toxicities of the different arsenic species are reviewed by the CONTAM panel of the EFSA in the scientific opinion on arsenic in food (EFSA, 2009). Below is a short resumé of their review.

Humans do not metabolise arsenobetaine, which is excreted in urine within 24 hours after intake. Arsenobetaine is assumed "to be of no toxicological concern". Arsenosugars and arsenolipids are metabolised mainly to dimethylarsinate, but specific information regarding their toxicity is not available. Inorganic arsenic is readily absorbed after ingestion; inorganic arsenic binds to plasma proteins and is distributed to most organs. Arsenate is reduced to arsenite, which is methylated to methylarsonate and dimethylarsinate. Inorganic arsenic and metabolites are excreted via urine and bile. Inorganic arsenic and metabolites may cause toxicities in animal models, e.g. inorganic arsenic is carcinogenic, but not genotoxic. Arsenic does not directly induce DNA damage, but many potential mechanisms for arsenic induced carcinogenicity are described, e.g. indirect genetic damage caused by oxidative stress.

Inorganic arsenic is classified as a human carcinogen by the International Agency for Research on Cancer (IARC). Dietary exposure to inorganic arsenic may lead to skin lesions and cancers of the urinary bladder, lung and skin. The CONTAM Panel concluded that the provisional tolerable weekly intake (PTWI) of 15 µg/kg bw established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1989 was no longer appropriate (EFSA, 2009). New epidemiological studies showed that inorganic arsenic causes cancers of the urinary bladder and lungs in addition to cancer of the skin. Also, adverse effects were seen at lower exposure levels. The CONTAM Panel evaluated the new epidemiological studies and identified BMDL<sub>01</sub> values, ranging from 0.3 to 8.0  $\mu$ g/kg bw/day for cancers of the lung, skin and bladder, and skin lesions (EFSA, 2009). The CONTAM panel concluded that the overall range of BMDL<sub>01</sub> values, rather than a single reference point, should be used in risk characterisation of inorganic arsenic (EFSA, 2009). They also noted that inorganic arsenic is not directly DNA-reactive and there are proposed mechanisms of carcinogenicity for which "threshold mechanisms can be postulated". However, due to uncertainties related to possible dose-relationships the CONTAM Panel concluded that it is not appropriate to establish a tolerable daily or weekly intake, and recommends using the margin of exposure (MOE) approach in risk assessment of inorganic arsenic exposure (EFSA, 2009).

In their risk characterisation, the CONTAM panel compared the estimated dietary exposures for mean and high adult consumers in Europe directly with the range of BMDL values. As the exposures are within the BMDL range, the CONTAM panel concluded, "there is little or no MOE and the possibility of a risk to some consumers cannot be excluded" (EFSA, 2009).

#### 1.3 Legislation

Commission Regulation (EC) No 1881/2006 sets maximum levels for certain contaminants in foodstuffs. So far, arsenic has not been regulated. However, following the scientific opinion on arsenic in food by the CONTAM Panel of the EFSA (EFSA, 2009) maximum levels for arsenic and inorganic arsenic in some foods have been discussed by the European Commission and maximum levels for inorganic arsenic were implemented January 1st 2016. The maximum levels are now in the process of being implemented in Norwegian food legislation.

Commission Regulation (EU) 2015/1006 sets maximum levels for inorganic arsenic in foodstuffs. Some of the reasons for the maximum levels were;

- "The scientific opinion (EFSA, 2009) identified high consumers of rice in Europe, such as certain ethnic groups, and children under three years of age as the most exposed to inorganic arsenic dietary exposure. Dietary exposure to inorganic arsenic for children under three years old, including from rice-based foods, is in general estimated to be about 2 to 3-fold that of adults."
- "Since the analysis of inorganic arsenic is reliable for rice and rice based products, maximum levels for inorganic arsenic should be set for rice and rice based products. Differentiated maximum levels should be proposed in view of the arsenic content."
- "The occurrence data demonstrate that rice waffles, rice wafers, rice crackers and rice cakes can contain high levels of inorganic arsenic and these commodities can make an important contribution to the dietary exposure of infants and young children. Therefore, a specific maximum level for these commodities should be envisaged."
- "Rice is an important ingredient in a broad variety of food for infants and young children. Therefore, a specific maximum level should be established for this commodity when used as an ingredient for the production of such food."

