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Risk assessment of dietary exposure to acrylamide in the Norwegian population

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

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Risk assessment of dietary exposure to acrylamide in the Norwegian population

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Assessed and approved

The risk assessment 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, Irma Oskam, 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 to answer the request from the Norwegian Food Safety Authority. Project leader from the VKM secretariat has been Edel Holene. Anne Lise Brantsæter, Helle K. Knutsen and Inger Therese L. Lillegaard are acknowledged for their valuable work on this opinion. The Panel on Contaminants is highly 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 the Norwegian Scientific Committee for Food Safety (VKM) to assess whether Norwegians in general or subgroups in the population could be expected to have different dietary exposure to acrylamide than reported for other European population groups, and if found to be different to calculate their exposure. Furthermore, VKM was asked to identify food categories with a high potential to increase acrylamide exposure; both for the whole population and for specific groups. Finally, VKM was asked to characterise the risk of acrylamide exposure to the Norwegian population compared to the rest of the European population. The Norwegian Food Safety Authority intends to use this risk assessment as a basis for the Norwegian contribution to the ongoing legislative work in the EU and to consider the necessity to adjust the existing national dietary advices or to issue new ones.

How VKM has addressed the request

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

What acrylamide is and its toxicity to humans

Acrylamide is a water-soluble organic chemical formed in carbohydrate-rich foods from naturally present carbohydrates and amino acids during cooking or other heat processing at temperatures above 120 °C. Acrylamide is a widely used industrial chemical and is also formed in tobacco smoke.

Acrylamide is known to be neurotoxic in humans and is classified as a probable human carcinogen. Concerns about exposure to acrylamide in the general population arose in 2002 when it was discovered in heat-treated foods.

Dietary acrylamide exposure in Europe and Norway

Dietary acrylamide exposure has been assessed by combining food consumption data and acrylamide concentration data and by biological markers of exposure both in Norway and different European countries. In the EFSA 2015 Scientific Opinion on acrylamide in food, chronic dietary exposure was calculated for 61,338 individuals from 28 surveys and 17 different European countries covering the following age groups: infants (<1 year old), toddlers (≥1 year to <3 years old), other children (≥3 years to <10 years old), adolescents (≥10 years to <18 years old), adults (≥18 years to <65 years old), elderly (≥65 years to <75 years old) and very elderly (≥75 years old). The estimation of human exposure to

acrylamide revealed that infants, toddlers and other children were the most exposed groups, but EFSA concluded that dietary acrylamide represents a health concern for all age groups.

In previous Norwegian studies reporting dietary acrylamide exposure, the mean and median exposure in adolescents and adults were in the range of 0.3-0.5 µg/kg bw per day. These estimates are in the same range as the mean daily exposures estimated by EFSA for adolescents (0.4-0.9 µg/kg bw) and adults (0.4-0.5 µg/kg bw). Taking into consideration the results from previous exposure estimates and knowledge about food consumption patterns in recent consumption surveys in Norway, VKM concludes that Norwegian adults, adolescents and children older than three years of age are not likely to have a different exposure to acrylamide than corresponding age groups in other European countries. VKM therefore decided not to perform a new exposure assessment in these age groups.

No previous studies in Norway have assessed acrylamide exposure in infants and children less than three years of age. Information from national and European dietary surveys shows that Norwegian 1-year-olds, but not 2-year-olds, have higher consumption of infant porridge than other European toddlers. VKM therefore decided to conduct a full exposure estimate in 1-year-old toddlers.

The comparison of data on acrylamide occurrence in food reported by EFSA (2015) and in foods sampled in Norway showed that acrylamide concentrations in the main food categories do not differ essentially, with the exception of three categories. The category "Potato crisps and snacks" has higher acrylamide concentrations in Norwegian samples than in those reported by EFSA, while the categories "Baby foods, other than cereal-based" and "Processed cereal-based baby food" (i.e. infant porridge) have lower concentrations in Norwegian samples than in those reported by EFSA. VKM considered that Norwegian analytical values were sufficient for exposure calculations if the concentrations were analysed in 16 samples or more. Infant porridge had 52 analysed samples and VKM considered that the brands sampled are representative for infant porridge on the Norwegian market.

VKM calculated acrylamide exposure based on food consumption in Norwegian 1-year-olds by two approaches: one using EFSA concentration data only; and the other using Norwegian concentration data for food categories including 16 samples or more, and EFSA data for the remaining categories. Both approaches resulted in acrylamide exposures within the exposure range for toddlers reported by EFSA (2015). When using EFSA concentration data only the calculated daily exposure (mean: 1.6 µg/kg bw and P95: 3.2 µg/kg bw) is in the upper range calculated by EFSA for toddlers (mean range: 0.9-1.9 µg/kg bw, P95 range: 1.2-3.4 µg/kg bw). When using Norwegian concentration data for food categories including 16 Norwegian samples or more and EFSA data for the remaining categories, the calculated daily exposure (mean: 0.9 µg/kg bw, P95: 1.6 µg/kg bw) is in the lower range of what EFSA has calculated for toddlers.

The dietary exposure for acrylamide in Norwegian 1-year-olds is within the same range as reported by EFSA for European toddlers. Although the acrylamide-concentration was lower in infant porridge (i.e. "Processed cereal-based baby food") sampled in Norway than in those reported by EFSA, Norwegian 1-year-olds have higher consumption of infant porridge than European toddlers. In addition to infant porridge, soft bread is a major source of acrylamide in Norwegian 1-year-olds.

Food categories with high potential to increase acrylamide exposure

Baby food and soft bread contributed most to acrylamide exposure in the 1-year-olds, while food items contributing the most to acrylamide exposure in adults are fried potato products, coffee, biscuits, crackers and crisp breads, and soft bread.

Previous Norwegian studies and EFSA (2015) showed that in all populations groups except toddlers, 'fried potato products' is a food group with high potential to increase acrylamide exposure. Acrylamide is also contributed by food items commonly consumed such as coffee and bread, and this is of concern in Norway as well as in the rest of Europe.

The EFSA risk assessment included exposure scenarios addressing the potential impact of home-cooking habits, locations of consumption, and preferences for particular food products. These scenarios showed that food preparation, and particularly conditions of potato frying, resulted in large variations and a possible increase of acrylamide exposure by as much as 80%. VKM considers that these scenarios carried out by EFSA are equally relevant for the Norwegian population. The temperature and browning of fried potato products will have a considerable impact on the exposure to acrylamide.

VKM calculated three simplified scenarios to illustrate the influence of consumption of particular food items on acrylamide exposure. These scenarios confirmed that potato crisps, French Fries and coffee are food items with high potential to increase acrylamide exposure.

Risk characterisation of dietary acrylamide exposure in Norway

VKM used the same reference points as EFSA (2015), and calculated Margin of Exposures (MOEs) for assessing health risk. MOE is the ratio between a reference value and the estimated dietary exposure. The MOE approach provides an indication of the level of safety but it does not quantify the risk as such.

For non-neoplastic effects, EFSA used a $BMDL_{10}$ value of 0.43 mg/kg bw/day as the reference point based on animal studies of neurotoxicity, and considered a substance-specific MOE of 125 or above as a sufficient safety margin for no health concern.

For neoplastic effects, EFSA used a $BMDL_{10}$ value of 0.17 mg/kg bw/day as the reference point based on animal studies, and taking into account overall uncertainties in the interpretation, EFSA concluded that a MOE of 10 000 or higher would be of low concern for public health.

The EFSA risk assessment concluded that the MOEs for non-neoplastic effects were above 125 for all age groups indicating no health concern, whereas the MOEs for non-neoplastic effects were substantially lower than 10 000, indicating a health concern for all age groups.