The maximum levels for inorganic arsenic (sum of arsenate and arsenite) are;

- Non-parboiled milled rice (polished or white rice): 0.20 mg/kg
- Parboiled rice and husked rice: 0.25 mg/kg
- Rice waffles, rice wafers, rice crackers and rice cakes: 0.30 mg/kg
- Rice destined for the production of food for infants and young children: 0.10 mg/kg

# 2 Previous exposure and risk assessments

#### 2.1 EFSA opinions and reports on dietary exposure to arsenic

#### 2.1.1 Scientific opinion of total and inorganic arsenic in food, EFSA 2009

In 2009, the EFSA CONTAM Panel published a Scientific Opinion on Arsenic in Food. More than 100 000 food samples (including drinking water) collected in 15 European countries were used to calculate dietary exposure to both total arsenic and inorganic arsenic in the European populations. However, only about 2% of the occurrence data were on inorganic arsenic and the remaining data on total arsenic.

The mean upper bound dietary exposure (food and water) to total arsenic ranged from 0.65 to 4.57  $\mu$ g/kg bw/day, with the highest exposure found for the Norwegian population, based on consumption data from Norkost 97 (Johansson and Solvoll, 1999). The estimation of the exposure to inorganic arsenic from food and water was based on exposure scenarios and included a number of assumptions. For all species of fish and seafood, the concentration of inorganic arsenic was set to 30  $\mu$ g/kg, and 100  $\mu$ g/kg, respectively. While for all other foods, the concentration of inorganic arsenic was set to 70% of the total arsenic concentration. The exposure to inorganic arsenic was estimated to range from 0.13 to 0.56  $\mu$ g/kg bw/day for average adult consumers, and from 0.37 to 1.22  $\mu$ g/kg bw/day for the 95-percentile of adult consumers. For children under three year of age the exposure was estimated to be 2- to 3-fold higher than that of adults due to the higher food intake per kg bw in children (EFSA, 2009).

The largest contributors to the overall median dietary exposure to total arsenic in the European population were the food categories 'fish and seafood' (approximately 0.52 µg/kg bw/day) and 'cereals and cereal products'. Major contributors to the median dietary exposure to total arsenic were 'vegetables, nuts, pulses including carrots, tomato and leafy vegetables', 'fruit and vegetable juices, soft drinks and bottled water', 'coffee, tea, cocoa (expressed as liquid)', 'alcoholic beverages', and 'miscellaneous/food for dietary purposes'.

The main contributors to dietary exposure of inorganic arsenic in the general European population were the food subclasses 'cereal grains and cereal based products', 'food for special dietary use', 'bottled water' 'coffee and beer', and 'rice grain and rice-based products', while the contribution from "fish and seafood" was low (0.010  $\mu$ g/kg bw/day) (EFSA, 2009).

The most pronounced limitation regarding EFSA's Scientific Opinion (2009) was that dietary exposure to inorganic arsenic was not based on measured values of inorganic arsenic, but estimated values as described above, leading to an overestimation of the exposure.

EFSA concluded that "the estimated dietary exposures to inorganic arsenic for average and high level consumers in Europe are within the range of the  $BMDL_{01}$  values identified, and therefore there is little or no margin of exposure and the possibility of a risk to some consumers cannot be excluded."

#### 2.1.2 Dietary exposure to inorganic arsenic in the European population, Scientific report of EFSA 2014

In 2014, the EFSA published the scientific report: "Dietary exposure to inorganic arsenic in the European population", an updated exposure assessment for the exposure to inorganic arsenic in the European population. Norwegian consumption data and occurrence data were not included and the exposure to inorganic arsenic in the Norwegian population was not assessed.

A total of 103733 food samples (including drinking water), collected in 21 European countries, were used to calculate dietary exposure to inorganic arsenic. However, of the 103733 analyses, only 2753 analyses were of inorganic arsenic and the remaining of total arsenic. For fish and seafood, only reported data on inorganic arsenic were used in the estimation of exposure to inorganic arsenic. For all other food categories, the concentration of inorganic arsenic was set to 70% of the total arsenic concentration.

When using middle bound estimations, the main contributors to dietary exposure of inorganic arsenic were the food groups "grain-based processed products (non rice-based)", "rice", "milk and dairy products" and "drinking water" for the age groups over 3 years of age. For infants and toddlers, the main contributor was "milk and dairy products", then "drinking water", "grain-based processed products (non rice-based)" and "Food for infants and young children". Rice also contributed to the exposure to inorganic arsenic. In infants, rice contributed with 4-5%, while in toddlers the contribution was approximately 7%.

The exposure to inorganic arsenic ranged from 0.09 to 0.38  $\mu$ g/kg bw/day for average adult consumers (including elderly and very elderly), and from 0.14 to 0.64  $\mu$ g/kg bw/day for 95-percentile adult consumers. For adolescents the mean exposure to inorganic arsenic ranged from 0.12 to 0.48  $\mu$ g/kg bw/day, while the 95-percentile exposure ranged from 0.23 to 0.84  $\mu$ g/kg bw/day. For children below the age of 10 the exposure ranged from 0.20 to 1.37  $\mu$ g/kg bw/day, and from 0.36 to 2.09  $\mu$ g/kg bw/day for the 95-percentile.

For adults, the estimated dietary exposure (mean and 95-percentile) to inorganic arsenic was in 2014 considerably lower than in 2009 (EFSA, 2014) (see table 2.4.1-1). There are different factors that may explain these differences. The EFSA stated "... the most important being that in this report a more detailed codification to classify the foods (more disaggregated) was used (FoodEx classification), which also avoided the use of sampling

adjustment factors (SAF) which were applied in the 2009 EFSA opinion" (EFSA, 2014). Other factors were that more inorganic arsenic occurrence data were available, and for categories like fish and seafood only occurrence data for inorganic arsenic were included.

# 2.2 Previous risk assessments of dietary exposure to inorganic arsenic through rice and rice products in European countries

## 2.2.1 The Federal Institute for Risk Assessment, Germany, 2014, "Arsen in Reis und Reisprodukten"

The Federal Institute for Risk Assessment (BfR) has assessed the mean dietary exposure to inorganic arsenic from rice and rice products in the German population. For the adult population (age 14 to 80 years) the mean exposure was 0.008  $\mu$ g/kg bw/day, while for the 95 percentile the exposure was 0.025  $\mu$ g/kg bw/day (BfR, 2014). For children (age 6 months to 5 years) the mean dietary exposure to inorganic arsenic from rice and rice products ranged from 0.019 to 0.034  $\mu$ g/kg bw/day, while for the 95 percentile the exposure ranged from 0.019 to 0.170  $\mu$ g/kg bw/day (BfR, 2014). For 6 to 11-year-old children the mean exposure is 0.02  $\mu$ g/kg bw/day, and for the 95 percentile the exposure was 0.088  $\mu$ g/kg bw (BfR, 2014). For 12-year-old children to 17-year-old adolescents the mean exposure is 0.016  $\mu$ g/kg bw/day, while for the 95 percentile the exposure is 0.016  $\mu$ g/kg bw/day, while for the 95 percentile the exposure is 0.016  $\mu$ g/kg bw/day, and for the 95 percentile the exposure is 0.016  $\mu$ g/kg bw/day, while for the 95 percentile the exposure is 0.016  $\mu$ g/kg bw/day, while for the 95 percentile the exposure is 0.016  $\mu$ g/kg bw/day, while for the 95 percentile the exposure is 0.016  $\mu$ g/kg bw/day, and for the 95 percentile the exposure is 0.016  $\mu$ g/kg bw/day, while for the 95 percentile the exposure is 0.016  $\mu$ g/kg bw/day, while for the 95 percentile the exposure is 0.016  $\mu$ g/kg bw/day, and ifferent food consumption studies (four studies covering the following age groups; 6 months to 5 years, 6 to 11 years, 12 to 17 years, and 14 to 80 years) and German occurrence data.

The BfR concluded "health impairments concerning the risk of cancers are possible" following exposure to inorganic arsenic from rice and rice products (BfR, 2014). The BfR recommended that levels of inorganic arsenic in rice and rice products should be reduced to levels as low as reasonably achievable (ALARA principle) (BfR, 2014).

#### 2.2.2 National Food Agency, Sweden, 2015, «Del 2 – Riskvärdering; Oorganisk arsenik i ris och risprodukter på den svenska marknaden"

The median total dietary exposure to inorganic arsenic in the Swedish population ranged from 0.07  $\mu$ g/kg bw in adults to 0.18  $\mu$ g/kg bw/day in 4-year-old children (Livsmedelsverket, 2015a). For 8- and 9-year-old children the median exposure was 0.13  $\mu$ g/kg bw/day, while for 11- and 12-year-old children the median exposure was 0.10  $\mu$ g/kg bw/day (Livsmedelsverket, 2015a). For the 95 percentile, the exposure to inorganic arsenic ranged from 0.1  $\mu$ g/kg bw/day in adults to 0.27  $\mu$ g/kg bw/day in 4-year-olds (Livsmedelsverket, 2015a). Rice was identified as the food contributing the most to the exposure to inorganic arsenic rangenic arsenic in adults (27%) and children (31%) (Livsmedelsverket, 2015a).

The National Food Agency characterized the risk of consuming one product over a long time using scenario analyses (Livsmedelsverket, 2015a). The acceptable weekly intake of inorganic arsenic was set to 0.315  $\mu$ g/kg body weight. For rice cakes, this corresponds to the consumption of 2-8 rice cakes per week for children of the ages of 8 months, 2, 4 and 8/9 years.

The National Food Agency classified the majority of the estimated exposures as low to moderate concern level. The National Food Agency concluded "For children (small children especially) the exposure to inorganic arsenic is close to, or above, the level considered acceptable from a health perspective.", and "For adults, the median consumption of rice is not regarded to pose a health concern. Considering the uncertainties involved, however, it cannot be excluded that the dietary exposure to inorganic arsenic is higher than desirable for parts of the adult population." (Livsmedelsverket, 2015a).