The dietary acrylamide exposure in Norwegian adolescent and adults reported in previous studies were within the range calculated by EFSA for these age groups. VKM therefore concludes that the resulting MOEs for non-neoplastic and neoplastic effects of acrylamide for adolescent and adults will be similar to those calculated by EFSA.

VKM calculated acrylamide exposure based on food consumption in Norwegian 1-year-olds by two approaches: one using EFSA concentration data only; and the other using Norwegian concentration data for food categories including 16 samples or more, and EFSA data for the remaining categories. Both approaches resulted in comparable MOEs.

For both non-neoplastic and neoplastic effects, MOEs for 1-year-olds were similar to those reported in EFSA 2015.

For non-neoplastic effects of dietary acrylamide exposure, VKM reached the same conclusion as EFSA, which is that the MOEs across all age groups indicate no health concern.

For neoplastic effects of dietary acrylamide exposure, VKM reached the same conclusion as EFSA, which is that the MOEs across all age groups were substantially lower than 10 000, indicating a health concern.

VKM is of the opinion that the conclusion reached by EFSA's risk assessment of acrylamide, which states that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups, also applies to Norwegians.

Uncertainties and data gaps

There is uncertainty in the calculation of dietary acrylamide exposure. One of the reasons is that none of the existing dietary methods are able to capture the "true" long-term food consumption in individuals. Another reason is that the large variation in acrylamide concentrations in food items, even within the same food category. Acrylamide concentrations in food depend on how food is being processed and cooking practises both at home and in restaurants. Cooking practises and preferences, in especially the degree of browning, represent particular uncertainties when estimating dietary acrylamide exposure. More knowledge about this is needed in order to provide a better basis for up-to-date exposure estimates in Norway.

Key words: Acrylamide, dietary exposure, fried potato products, health concern, margin of exposure, Norwegian Scientific Committee for Food Safety, risk assessment, toddlers, VKM

Sammendrag på norsk

Oppdrag fra Mattilsynet

Mattilsynet ba Vitenskapskomiteen for mattrygghet (VKM) å vurdere om nordmenn generelt eller grupper av befolkningen kunne forventes å ha forskjellig eksponering for akrylamid fra mat enn det som er rapportert for andre europeiske befolkningsgrupper, og i så fall beregne eksponeringen. VKM ble videre bedt å identifisere matvarer som kan gi ekstra akrylamideksponering, både for hele populasjonen og for spesifikke grupper. Til slutt ble VKM bedt om å karakterisere risikoen for akrylamid eksponering hos den norske befolkningen sammenlignet med andre europeiske befolkningsgrupper. Mattilsynet vil bruke risikovurderingen som grunnlag for det norske bidraget i det pågående regelverksarbeidet i EU og til å vurdere om det er nødvendig å justere eksisterende nasjonale kostholdsråd eller om nye må etableres.

Slik har VKM besvart bestillingen

VKM nedsatte en arbeidsgruppe som besto av medlemmer av Faggruppen for forurensninger, naturlige toksiner og medisinrester for å svare på bestillingen. Faggruppen har gjennomgått og revidert utkastet utarbeidet av arbeidsgruppen, og har godkjent risikovurderingen av akrylamidinntak i den norske befolkningen.

Hva akrylamid er og hvor farlig det er for mennesker

Akrylamid er en vannløselig, organisk, kjemisk forbindelse som dannes i karbohydratrike matvarer fra karbohydrater og aminosyrer som finnes i maten ved varmebehandling over 120 °C. Akrylamid er en mye brukt industrikjemikalie og dannes også i tobakksrøyk.

Akrylamid kan skade nervesystemet og er klassifisert som et sannsynlig kreftfremkallende stoff for mennesker. Bekymringer for akrylamid-eksponering i den generelle befolkningen oppsto i 2002 da stoffet ble oppdaget i varmebehandlede matvarer.

Eksponering for akrylamid fra mat i Europa og Norge

Eksponering for akrylamid gjennom kostholdet er blitt vurdert både i Norge og ulike europeiske land ved å kombinere konsumdata med akrylamid-konsentrasjonen i matvarene. Eksponeringen er også undersøkt ved måling av biologiske markører for akrylamid i blod og urin. EFSAs risikovurdering av akrylamid i mat fra 2015 beregnet den kroniske eksponeringen gjennom kostholdet for 61,338 personer. Tallmaterialet kom fra 28 undersøkelser og 17 forskjellige europeiske land. Følgende aldersgrupper ble dekket: spedbarn (<1 år), småbarn (≥1 år til <3 år), andre barn (≥3 år til <10 år), ungdom (≥ 10 år til <18 år), voksne (≥ 18 år til <65 år), eldre (≥ 65 år til <75 år) og meget eldre (≥ 75 år). Eksponeringsberegningen viste at spedbarn, småbarn og andre barn hadde høyest eksponering, men EFSA konkluderte med at akrylamid fra mat gir grunn til bekymring for skadelige helseeffekter for alle aldersgrupper.

Tidligere norske studiene hos ungdommer og voksne har vist at både den gjennomsnittlige og mediane eksponeringen for akrylamid fra mat er i området 0,3-0,5 µg/kg kroppsvekt per dag. Disse estimatene er i samme størrelsesorden som de daglige gjennomsnittlige eksponeringene EFSA nylig (2015) har beregnet for ungdom (0,4 til 0,9 µg/kg kroppsvekt) og voksne (0,4-0,5 µg/kg kroppsvekt). Basert på resultatene fra de tidligere norske studiene og kjennskap til spisemønstre i Norge, konkluderer VKM med at norske voksne, ungdom og barn eldre enn tre år sannsynligvis ikke har ulik eksponering for akrylamid enn tilsvarende aldersgrupper i andre europeiske land. VKM besluttet derfor at det ikke var behov for å gjennomføre nye eksponeringsberegninger for disse aldersgruppene.

Det finnes ingen studier som har beregnet akrylamid-eksponeringen hos norske spedbarn og barn under tre år. Informasjon fra nasjonale og europeiske kostholdsundersøkelser viser at norske ettåringer har høyere konsum av barnegrøt enn andre europeiske småbarn. Det samme gjelder ikke for norske toåringer. VKM besluttet derfor å gjennomføre en fullstendig eksponeringsberegning for ettåringer.

Sammenligningen av data fra Norge og EFSA viste at akrylamid-konsentrasjonene i de fleste matvarekategorier er ganske lik, bortsett fra for tre. For kategorien «Potetchips og potetsnacks» var akrylamid-konsentrasjonene i norske prøver høyere enn i prøver fra EFSA, mens for kategoriene "Barnemat, annet enn kornbaserte" og "Bearbeidede kornbaserte barnemat" (dvs. barnegrøtpulver) var det lavere konsentrasjoner i norske prøver. VKM vurderte at norske akrylamid-konsentrasjoner kunne brukes i eksponeringsberegninger dersom de var blitt analysert i 16 prøver eller mer. Det var 52 analyserte prøver av barnegrøt og VKM anser utvalget som representativt for barnegrøt på det norske markedet.

VKM beregnet akrylamid-eksponeringen hos norske ettåringer ut i fra matinntaket deres med to tilnærminger: en ved kun bruk av EFSAs konsentrasjonsdata; og den andre ved bruk av norske konsentrasjonsdata for matvarekategorier som inkluderte 16 prøver eller flere, og EFSA-data for de øvrige. Begge tilnærmingene resulterte i akrylamid-eksponeringer som var innenfor det EFSA (2015) rapporterte for småbarn. Ved kun å bruke EFSAs konsentrasjonsdata er beregnet daglig eksponering (gjennomsnitt: 1,6 µg/kg kroppsvekt, P95: 3,2 µg/kg kroppsvekt) i det øvre området av hva EFSA beregnet for småbarn (gjennomsnitt: 0,9 til 1,9 µg/kg kroppsvekt, P95: 1,2 til 3,4 µg/kg kroppsvekt). Ved bruk av norske konsentrasjonsdata for matvarekategorier som inkluderte 16 norske prøver eller mer, og EFSA-data for resten, er den beregnede daglige eksponeringen (gjennomsnitt: 0,9 µg/kg kroppsvekt, P95: 1,6 µg/kg kroppsvekt) i det nedre området av hva EFSA beregnet for småbarn.