# 2.2.3 National Food Institute, Denmark, 2013, «Notat; Uorganisk arsen i rismel og fuldkornsrismel til brug i babymad»

The mean total dietary exposure to inorganic arsenic in the Danish population (age 4 to 75 years) has been calculated as  $0.12 \mu g/kg bw/day$ , while the 95 percentile represented an exposure of more than  $0.21 \mu g/kg bw/day$  (Fødevareinstiutettet, 2013). The two food groups contributing the most to the total exposure to inorganic arsenic were beverages (45.8%) and cereals (26.2%) (Fødevareinstiutettet, 2013).

The exposure to inorganic arsenic from rice and rice products was evaluated (Fødevareinstiutettet, 2013). For children (5 to 37 months old) the mean exposure to inorganic arsenic from rice ranged from 0.01 to 0.04  $\mu$ g/kg bw/day, while for the 95 percentile the exposure ranged from 0.08 to 0.20  $\mu$ g/kg bw/day. For children and adults (age 4 to 75 years) the mean exposure to inorganic arsenic from rice was 0.01  $\mu$ g/kg bw/day, while the 95 percentile exposure was 0.06  $\mu$ g/kg bw/day (Fødevareinstiutettet, 2013). Regarding the consumption of rice waffles ("riskiks") the mean exposure to inorganic arsenic ranged from 0.01 to 0.02  $\mu$ g/kg bw/day, while the 95 percentile exposure was 0.06  $\mu$ g/kg bw/day (Fødevareinstiutettet, 2013). Regarding the consumption of rice waffles ("riskiks") the mean exposure to inorganic arsenic ranged from 0.01 to 0.02  $\mu$ g/kg bw/day, while the 95 percentile exposure ranged from 0.25 to 0.27  $\mu$ g/kg bw/day for children (5 to 37 months old). For older children consumption data were not available, but assuming a child of 19 kg bw ate one rice waffle a day, the exposure to inorganic arsenic from rice and rice products was high in small children, children and adults, and from a health perspective, the exposure should be lowered.

# 2.2.4 Summary of risk assessments of dietary exposure to inorganic arsenic through rice products

Rice was identified as one of the main contributors to the dietary exposure of inorganic arsenic (EFSA, 2014). High consumption of rice and additional consumption of rice products may lead to an increase in the exposure to inorganic arsenic, resulting in an added health

risk. The national food safety authorities in Germany, Sweden and Denmark have assessed the dietary exposure to inorganic arsenic through rice and rice products. All three authorities find that the exposure to inorganic arsenic from rice and rice products is high and of health concern.

# 2.3 Previous risk assessments of dietary exposure to inorganic arsenic through Hijiki seaweed in European countries

# 2.3.1 The Superior Health Council of Belgium, 2015, "Arsenic and other elements in algae and dietary supplements based on algae"

The exposure to inorganic arsenic though the consumption of edible algae, i.e. seaweed, in Belgium was estimated using a scenario approach (Superior Health Council, 2015). Two groups of consumers were considered; 1. Specific consumer, e.g. vegetarians, eating 7 g/person/day, and 2. High consumers eating 21 g/person/day. The amounts of seaweed are considered "as sold, i.e. not hydrated before consumption".

For the specific consumers the daily exposure to inorganic arsenic through the consumption of Hijiki seaweed was 6.48  $\mu$ g/kg bw/day, while the exposure through the consumption of other edible seaweed was 0.035  $\mu$ g/kg bw/day. For the high consumer the exposures were 19.4 and 0.11  $\mu$ g/kg bw/day following the consumption of Hijiki and other edible seaweed, respectively.

The Superior Health Council of Belgium concludes that the consumption of Hijiki seaweed is associated with severe health risks and must be avoided", while the consumption of other edible seaweeds "can lead to possible exposure levels close to the lowest BMDL without any margin of exposure left".

The Superior Health Council of Belgium recommends consumers to avoid the consumption of Hijiki seaweed and to limit the consumption of other types of edible algae to 7 g per day. The Food Standards Agency, UK, and the Danish Veterinary and Food Administration also advise consumers not to eat Hijiki seaweed due to its high levels of inorganic arsenic.

#### 2.4 Dietary exposure to arsenic in the Norwegian population

## 2.4.1 Previous estimates of dietary exposure to total and inorganic arsenic in the Norwegian population

A literature search in PubMed using the following search string (arsenic [Title/Abstract]) AND (diet OR food) AND Norway AND human) returned 22 abstracts, of which only one included a dietary arsenic exposure estimate in Norwegian adults

The dietary exposure to arsenic and inorganic arsenic was estimated for 187 participants in part C of the Norwegian Fish and Game Study (Birgisdottir et al., 2013). The study, conducted in 2003, was an in-depth assessment of exposures to environmental contaminants. The study populations included 111 subjects with high consumption of foods known to have high levels of environmental contaminants including fish and other seafood and game meat, and 76 subjects representing the general population. The estimated exposure to total arsenic was based on an extensive food frequency questionnaire and a database that was compiled especially for this study (Birgisdottir et al., 2013). Taking individual body weights into account, the median (P95) exposure to total arsenic was 7.4 (17.9) µg/kg bw/day. Up to 95% of the estimated exposure to total arsenic originated from the consumption of fish and seafood. Total arsenic was also analysed in blood and urine sampled from the study subjects, and the estimated dietary exposure correlated significantly with the total arsenic concentrations in blood ( $r_s = 0.5$ ; 95% CI: 0.4, 0.6) and urine ( $r_s =$ 0.4; 95% CI: 0.3, 0.6) (Birgisdottir et al., 2013). The median (P5, P95) total blood arsenic concentration was 5.9 (0.8, 41)  $\mu$ g/L. The exposure to inorganic arsenic was estimated by adding the calculated daily intake of total arsenic not originating from seafood (<5%) to the calculated intake of inorganic arsenic from seafood using Norwegian measurements of inorganic arsenic concentrations in seafood (Birgisdottir et al., 2013; NIFES, 2011). Taking individual body weights into account, the median (P95) exposure to inorganic arsenic was  $0.21 (0.39) \mu q/kg bw/day (n = 187) (Table 2.4.1-1).$ 

The study population in the Norwegian Fish and Game Study included persons with high consumption of fish and other seafood and game meat, as well as persons representing the general population (Birgisdottir et al., 2013). The arsenic exposure estimates were within the exposure ranges reported by the EFSA (2014) suggesting that Norwegian adults do not have specific eating patterns leading to a different dietary exposure to inorganic arsenic than other European adult populations. However, there may be population groups with consumption patterns relevant for arsenic exposure that are not covered by the study by Birgisdottir et al. (2013).

Although the general rice consumption in Norway is known from NORKOST 3 (Totland et al., 2012) there is no information regarding the dietary exposure to inorganic arsenic in specific subgroups of the Norwegian population, e.g. subgroups that replace grain-based food with rice and rice products due to gluten intolerance. There is no information regarding the consumption of other foods containing elevated levels of inorganic arsenic, e.g. Hijiki seaweed.

**Table 2.4.1-1** Dietary exposure to inorganic arsenic (µg/kg bw/day) in the European and Norwegian population. The Norwegian study population was 187 persons.

	Mean	Median	95-percentile	References
	exposure	exposure	exposure	
Europe		·	·	
Adults	0.13 - 0.56		0.37 - 1.22	EFSA 2009
		·	·	
Adults	0.09 - 0.38		0.14 - 0.64	EFSA 2014
Adolescents	0.12 - 0.48		0.23 – 0.84	EFSA 2014
Children (<10 years)	0.20 - 1.37		0.36 - 2.09	EFSA 2014
Norway		·	·	
Adults	0.21 0.39 Birgis		Birgisdottir et al.	
				(2013)

# 3 Occurrence of inorganic arsenic

#### **3.1** Inorganic arsenic in Norwegian samples of fish and rice

The Norwegian Food Safety Authority has provided analytical data for inorganic arsenic concentrations in Norwegian food samples since 2006. VKM has compiled the data of in total 1703 analytical values for inorganic arsenic from Norwegian food samples (Table 3.1-1, for more detailed information see Appendix I, Table A-1 and Table A-2). Of these, 1695 samples originated from 15 different species of fish and seafood and 8 samples from rice. Drinking water contained low concentrations of arsenic (<0.2  $\mu$ g/L) (unpublished data from Norwegian waterworks).

The occurrence data are organised in different food groups by EFSA and in Norway. This makes it difficult to directly compare the calculated means of the food groups since EFSA (2014) has combined fish and other seafood in one food group, while the Norwegian data are split into two food groups (Table 3.1-1). In Norwegian samples, the inorganic arsenic level is low in fish, but high in other types of seafood. In fish, the mean middle bound concentration of inorganic arsenic was 1.6  $\mu$ g /kg ww, while in crabs and shellfish the mean middle bound concentration was 27  $\mu$ g /kg ww (Table 3.1-1). In rice on the Norwegian market, the mean middle bound concentration of inorganic arsenic of inorganic arsenic was 49  $\mu$ g /kg ww, ranging from 23 to 83  $\mu$ g /kg ww (Table 3.1-1 and Appendix I). The Norwegian occurrence data from rice are below or in the lower end of the occurrence data presented by (EFSA, 2014), and below the maximum levels for inorganic arsenic set by the Commission Regulation (EU) 2015/1006 (see 1.3).