Norske ettåringer får i seg omtrent like mye akrylamid fra mat som andre småbarn i Europa. Selv om akrylamid-konsentrasjoner målt i norske prøver av barnegrøtpulver var lavere enn i prøver fra EFSA, spiser norske ettåringer mer barnegrøt enn andre europeiske småbarn. I tillegg til barnegrøt er brødmat en vesentlig kilde til akrylamid hos ettåringer.

Matvaregrupper som spesielt kan øke akrylamideksponeringen

Barnegrøt og brød bidrar mest til akrylamid-eksponering hos norske ettåringer, mens matvarer som bidrar mest hos voksne både i Norge og i Europa er stekte potetprodukter som pommes frites, kaffe, kjeks, knekkebrød og brød.

Både tidligere norske studier og EFSAs risikovurdering fra 2015 har vist at hos alle befolkningsgrupper unntatt småbarn, har 'stekte potetprodukter' stort potensial for å øke akrylamid-eksponeringen. Akrylamid kommer også fra vanlig konsumerte matvarer som kaffe og brød, og dette er til bekymring i Norge så vel som i resten av Europa.

EFSAs risikovurdering inkluderte eksponeringsscenarier som bl.a. tok for seg hvordan både matlaging i hjemmet, hvor man spiser (hjemme vs. spisesteder ute) og preferanser for bestemte matvarer kan påvirke akrylamid-eksponeringen. Scenariene viste at tilberedning av maten, og spesielt hvor mye potetene ble stekt (bruningsgrad), resulterte i store variasjoner av akrylamid-eksponeringen, som kunne øke med så mye som 80 %. VKM mener at de scenariene EFSA har gjort også er relevante for den norske befolkningen. Både temperaturen ved tilberedning av og bruningsgraden på stekte potetprodukter vil ha en betydelig innvirkning på eksponering for akrylamid.

VKM beregnet tre forenklede scenarier for å illustrere hvilken betydning inntak av visse matvarer kan ha på akrylamideksponering. Disse scenariene bekreftet at potetchips, pommes frites og kaffe er matvarer som spesielt kan øke akrylamideksponeringen.

Risikokarakterisering av akrylamideksponering i Norge

VKM brukte samme referansedoser som EFSA for å regne «eksponeringsmargin» (Margin of exposure, MOE) som et estimat for helserisiko. MOE er forholdet mellom en referansedose og den beregnede eksponeringen fra mat. Metoden gir en indikasjon på om eksponeringen er av en størrelsesorden som indikerer økt risiko for negative helseeffekter, men den angir ikke hvor stor en eventuell risiko er.

For andre uheldige effekter enn svulstdannelse (dvs. ikke-neoplastiske effekter) brukte EFSA en referansedose på 0,43 mg/kg kroppsvekt/dag ut i fra dyrestudier som viste skader på nervesystemet (nevrotoksisitet), og anså at en MOE på 125 eller høyere er tilstrekkelig til å anta at det ikke er grunn til helsebekymring.

For svulstdannende (dvs. neoplastiske) effekter brukte EFSA referansedosen 0,17 mg/kg kroppsvekt/dag ut i fra dyrestudier, og ved å ta i betraktning alle usikkerhetene i tolkningen ble en MOE på 10 000 eller høyere ansett som tilstrekkelig til å anta at det er liten grunn til helsebekymring.

EFSAs risikovurdering viste at eksponeringsmarginene for ikke-neoplastiske effekter var høyere enn 125 for alle aldersgrupper og at det ikke var grunn til helsebekymring, mens eksponeringsmarginene for neoplastiske effekter var betydelig lavere enn 10 000 og derved indikerer grunn til bekymring for alle aldersgrupper.

Tidligere norske studiene hos ungdommer og voksne viste at akrylamid-eksponeringen var innenfor variasjonsbredden som de EFSA beregnet for disse aldersgruppene. VKM konkluderer derfor at eksponeringsmarginene for ikke-neoplastiske og neoplastiske effekter av akrylamid for disse gruppene vil være omtrent som de EFSA beregnet.

VKM beregnet akrylamid-eksponeringen hos norske ettåringer ut i fra matinntaket deres med to tilnærminger: en ved kun bruk av EFSAs konsentrasjonsdata og den andre ved bruk av norske konsentrasjonsdata for matvarekategorier som inkluderte 16 prøver eller mer, og EFSA data for resten. Begge tilnærmingene resulterte i omtrent like eksponeringsmarginer.

For både ikke-neoplastiske og neoplastiske effekter var eksponeringsmarginene for norske ettåringer tilnærmet like de som ble rapportert i EFSA 2015.

For ikke-neoplastiske effekter av akrylamid-eksponeringen kom VKM fram til samme konklusjon som EFSA, som er at eksponeringsmarginene for alle aldersgruppene indikerer at det ikke er grunn til helsebekymring.

VKM konkluderte likt med EFSA også for neoplastiske effekter av akrylamid-eksponeringene. Eksponeringsmarginene var betydelig lavere enn 10 000 for alle aldersgrupper og gir grunn til helsebekymring.

VKM mener at konklusjonen i EFSAs risikovurdering av akrylamid, som sier at akrylamid fra mat kan øke risikoen for utvikling av kreft hos mennesker i alle aldersgrupper, også gjelder for befolkningen i Norge.

Usikkerhet og kunnskapsbehov

Det er usikkerhet i beregninger av akrylamideksponering fra mat. En av årsakene er at ingen av dagens metoder for kostholdsundersøkelser fanger opp det sanne, langsiktige matkonsumet hos enkeltindivider. En annen årsak er stor variasjon i akrylamid-konsentrasjonene i mat, også innen samme matvarekategori. Akrylamid-konsentrasjoner i mat avhenger av hvordan maten blir produsert og hvordan den tilberedes både hjemme og på utesteder. Tilberedning av maten og preferanser, spesielt bruningsgrad, representerer særlig usikkerhet ved estimering av akrylamideksponering. Det er nødvendig med mer kunnskap om dette for å gi et enda bedre grunnlag for oppdaterte eksponeringsestimater i Norge.

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Abbreviations and/or glossary

Abbreviations

AA	acrylamide
$BMDL_{10}$	Benchmark Dose Lower Confidence Limit (for 10% effect change)
bw	body weight
EFSA	European Food Safety Agency
CONTAM	EFSA Panel on Contaminants in the Food Chain
FFQ	Food Frequency Questionnaire
FD	Food diary
Hb	haemoglobin
IARC	International Agency for Research on Cancer”
kg	kilogram
LB	lower bound
LOD	limit of detection
MoBa	the Norwegian Mother and Child Cohort Study
MOE	Margin of exposure
MB	middle bound
mg	milligram
µg	mikrogram
N	number of samples
NFSA	Norwegian Food Safety Authority
SNT	In Norwegian: Statens næringsmiddeltilsyn. Today: Norwegian Food Safety Authority
TDI	tolerable daily intake
ToR	terms of reference
UB	upper bound
µg	microgram

Glossary

Age groups in European countries are infants (<1 year old), toddlers (≥1 year to <3 years old), other children (≥3 years to <10 years old), adolescents (≥10 years to <18 years old), adults (≥18 years to <65 years old), elderly (≥65 years to <75 years old) and very elderly (≥75 years old).