		Norway		EFSA			
Food categories	n	mean <sup>2</sup>	Year	n	mean <sup>2</sup>	Year	
		MB(LB – UB)			MB (LB-UB)		
Fish <sup>1</sup>	1053	1.6	2006-2014				
		(0.42 – 2.8)					
Crabs and shellfish	642	27 (27 – 28)	2006-2014	-	-	-	
				1012	26	2003-2012	
Fish and other seafood					(20 – 32)		
Rice	8	49	2009	706	101	2003-2012	
					(93 – 110)		

**Table 3.1-1**Occurrence of inorganic arsenic (µg/kg ww) in Norway and Europe (EFSA, 2014)

<sup>1</sup>Including fish filet, fish products, and whale meat (n=20).

<sup>2</sup> Mean concentrations reported as middle bound (MB), lower bound (LB), and upper bound (UB)

#### 3.2 Recent data on inorganic arsenic in rice and rice products

In 2013, the Danish Veterinary and Food Administration and the National Food Institute, Technical University of Denmark conducted a survey of the content of inorganic arsenic in rice and rice products on the Danish market (Fødevareinstiutettet, 2013). White rice (white rice, parboiled rice and porridge rice ("grødris")) contained a mean concentration of inorganic arsenic of  $89 \pm 37 \ \mu g/kg (n = 63)$ , while rice with shell contained a mean concentration of inorganic arsenic of  $189 \pm 100 \ \mu g/kg (n = 19)$ . Rice crackers ("riskiks") contained the highest mean concentration of inorganic arsenic of  $320 \pm 80 \ \mu g/kg (n = 19)$ .

The Swedish National Food Agency recently surveyed the content of inorganic arsenic in rice and rice products on the Swedish market (Livsmedelsverket, 2015b). The highest mean concentration of inorganic arsenic was found in rice crackers, 152 µg/kg (min 86 – max 322 µg/kg). Whole meal rice and brown rice contained a mean concentration of inorganic arsenic of 117 µg/kg (n = 9, min 75 – max 177 µg/kg), while lower concentrations were found in Basmati (63 µg/kg inorganic As; n = 17) and Jasmine rice (69 µg/kg inorganic As; n = 17).

In a German survey (2010-2011; summarised in BfR (2014)), the highest mean concentration of inorganic arsenic were also found in rice crackers ("Reiswaffeln"), 260  $\mu$ g/kg (n =51). White rice (n = 74) contained a concentration of inorganic arsenic of 101  $\mu$ g/kg, while brown rice (n = 6) contained a concentration of inorganic arsenic of 141  $\mu$ g/kg.

#### 3.3 Inorganic arsenic in Hijiki seaweed

In 2004, the Food Standards Agency, UK, conducted a survey of the content of inorganic arsenic in imported seaweed (Food Standards Agency, 2004). The highest concentrations of inorganic arsenic were seen in Hijiki seaweed, the mean concentration was 77000  $\mu$ g/kg (66700 – 96100  $\mu$ g/kg, n =9). After preparation (soaking in water) the mean concentration of inorganic arsenic was reduced to 11000  $\mu$ g/kg ww (n = 9). The concentrations of inorganic arsenic were below the level of detection (30  $\mu$ g/kg) in all the other analysed seaweed species (Arame, Wakame, Kombu and Nori).

# 4 Evaluation of the need for a new exposure assessment

There was little variation in the estimated dietary exposures to inorganic arsenic in the European population (EFSA, 2014). The dietary exposure to inorganic arsenic was estimated for the Norwegian adult population based on a study population that included participants with high consumption of fish and other seafood and game meat, as well as participants representing the general population (Birgisdottir et al, 2013). The inorganic arsenic exposure estimates were within the exposure ranges reported by EFSA (2014) (Table 3.1.2-1), suggesting that Norwegian adults do not have specific eating patterns leading to a different dietary exposure to inorganic than other European adults. However, there may be population subgroups with consumption pattern relevant for arsenic exposure that are not covered by this study (Birgisdottir et al., 2013). Also, the study only addressed the adult population.

The Norwegian occurrence data for inorganic arsenic only include fish (n=1695) and a few samples of rice (n=8) (Table 2.3.1; Appendix I). In comparison, the database on arsenic content in European food used by EFSA included a total of 101020 food samples of total arsenic and 2753 food samples of inorganic arsenic (EFSA, 2014). VKM has thus concluded that the Norwegian occurrence database is limited and not extensive enough, concerning the number of food groups and number of analyses, to perform a risk assessment of the dietary exposure to inorganic arsenic in the Norwegian population.