Carcinogenic substances cause development of cancer.

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.

Genotoxic substance causes damage to DNA, the genetic material of cells.

Hazard is a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Lower bound is when analytical values below the limit of detection (LOD) or limit of quantification (LOQ) are set to zero.

Maillard reaction is a chemical reaction between certain amino acids, such as asparagine, and reducing sugars in food. It is responsible for the brown colour and characteristic taste of cooked food, but also for formation of unwanted substances like acrylamide.

Margin of exposure (MOE) is an approach risk assessors at EFSA use to consider possible safety concerns arising from the presence of substances which are both genotoxic and carcinogenic in food and feed. The MOE is a ratio of two factors which assesses 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.

Middle bound (MB) is when analytical values below the limit of detection (LOD) or limit of quantification (LOQ) are replaced by half of the respective LOD/LOQ values (i.e. middle bound estimates).

'Neoplastic effects' is a common used term referring to abnormal tissue growth and the process of tumour formation.

'Non-neoplastic effects' is a common term referring to adverse health effects other than neoplastic effects.

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

Percentile is a common term for visualising the low, medium and high occurrences of a measurement (e.g. acrylamide intake) 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 may be found.

Risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food (Codex alimentarius).

Risk assessment is a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization (Codex alimentarius)

Risk characterization is the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment (Codex alimentarius).

Risk estimate is the quantitative estimation of risk resulting from risk characterization (Codex alimentarius).

Upper bound is when analytical values below the limit of detection (LOD) or limit of quantification (LOQ) are set equal to the LOD or LOQ.

Background as provided by the Norwegian Food Safety Authority

Acrylamide is an organic substance which is mainly formed in starch rich food at temperatures above 120 °C and low moisture conditions, for instance in processes like baking, grilling, roasting and frying. Acrylamide also has many non-food industrial uses, like in the production of polymers (polyacrylamide). It is present in tobacco smoke. The main chemical process that causes the formation of acrylamide in food is known as the Maillard Reaction; it is the same reaction that 'browns' food and affects its taste. The compound forms from sugars and amino acids (mainly one called asparagine) that are naturally present in many types of food.

Acrylamide was first discovered in food by Swedish scientists in 2002 but has always been present in food prepared at high temperatures. Since then, numerous risk assessments have been performed, one of the first by the Scientific Committee of the Norwegian Food Control Authority. Its conclusion was that about 40 annual cancer incidents could be caused by exposure to acrylamide through food. In a 2005 statement, EFSA supported the summary report on acrylamide in food of the Joint FAO/WHO Expert Committee on Food Additives. JECFA considered the margins of exposure to be low for a compound that is genotoxic and carcinogenic, and that they may indicate a human health concern. This conclusion was confirmed in 2010 and JECFA recommended that efforts to reduce AA concentrations in foodstuffs should continue.

Monitoring results are compiled by EFSA. Between 2009 and 2012 four reports containing occurrence data of acrylamide were published. Norwegian data were included in these reports. The levels in food did not systematically decrease in all concerned food commodities, as demonstrated by the results compiled since 2007. Following an extensive public consultation, EFSA published a new, comprehensive risk assessment in the summer of 2015.

Acrylamide is formed both in industrial processes and in normal home cooking practice. Industry has developed a so-called 'toolbox' containing measures that can be applied by the different sectors of food industry to bring acrylamide levels down. There is also a Code of Practice in Codex. The authorities expect the industry to implement these measures in their quality control.

The EU Commission has made a recommendation which asks Member States to carry out further investigations at food operator's premises in case high acrylamide levels are found. Indicative values have been established in that recommendation. If an indicative value is exceeded, an investigation should be carried out. The indicative values are not legal limits and do not require enforcement action if they are exceeded. The Commission is currently assessing the approach taken and will in the near future decide whether further appropriate measures are required.

The current advices to Norwegian consumers are about cooking practices and that high consumers of coffee and potato crisps should limit their intake.

In order to revise existing consumer advice and assess whether additional ones should be issued, The Food Safety Authority needs an updated exposure calculation. Such a calculation would also be beneficial for the Norwegian contributions to the ongoing legislative work in the EU.

Terms of reference as provided by the Norwegian Food Safety Authority

EFSA has recently published a scientific opinion which confirms previous evaluations that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups. As a basis for further risk management, the Food Safety Authority needs to know how the EFSA report affects the Norwegian population and requests the Scientific Committee for Food to

- assess whether the consumption pattern of the Norwegian population or specific groups deviates from the European population in a way which could lead to a different acrylamide exposure through food. If found to be different, calculate the exposure for the identified population groups
- identify food categories with high potential to increase acrylamide exposure – both for the whole population and specific groups
- characterise the risk to the Norwegian population compared to the rest of the European population

Assessment

1 Introduction

Following a request from the European Commission, the Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority (EFSA) delivered a Scientific Opinion on acrylamide in food in June 2015. The following chapter gives a brief summary of the hazard identification and characterisation chapter in the EFSA Scientific Opinion (EFSA, 2015).

1.1 What acrylamide is and how it is formed

Acrylamide is a low molecular weight, water-soluble organic chemical formed in carbohydrate-rich foods from naturally present carbohydrates and amino acids during cooking or other heat processing. It is a widely used industrial chemical and is also formed in tobacco smoke.

Concern about exposure to acrylamide in the general population arose in 2002 when it was discovered that it forms when certain foods are prepared at temperatures usually above 120 °C and low moisture. It forms, at least in part, due to a Maillard reaction between certain amino acids, such as asparagine, and reducing sugars such as such as fructose and glucose. However, several other pathways and precursors have also been proposed to contribute to the formation of acrylamide. Acrylamide is present in numerous baked or fried carbohydrate-rich foods such as French fries, potato crisps, breads, biscuits and coffee (EFSA, 2015).

1.2 Toxicity to humans

Acrylamide is known to be neurotoxic in humans and is classified by the International Agency for Research on Cancer (IARC) as a Group 2A probable human carcinogen.

Following ingestion, acrylamide is readily absorbed from the gastrointestinal tract, distributed to all organs, metabolised and excreted as urinary mercapturic acid metabolites. An important metabolic pathway is the cytochrome P450 CYP2E1-dependant oxidation of acrylamide forming the genotoxic epoxide glycidamide. Following glutathione conjugation, acrylamide and glycidamide are excreted as urinary mercapturic acids derivatives (EFSA, 2015).

The EFSA CONTAM panel identified four possible critical endpoints for acrylamide toxicity, i.e. the non-neoplastic endpoints neurotoxicity, effects on male reproduction, developmental toxicity, and the neoplastic endpoint carcinogenicity. Based on animal studies, EFSA confirmed previous evaluations that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups. Consequently, the CONTAM Panel considered it inappropriate to establish a tolerable daily intake (TDI), and instead applied the Margin of Exposure (MOE) approach. The experts estimated the dose range within which acrylamide is likely to cause a small but measurable tumour incidence (neoplastic effects) or other effects (non-neoplastic effects; neurological, pre- and postnatal development, and male reproduction) in experimental animals. The lower limit of this range is denoted the Benchmark Dose Lower Confidence Limit ($BMDL_{10}$). EFSA identified a $BMDL_{10}$ of 0.43 mg/kg bw per day for non-neoplastic effects (peripheral neuropathy in rats) and of 0.17 mg/kg bw per day for neoplastic effects (tumour incidence in mice) (EFSA, 2015).