## 5 Uncertainties

The uncertainties associated with exposure estimates described by EFSA (EFSA, 2009; EFSA, 2014) also apply for the present assessment.

The estimated exposure to total and inorganic arsenic in the Norwegian population was based on a small study population (Birgisdottir et al., 2013). The study population does not cover the whole Norwegian population, but only high consumers of fish and other seafood and game meat.

# 6 Answers to the terms of reference

The Norwegian Food Safety Authority (NFSA) has requested a statement from the VKM on the dietary exposure to inorganic arsenic in the Norwegian population.

The VKM has the following answers to the questions in the terms of reference (ToR):

### ToR 1: EFSA assessment from 2009, Comment on why EFSA identify Norwegians as a population with a high exposure to arsenic

In the EFSA Scientific Opinion on Arsenic in Food (2009), dietary exposure to total arsenic was estimated for the Norwegian population. The Norwegian exposure levels were the highest and approximately twice as high as for the population with the second highest exposure, the Italian population. A high exposure to total arsenic for Norwegian adults was also estimated in the Norwegian Fish and Game study (Birgisdottir et al., 2013). Fish and seafood are the main contributors to the dietary exposure to total arsenic. In the estimates made by EFSA (2009) approximately half of the exposure originated from fish and seafood, while up to 95% of the estimated exposure to total arsenic in the Norwegian Fish and Game study originated from fish and seafood. Thus, a high consumption of fish and seafood leads to a high dietary exposure to total arsenic.

Although fish and seafood contain high levels of total arsenic, the concentration of inorganic arsenic is low. In 2009, due to lack of data, EFSA used a fixed value of 30  $\mu$ g/kg for all fish species when calculating inorganic arsenic exposure. This is an overestimate of inorganic arsenic concentrations in fish, and consequently led to an overestimate of the exposure to inorganic arsenic.

# ToR 2: EFSA assessment 2014, Comment on whether the population in Norway or special groups of the population have different food consumption patterns, which could lead to different dietary exposure to inorganic arsenic than what is reported for the European population

There was little variation in the estimated dietary exposures to inorganic arsenic in the European population (EFSA, 2014). The dietary exposure to inorganic arsenic has been estimated for the Norwegian adult population based on a study population that included participants with high consumption of fish and other seafood and game meat, as well as participants representing the general population (Birgisdottir et al., 2013). The estimates for inorganic arsenic exposure were within the ranges reported by (EFSA, 2014), suggesting that Norwegian adults do not have specific eating patterns leading to a different dietary exposure to inorganic arsenic than other European adult populations.

Norwegians have a high consumption of fish and seafood. However, fish and seafood contain low levels of inorganic arsenic (table 3.1-1. and appendix A-1), and are therefore not

important sources of inorganic arsenic in the adult Norwegian population (Birgisdottir et al., 2013).

VKM has no information indicating that Norwegians have specific food consumption patterns that may lead to dietary exposures to inorganic arsenic different from the European population.

In the European population (children, adolescents and adults), the main contributors to dietary exposure of inorganic arsenic were the food groups "grain-based processed products (non rice-based)", "rice", "milk and dairy products" and "drinking water" (EFSA, 2014).

There is no information regarding specific dietary patterns of Norwegian sub-populations possibly leading to a higher exposure to inorganic arsenic.

# ToR 3: Comment on whether the inorganic arsenic in rice and rice products (for example rice cakes) and Hijiki seaweed could pose additional health risks for children and adults who eat such food

The dietary exposures to inorganic arsenic in the European populations are within the range of  $BMDL_{01}$  values and possible health risks cannot be excluded (EFSA, 2009; EFSA, 2014). The estimated dietary exposure to inorganic arsenic in the Norwegian adult population (Birgisdottir et al., 2013) is also within the range of  $BMDL_{01}$  values.

Rice was identified as one of the main contributors to the dietary exposure of inorganic arsenic (EFSA, 2014). Rice and rice products contain higher levels of inorganic arsenic than other food groups and individuals with a high consumption of rice and rice products may have a higher exposure to inorganic arsenic than the rest of the population, resulting in an added health risk.

For infants and toddlers, rice and rice products are not an important source of inorganic arsenic (EFSA, 2014). According to EFSA, the main inorganic arsenic contributors in infants and toddlers were "milk and dairy products", then "drinking water", "grain-based processed products (non rice-based)" and "Foods for infants and young children" (EFSA, 2014). However, the dietary exposure to inorganic arsenic in infants, toddlers and other children is higher than in adults because of higher food consumption relative to body weight (EFSA, 2014). Rice cakes have been identified as a product, which may contain particular high levels of inorganic arsenic and which may be consumed by children. Daily consumption of rice cakes by children will clearly increase their exposure to inorganic arsenic (Fødevareinstiutettet, 2013; Livsmedelsverket, 2015a). Thus, Norwegian infants, toddlers and other children with a high consumption of rice and rice products, such as rice cakes, will have a higher exposure to inorganic arsenic than other infants and toddlers, resulting in an added health risk.