2 Exposure to acrylamide

The Norwegian Food Safety Authority has provided analytical data for acrylamide concentrations in Norwegian food samples since 2002. The most recent report published in 2014 included 171 different food items, and a total of 352 samples have been analysed in the time period 2010-2013. Of these, 51 were included in the database on acrylamide occurrence in food items in Europe used by EFSA in their 2015 scientific opinion (EFSA, 2015). These Norwegian samples comprised bread, breakfast cereals, crisp bread, biscuits, soft bakery wares, rice, pasta, flour, snacks, processed potato products, infant porridge and formula milk.

2.1 European dietary acrylamide exposure

The EFSA (2015) Scientific Opinion on acrylamide in food included 43 419 analytical results of food commodities collected and analysed since 2010 by 24 European countries and six food associations (EFSA, 2015). The data provided by European countries and those provided by food associations gave overall consistent and complementary information. Acrylamide was found at highest levels in "Coffee substitutes (dry)", "Coffee (dry)", "Potato crisps and snacks" and "Potato fried products". Lower levels were found in "Processed cereal-based baby foods", and "Baby foods, other than cereal-based". A time trend analysis of fresh sliced potato crisps from 20 European countries for the years 2002-2011 showed a substantial downward trend for mean acrylamide levels. For other food categories, a similar downward trend was not observed (EFSA, 2015). For a short overview, see Appendix I, Table A1-1.

The EFSA Comprehensive European Food Consumption Database provided data for food consumption and exposure calculation. The Comprehensive Database is a compilation of existing national information on food consumption at the individual level. It was first built in 2010 and then updated with new data available at the national level. Data from the Norwegian national food consumption surveys are not included in the EFSA Comprehensive database.

EFSA calculated acrylamide exposure from 61,338 individuals from 28 surveys and 17 different European countries covering the following age groups: infants (<1 year old), toddlers (≥1 year to <3 years old), other children (≥3 years to <10 years old), adolescents (≥10 years to <18 years old), adults (≥18 years to <65 years old), elderly (≥65 years to <75 years old) and very elderly (≥75 years old). The estimation of human exposure to acrylamide revealed that infants, toddlers and other children were the most exposed groups.

Depending on the survey and age group, chronic dietary exposure in infants, toddlers and other children was estimated to be on average between 0.5 and 1.9 µg/kg bw per day and the 95-percentile was between 1.4 and 3.4 µg/kg bw per day. The chronic dietary exposure in adolescents, adults, elderly and very elderly was estimated to be on average between 0.4

and 0.9 µg/kg bw per day and the 95-percentile (P95) was between 0.6 and 2.0 µg/kg bw per day depending on the survey and age group (Table 2.1-1). It should be noted that EFSA rounded the estimated acrylamide exposures for each age group in the table below to avoid the impression of too high precision (EFSA, 2015).

Table 2.1-1 Exposure to acrylamide in µg/kg bw per day shown as medians of the mean and P95-exposure levels across different surveys and age groups (From Table 8, page 61 in EFSA, 2015).

Age groups	**N [a]**	**Mean, µg/kg bw per day**		**P95, µg/kg bw per day**	
		Median [Minimum-Maximum]		**Median [Minimum-Maximum]**	
		LB	**UB**	**LB**	**UB**
Infants	**4/3**	0.8 [0.5 – 1.4]	1.0 [0.7 – 1.6]	1.8 [1.4 – 2.3]	2.1 [1.6 – 2.5]
Toddlers	**8/5**	1.3 [0.9 – 1.9]	1.4 [0.9 – 1.9]	2.3 [1.4 – 3.4]	2.4 [1.5 – 3.4]
Other children	**17/17**	1.2 [0.9 – 1.6]	1.2 [0.9 – 1.6]	2.2 [1.4 – 3.2]	2.3 [1.4 – 3.2]
Adolescents	**17/16**	0.7 [0.4 – 0.9]	0.7 [0.4 – 0.9]	1.4 [0.9 – 2.0]	1.4 [0.9 – 2.0]
Adults	**16/16**	0.5 [0.4 – 0.6]	0.5 [0.4 – 0.6]	1.0 [0.8 – 1.3]	1.0 [0.8 – 1.3]
Elderly	**11/11**	0.4 [0.4 – 0.5]	0.5 [0.4 – 0.5]	0.8 [0.7 – 1.0]	0.9 [0.7 – 1.0]
Very elderly	**9/8**	0.4 [0.4 – 0.5]	0.5 [0.4 – 0.6]	0.9 [0.6 – 1.0]	0.9 [0.6 – 1.0]

N: number of samples; P95: the 95 percentile; LB: lower bound; UB: Upper bound.
[a] Number of surveys used to derive the minimum/median/maximum mean exposure levels / number of surveys used to derived the minimum/median/maximum P95-exposure levels.

The main contributor to the total acrylamide exposure of infants was 'baby foods, other than processed cereal-based' contributing up to 60% ('fruit purée' contributing up to 34% and 'ready to eat meals' up to 25%) followed by 'other products based on potatoes' (contributing up to 48%) and 'processed cereal-based baby foods' (of which infant porridge contribute up to 28%). The main contributors to the total exposure in toddlers were 'other products based on potatoes' (contributing up to 38%), and 'soft bread', 'other products based on cereal', 'breakfast cereals', 'biscuits, crackers crisp bread' (each contributing up to 25-30%).

The main contributor in other children and adolescents was 'Potato fried products (except potato crisps and snacks)', representing up to half the total exposure, followed by 'Soft bread', 'Breakfast cereals', 'Biscuits, crackers, crisp bread', 'Other products based on cereals' and 'Other products based on potatoes'. These foods groups were also the main contributors to the total exposure of adults, elderly and very elderly together with 'Coffee'. Although food items in the food group 'Potato crisps and snacks' had high acrylamide concentrations, the contribution to total acrylamide exposure from this food group was low. The highest contribution from the food group 'Potato crisps and snacks' was seen in adolescents (contributing up to 11%). Home cooking preferences were reported to have a substantial impact on the dietary exposure, with temperature and heating time correlating with darker food colour and acrylamide concentration (EFSA, 2015).

2.2 Previous dietary estimates and exposure to acrylamide in Norway

Estimated dietary acrylamide exposure has been reported for different age and population groups in previous studies in Norway. These studies are summarised in detail in this chapter, and some also included biomarkers of acrylamide exposure in addition to the estimated dietary acrylamide exposure. Two different biomarkers of acrylamide exposure have been established. Quantification of acrylamide mercapturic acid metabolites in 24-hour urine provides a marker of short-term acrylamide exposure (Bjellaas et al., 2007a) (Bjellaas et al., 2005) (Boettcher et al., 2006). Quantification of the reaction products of acrylamide and its metabolite glycidamide with haemoglobin provides a marker of acrylamide present in the circulation of the lifetime of the erythrocytes (approximately 125 days) and gives an estimate of longer term average acrylamide exposure (Bergmark, 1997) (Hagmar et al., 2001).

2.2.1 Literature search

The aim of the literature search for this opinion was to identify all published studies reporting estimated dietary acrylamide exposure in Norwegian population groups. The following search string in PubMed returned 20 abstracts, of which 12 were considered relevant (((acrylamide [Title/Abstract]) AND (diet OR food)) AND (Norway)). Some of these studies included biomarkers of acrylamide exposure, and additional biomarker studies were identified by hand search or expert knowledge. All relevant studies are summarised below.

2.2.2 Dietary acrylamide exposure based on National dietary surveys

The first estimated exposure to acrylamide in Norway was published by Dybing and Sanner in 2003 and was based on data from National dietary surveys (Dybing and Sanner, 2003). In 2002, acrylamide concentrations had been measured by the Norwegian Food Safety Authority in 30 different food products and eight brands of coffee bought on the Norwegian market (Norwegian Food Safety Authority, 2002a; Norwegian Food Safety Authority, 2002b). Data on food consumption in the adult population were taken from the national food survey NORKOST 1997 and based on a quantitative food frequency questionnaire (Johansson and Solvoll, 1999), while food consumption in 9-year-old children and 13-year-old adolescents was taken from the national food survey UNGKOST 2000 and based on a 4-day food intake registration in which portions were assigned according to a picture booklet (Øverby and Andersen, 2002). Estimated mean and 90-percentile values showed that acrylamide exposure was higher in males than in females in all age groups and the highest exposure was seen in 13-year old boys (Table 2.2.2-1).

The same estimates were also used in a review on human exposure to acrylamide in food (Dybing et al., 2005).

Table 2.2.2-1 Estimated dietary acrylamide (AA) exposure in nationally representative samples of adults, children and adolescents (Dybing and Sanner, 2003)

Survey and dietary method	N	Sex	Age (year)	Mean AA exposure (µg/kg bw per day)	90-percentile (µg/kg bw per day)
NORKOST 1997 (FFQ)[1]	1291	men	16-79	0.49	1.01
	1381	women	16-79	0.46	0.86
UNGKOST 2000 (4-day food registration)[2]	1299	boys	9	0.36	0.72
	1658	girls	9	0.32	0.61
	1711	boys	13	0.52	1.35
	2068	girls	13	0.49	1.20

[1]FFQ: Food Frequency Questionnaire
[2]UNGKOST 2000: it should be noted that the acrylamide exposures in 9- and 13-year-olds were estimated as acute exposure with the single days in the food diary treated as independent observations rather than an average intake over the 4-days registration per individual.

2.2.3 Dietary acrylamide exposure in employees at the Norwegian Institute of Public Health

Bjellaas et al. (2007a), reported acrylamide exposure in a convenience sample comprising 53 employees at the Norwegian Institute of Public Health (NIPH). The objective of the study was to evaluate quantification of the acrylamide metabolites excreted in urine (mercapturic acid derivatives) as a biomarker for external acrylamide exposure (Bjellaas et al., 2007a). Participants collected all urine excreted during 24 hours and were asked to recall all food and beverage intake during the same time period as the urinary collection (24-h recall). The Norwegian Food Safety Authority provided new analytical data on acrylamide concentrations in food bought in Norway during the years 2002-2006 (Norwegian Food Safety Authority, 2002a; Norwegian Food Safety Authority, 2002b; Norwegian Food Safety Authority, 2006), and the estimated exposure to acrylamide in this study included more food items than in the previous study (Dybing and Sanner, 2003). The median (range) dietary exposure estimate based on the 24-h recall was 0.47 (0.17-1.16) µg/kg bw per day (Table 2.2.3-1). There were no statistically significant differences in dietary acrylamide intakes between men and women.

Table 2.2.3-1 Estimated dietary acrylamide (AA) exposure in a study among employees at the Norwegian Institute of Public Health (NIPH) (Bjellaas et al., 2007a)

Dietary method	N	Sex	Mean age (year)	Median AA exposure (µg/kg bw per day)	Minimum-maximum (µg/kg bw per day)
One 24-h recall	20	Men	45	0.47	0.17-1.16
	33	Women	42		

The median (range) total excretion of acrylamide metabolites in urine in non-smokers (n=47) was 16 (4-47) µg/24h. There was no difference between men and women in the amount of acrylamide metabolites excreted in urine, and no difference with regard to age, but a positive correlation was found between urinary excretion of acrylamide and increasing body weight. In smokers, the total amount of acrylamide excreted as urinary metabolites were on average 3.5 times higher than in non-smokers.

The recovery of acrylamide in human urine has previously been estimated to be between 50% (Boettcher et al., 2006) and 60% (Fuhr et al., 2006). Assuming that 55% of acrylamide is excreted in urine, the urinary acrylamide in non-smokers would correspond to a median total exposure of 29 (12-86) µg acrylamide over 24 hours, while the estimated exposure through diet was 21 (3-178) µg. There was no correlation between total intake of acrylamide estimated for each individual and urinary acrylamide metabolites in the 24 h urine. However, a statistically significant correlation between dietary acrylamide intake before 12.00 h and urinary acrylamide metabolite excretion before 18.00 h was found (Spearman rho=0.36, $p<0.05$) and between estimated intake after 18.00 h and excretion of acrylamide metabolites in morning urine (Spearman rho = 0.32, $p<0.05$) (Bjellaas et al., 2007a). Participants who had urinary acrylamide metabolite concentrations above the 95-percentile had consumed food items known to have high acrylamide concentration such as coffee, cereals, potato crisps, baked potatoes, pizza, bread and biscuits. Furthermore, consumption of fried food items for dinner also contributed to high acrylamide metabolite concentrations, pointing to the importance of home cooking methods for exposure to acrylamide. This study has also been described in detail in a masters' thesis (Stølen, 2006).

While urinary acrylamide metabolite excretion is considered a short term biomarker of exposure, the concentrations of hemoglobin adducts of acrylamide and it genotoxic metabolite glycidamide are considered biomarkers of average long-term exposure (Chapter 1.2). Bjellaas et al. (2007b) also quantified the concentrations of acrylamide- and glycidamide-haemoglobin (Hb) adducts in blood and examined the association between these Hb-adducts and the estimated long-term dietary acrylamide exposure assessed by a food frequency questionnaire capturing habitual intake over the last 12 months. Intake of chips and snacks correlated positively with acrylamide adducts while no associations with food intake were found for glycidamide adducts (Bjellaas et al., 2007b). Neither of the Hb-adducts correlated with the estimated long-term dietary acrylamide exposure.

2.2.4 Dietary acrylamide exposure in a subsample of pregnant women in the Norwegian Mother and Child Cohort Study

Brantsaeter et al. (2008a) evaluated different methods to assess dietary acrylamide exposure in pregnant women participating in a validation study of a food frequency questionnaire in the Norwegian Mother and Child Cohort Study (Brantsaeter et al., 2008a). In total, 119 women were recruited from February 2003 to February 2004. In addition to answering the food frequency questionnaire, participants completed a four-day food diary, donated blood and collected a 24-h urine sample on one of the days of the food diary (Brantsaeter et al., 2008b). Dietary acrylamide exposure was estimated by the food frequency questionnaire, by the food diary and by a probabilistic approach using food consumption data from the food diaries (Table 2.2.4-1). The authors prepared a database containing values of acrylamide concentrations reported from analyses of Norwegian food items (Norwegian Food Safety

Authority, 2002a; Norwegian Food Safety Authority, 2002b; Norwegian Food Safety Authority, 2006); (Scientific Committee of the Norwegian Food Control Authority, 2002) and the Swedish National Food Administration (Livsmedelsverket, 2002). For foods not analysed in Norway or Sweden, data were taken from the European Union database (Institute for Reference Materials and Measurements (IRMM), 2005). For food items with multiple analyses of acrylamide concentrations, the median concentration was used. Food items relevant to dietary acrylamide exposure were grouped into 17 food groups, based on similarity in nutrient profiles, culinary usage or processing. The mean acrylamide concentration within each group was assigned to all food items in a group when calculating the daily acrylamide exposure according to food intakes assessed by the food frequency questionnaire and the food diary. For the probabilistic approach, all concentration values were put into the database, of which 204 were from analysis of Norwegian food items. The food frequency questionnaire resulted in a slightly higher estimated median and P95-exposure than the food diary and probabilistic method, but the estimates were quite similar with the median exposure ranging from 0.41 to 0.48 µg/kg bw per day (Table 2.2.4-1). The main dietary sources of acrylamide in this study were potato crisps, crisp bread, biscuits, breakfast cereals and bakery products.