The seaweed Hijiki contains higher levels of inorganic arsenic than other types of seaweed. The contribution of Hijiki seaweed to the dietary exposure to inorganic arsenic is much higher (175 to 185 times) than for other types of seaweed (Superior Health Council, 2015). Any consumption of Hijkiji seaweed will lead to an additional exposure to inorganic arsenic, resulting in added health risk.

There is no information regarding the consumption of other foods containing elevated levels of inorganic arsenic, e.g. Hijiki seaweed, in Norway.

# 7 Data gaps

More occurrence data and updated food consumption data are needed in order to conduct an updated dietary exposure assessment of inorganic arsenic in different sub-groups of the Norwegian population.

There is a need for systematic surveillance of the levels of inorganic arsenic in food. Norwegian occurrence data are limited to fish and seafood and the samples consist mostly of fish filet. In addition, there are only eight data points for inorganic arsenic concentrations in rice.

Information on the consumption of foods with elevated levels of inorganic arsenic, such as rice and rice products and seaweed, is needed in order to improve the dietary exposure assessment of inorganic arsenic.

The level of inorganic arsenic depends in some foods, such as rice and Hijiki seaweed, on how the food is processed and prepared. Knowledge on how home-cooking practises impact on inorganic arsenic exposure is needed. Data on the levels of inorganic arsenic in food as consumed are necessary for a realistic exposure assessment.

A Total Diet Study (TDS) denotes an internationally recognised method to establish the average concentration of different substances, such as inorganic arsenic, in prepared food. In a TDS, samples of food at retail outlets throughout Norway are collected, prepared, and the "ready to eat" food is analysed. Combined with nationwide dietary surveys, the data would provide a good scientific basis for the population's dietary exposure to e.g. inorganic arsenic.

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# Appendix I

# A-1 Occurrence of inorganic arsenic in fish and seafood ( $\mu$ g/kg wet weight) in Norway

Species	N <sup>1</sup>	LB.	MB.	UB.	LOQ	n below	Year
		mean	mean	mean	(range)	LOQ	
Atlantic salmon (farmed)	56 <sup>2</sup>	0	2	5	4-6	56	2012- 14
Trout	4 <sup>2</sup>	0	3	5	4-5	4	2012- 13
Atlantic cod, fillet	190	0.2	1.1	2.2	2	175	2009
Herring, fillet (Norwegian spring spawning)	50	0	1.8	3.6	3-4	49	2007
Halibut, filet	20	0	1.6	3.2	2-5	20	2008- 2010
Mackerel, fillet(Northeast Atlantic)	157	0.9	2.4	3.9	2-10	126	2008- 2009
Mackerel, smoked	21	0	0.4	0.8	0.8	21	2006
Mackerel, canned	14	0	0.4	0.8	0.8	14	2006
Blue halibut, fillet	130	1.0	2.2	3.3	2-4	113	2006- 2008
Tusk, fillet	212	0.1	1.4	2.7	2-3	206	2008- 2009
Saithe, fillet	179	2.8	1.4	0.1	2-3.4	178	2010- 2011
Minke whale, meat	20	0	2	3	3-4	20	2011
Blue mussels <sup>3</sup>	454	55	55	55	2-3	33	2006- 2014
King crab, white meat <sup>4</sup>	100	23	23	23	3	1	2012
Crab (Cancer pagurus), brown meat <sup>4</sup>	12	54	54	54	2	1	2007- 11
Crabs (Cancer pagurus), white meat <sup>4</sup>	22	14	14	14	2-3	4	2007- 11
Scallops, muscle and gonad <sup>3</sup>	28 <sup>3</sup>	1	2	4	2	26	2006- 15
European oysters soft tissue <sup>3</sup>	26 <sup>3</sup>	16	16	16	2	0	2006- 15

 $^1\,\text{All}$  samples from NIFES,  $^2\text{Pooled}$  samples of five fish each,  $^3\text{Pooled}$  samples of more than one shellfish,  $^4\text{Cooked}$  samples

# A-2 Occurrence of inorganic arsenic in rice ( $\mu$ g/kg wet weight) in Norway<sup>1</sup>

Species	N	Inorganic arsenic µg/kg wet weight	% inorganic arsenic of total arsenic
Basmati rice	1	27	53
Jasmin rice	1	62	47
Basmati rice	1	38	67
Jasmin rice	1	33	25
Basmati and wild rice	1	23	54
Red rice	1	65	55
Basmati rice	1	58	89
Jasmin rice	1	82	66

<sup>1</sup>NIFES, all samples were analysed in 2009