Table 2.2.4-1 Estimated dietary acrylamide (AA) exposure in 119 pregnant women participating in a sub-study in the Norwegian Mother and Child Cohort study (Brantsaeter et al., 2008a)

Survey	N	Mean age (year)	Method	Median AA exposure (µg/kg bw per day)	95-percentile (µg/kg bw per day)
Validation study within the Norwegian Mother and Child Cohort study (MoBa Val)	119	31 (range 23-44)	FFQ[a]	0.48	0.92
			FD[b]	0.41	0.82
			Probabilistic estimation[c]	0.42	0.70

[a]FFQ: Food Frequency Questionnaire; [b]FD: Food diary; [c]Probabilistic estimation: a statistical tool applied to estimate a 'probable exposure' making use of the whole distribution of food intakes registered in the FD.

The median (range) total excretion of acrylamide mercapturic acid metabolites in urine for non-smokers was 11.2 (3.3-75.6) µg/24-h. Assuming that 55% of acrylamide is excreted in urine this would correspond to a median total exposure of 20.3 µg acrylamide/24-h (0.30 µg/kg bw/24-h) in non-smokers. The corresponding exposure in smokers was 91.1 µg acrylamide/24-h (1.21 µg/kg bw/24-h). In the non-smokers, there was a positive correlation between dietary acrylamide exposure estimated for each individual and the amount of acrylamide excreted in urine as mercapturic acid metabolites whether the intake was calculated by the food frequency questionnaire or the food diary (Spearman rho=0.26 and 0.34, respectively, $p<0.05$ for both). Therefore, the MoBa FFQ is considered useful for estimating dietary exposure to acrylamide in pregnant women and valid for ranking respondents according to high and low dietary acrylamide exposure (Brantsaeter et al., 2008a).

2.2.5 Dietary acrylamide exposure in a large sample of pregnant women in the Norwegian Mother and Child Cohort Study

Duarte-Salles et al. (2013) examined the association between estimated maternal acrylamide exposures during pregnancy in relation to birth weight of the children (Duarte-Salles et al., 2013). The Norwegian Mother and Child Cohort Study (MoBa) is a prospective population-based pregnancy cohort conducted by the Norwegian Institute of Public Health (Magnus et al., 2006). Participants were recruited through postal invitation from all over Norway from 1999-2008, and 40.6% of invited women consented to participate. The women were asked to provide biological samples at baseline and to answer questionnaires at regular intervals during pregnancy and after birth. Data on birth weight were obtained through linkage to the Norwegian Medical Birth Registry. Acrylamide exposure was estimated using the food frequency questionnaire and acrylamide concentrations described in detail by Brantsaeter et al. (2008a). The study population comprised 50,651 women who had responded to the relevant questionnaires and delivered a singleton baby. The estimated mean acrylamide intake during the first half of pregnancy was 0.4 µg/kg bw per day (Table 2.2.5-1). The food groups that had the largest impact on the predicted acrylamide intake were snacks, which included potato chips, nuts, and popcorn; fried potatoes; and crisp bread (Duarte-Salles et al., 2013).

Table 2.2.5-1 Estimated dietary acrylamide (AA) exposure in 50,651 pregnant women participating in the Norwegian Mother and Child Cohort study (Duarte-Salles et al., 2013)

Survey and dietary method	N	Mean age (year)	Mean AA exposure ± SD[b] (µg/kg bw per day)	Confidence interval (µg/kg bw per day)
The Norwegian Mother and Child Cohort study (MoBa)(FFQ[a])	50,651	30	0.4 ± 0.2	0.01-0.8

[a] FFQ: Food Frequency Questionnaire; [b] SD: standard deviation

This study also included a small biomarker study, as haemoglobin adducts from acrylamide and glycidamide were measured in 79 non-smoking mothers who gave birth between 2007 and 2009 in Oslo (participants of the MoBa sub-cohorts BraMiljø and Bramat). Maternal acrylamide intakes estimated by the FFQ correlated significantly with both acrylamide- and glycidamide-Hb adducts (Spearman rho=0.24 and 0.48, respectively, $p<0.05$ for both) (Duarte-Salles et al., 2013). Furthermore, another study that examined dietary predictors of acrylamide- and glycidamide-Hb adducts in the pregnant Norwegian women combined with data for pregnant women in four other European countries reported that 'fried potato products' were the main predictor of the adducts (Pedersen et al., 2012).

2.2.6 Dietary acrylamide exposure in Norwegian women in the European Prospective Investigation into Cancer and Nutrition cohort

The European Prospective Investigation into Cancer and Nutrition cohort (EPIC study) is a study initiated between 1992 and 1998 in ten European countries. The aim is to investigate the relationships between nutrition and lifestyle factors, and cancer and other chronic diseases. Two studies with about 300 000 non-smoking women (including 35 000 Norwegian women) examined the association between estimated acrylamide exposure and various cancers (Obon-Santacana et al., 2014; Obon-Santacana et al., 2015). The estimated dietary acrylamide exposure in the Norwegian sub-cohort was reported as a mean of 0.3 µg/kg bw per day in one study (Obon-Santacana et al., 2014), and as a median of 0.3 µg/kg bw per day in the other study (Obon-Santacana et al., 2015). The mean was slightly lower, while the median was the same as for the overall estimate in all European cohorts combined.

2.2.7 Summary of previous studies of dietary acrylamide exposure in Norway

Although the previous Norwegian studies differed with regard to the dietary assessment method used and number of food items analysed, the mean and median dietary acrylamide exposure estimates were in the range of 0.3-0.5 µg/kg bw per day in all studies. These estimates are in the same range as the mean exposures estimated in the EFSA Scientific Opinion (2015) for adult populations (0.4-0.5 µg/kg bw) (Table 2.1-1). Only one Norwegian study reported a P95-exposure (0.9 µg/kg bw), which was also within the range of P95-exposures estimated in European adult populations (0.6-1.3 µg/kg bw). Although the Norwegian acrylamide occurrence data as well as the dietary consumption data are subject to considerable uncertainties the derived exposure data fit well with the dietary estimates calculated from the observed biomarkers of exposure in urine and blood – thus, both approaches are mutually confirmative. This shows that dietary estimates are valid for distinguishing between high and low exposure. None of the studies were able to account for differences in home-cooking practices.

Only one previous Norwegian study estimated acrylamide exposure in younger age groups by including 9- and 13-year olds (Dybing and Sanner, 2003). The study was based on a small database on occurrence in food. The highest mean exposure was found for 13-year old boys (0.52 µg/kg bw) (Table 2.2.2-1) which is not very different from the mean for adolescents (0.7 µg/kg bw) estimated by EFSA (Table 2.1-1). The P95-exposure was higher in adolescents than in adults, but this may be due to the fact exposures were estimated as acute exposures.

2.3 Occurrence of acrylamide in Norwegian food

The Norwegian Food Safety Authority has provided analytical data for acrylamide concentrations in Norwegian food samples since 2002. With the intention to make the present Opinion comparable with the EFSA 2015 Opinion, VKM decided to use data from the same time period, i.e. 2010-2014. A total of 352 Norwegian food samples were analysed for acrylamide during this time period (Appendix I). All food samples were analysed by accredited laboratories.

The data set contained few samples with acrylamide levels below the limit of detection (LOD). For the samples below LOD, the middle bound (MB) approach was applied by using half of the LOD value. This approach is comparable to that used in the EFSA (2015) Scientific Opinion, where all the samples reported as below the LOD/LOQ were replaced by half their respective LOD/LOQ (i.e. middle bound (MB)) estimates.

2.3.1 Comparison of acrylamide concentrations in Norwegian food samples and the concentrations used in the EFSA Scientific Opinion (2015)

Table 2.3.1-1 shows the acrylamide concentrations in food reported by EFSA (2015), compared with those from Norway in the main food categories from FoodEx1. For more detailed information of occurrence data in sub-categories of food see Appendix I, Table A1-1.

The number of samples differs between EFSA and Norway. However, the mean concentrations of acrylamide in the main food categories do not differ substantially, except for three categories. In the group "potato crisp and snacks", the mean acrylamide concentration is two times higher in Norwegian samples than in the European samples. Possible explanations for this difference may be differences in potato species, processing and storage. Furthermore, the acrylamide concentrations in the two categories "Baby foods, other than cereal-based" and "Processed cereal-based baby food" are 1.4 and 7.3 times lower in Norwegian samples than in the European samples. According to the Norwegian Food Safety Authority, the acrylamide concentrations in samples of infant porridge have been substantially reduced from 2008/2009 to 2011 and 2014 (Norwegian Food Safety Authority, 2014), most likely due to improved industrial processing. To the best of VKM's knowledge, although the production of baby food is centralised, the products are tailored for regional preferences within Europe. VKM considers that the number of Norwegian infant porridge samples (n=52) is sufficient for exposure calculation, and that the brands sampled are representative for infant porridge on the Norwegian market. The baby food categories are only relevant for infants and toddlers. The broad category "Other products" contains only three Norwegian samples, and is consequently not comparable to EFSA data.

Table 2.3.1-1 Occurrence of acrylamide (µg/kg food) in Europa (EFSA, 2015, Table 6) and in Norway, based on main food categories from FoodEx1

	Main food categories from FoodEx1	EFSA N	EFSA MB mean	Norway N	Norway MB mean
1	Potato fried products	1694	308	33	296
2	Potato crisp and snacks	34501	389	47	791
4	Soft bread	543	42	31	17
5	Breakfast cereals	1230	161	41	120
6	Biscuits, crackers, crisp bread and similar	2065	265	73	205
7	Coffee and coffee substitutes	1545	578	17	412
8	Baby foods, other than cereal-based	416	24	32	10
9	Processed cereal-based baby food	736	73	53	10
10	Other products based on potatoes, cereals and cocoa	569	97	22	65
11	Other products	120	330	3	6

2.4 Evaluation of the need for new exposure calculations in subgroups of the Norwegian population

In accordance with the terms of reference, VKM assessed whether the Norwegian population, or subgroups of the population, have different food consumption patterns that could lead to different dietary acrylamide exposure than reported in other European population groups. VKM's evaluation of the need for new exposure calculations in groups of the population is presented in the following Chapters.

2.4.1 Adults

The previous estimates of dietary acrylamide exposure in Norwegian adults, including pregnant women, showed that mean or median exposures were 0.3-0.5 µg/kg bw per day, and the maximum reported exposure was 1.2 µg/kg bw per day (Chapter 2.2.6). These values are all within the range of estimated exposures in European adults (including elderly and very elderly) (Table 2.1-1), where mean (and 95%) exposure ranged from 0.4-0.6 µg/kg bw per day (0.6-1.3 µg/kg bw per day). Food groups identified as major sources of acrylamide exposure in Norway were the same as identified as main contributors to acrylamide exposure in adults and elderly by EFSA, i.e. fried potato products, coffee and cereal products. Furthermore, evaluation of urinary biomarkers of acrylamide metabolites identified home cooking methods among factors explaining high exposure.

The number of Norwegian food samples analysed for acrylamide was lower than the number of food sampled in Europe. However, the values for comparable food groups were comparable to those reported by EFSA, with the highest acrylamide concentrations found in the food groups "potato crisps and snacks" and "coffee".

Taking into consideration the results from previous exposure estimates and knowledge about food consumption patterns in recent consumption surveys in Norway, VKM concludes that

Norwegian adults are not likely to have a different exposure to acrylamide than other European adults. VKM therefore decided not to perform a new exposure assessment in adults.

In addition to baseline exposure estimates, EFSA (2015) calculated exposure scenarios to assess the influence of specific home-cooking methods and of preferences for particular products on the total dietary exposure to acrylamide. VKM concludes that these exposure scenarios are equally relevant for Norwegian population groups and results from these scenarios are discussed in Chapter 2.6 of this Opinion.

2.4.2 Adolescents and other children

Based on consumption data from the national food survey in 4-, 9- and 13-year-olds (Øverby and Andersen, 2002) (Pollestad et al., 2002), VKM concludes it is not likely that Norwegian adolescent and other children have specific eating patterns leading to a different dietary exposure to acrylamide than the corresponding European age groups. According to EFSA 2015, the major contributors to acrylamide exposure in these age groups were bread and food items (Chapter 2.1), which are also consumed on a regular basis in Norway.

Therefore, VKM decided not to carry out a full exposure estimate for adolescents (≥10 years to <18 years old) and other children (≥3 years to <10 years old). VKM concludes that Norwegian adolescents and children aged three years or more are not likely to have a different exposure to acrylamide than other European adolescents and children aged three years or more.

2.4.3 Toddlers and infants

No previous studies in Norway have assessed acrylamide exposure in infants (<1-year-old) and toddlers (≥1-year to 3-years-olds). The most recent national dietary survey in 6-month-old children was based on a semi-quantitative food frequency questionnaire (Øverby et al., 2008). The questionnaire did not include portion sizes for all food items and is therefore not appropriate for calculating food amounts and acrylamide exposure in the infant group.

For toddlers (≥1-year to 3-years-olds), the most recent national dietary survey assessed food consumption in 1- and 2-year-old Norwegian children (Øverby et al., 2009) (Kristiansen et al., 2009). Food consumption was assessed using a semi-quantitative food frequency questionnaire covering the last 14 days. Food amounts were estimated with predefined household units or photographs. Hence, given the available acrylamide concentrations for food items relevant for toddlers (Chapter 2.3), calculation of acrylamide exposure in toddlers was feasible.

Among the food items contributing to acrylamide exposure, cereal-based infant porridge is consumed by approximately 80% of all 1-year-old children (mean intake 34 g infant porridge powder/day), and infant porridge contributes about one quarter of the mean energy intake

(Øverby et al., 2009). The corresponding consumption of infant porridge in Norwegian 2-year-olds is only 2 g infant porridge powder/day (consumed by 17% of 2-year-old children).

Since Norwegian 1-year-olds have higher consumption of infant porridge than that reported in larger surveys of toddlers in EFSA 2015 (EFSA Comprehensive European Food Consumption Database), VKM decided to conduct a full exposure estimate in 1-year-old toddlers.

2.5 Exposure assessment in 1-year-old Norwegian toddlers

The nation-wide food consumption survey in Norwegian 1-year-olds was conducted in 2007. Spedkost 2006-2007 is based on a semi-quantitative food frequency questionnaire (FFQ). In addition to predefined household units, food amounts were also estimated from photographs. A total of 1635 1-year-old children participated (Øverby et al., 2009).

For food groups relevant for 1-year-olds, acrylamide concentrations were available both from European (EFSA, 2015) and Norwegian food analyses (Table 2.3.1-1, Appendices I and II). VKM considered that Norwegian analytical values were sufficient if concentrations were analysed in 16 samples or more. Of the Norwegian food groups, the following had the largest number of analytical values: 'Biscuits, crackers, crisp bread' (n=73), 'Potato crisps and snacks' (n= 58), 'Processed cereal-based baby food' (n=53, of which 'cereals to be reconstituted' i.e. infant porridge comprised 52 samples), and 'Baby foods, other than cereal-based' (n=35, of which 'ready-to-eat meals and dessert' comprised 32 samples)(Appendix I, Table A1-1). The acrylamide concentrations in Norwegian infant porridge were lower than the corresponding European values (food category "Processed cereal-based baby food", sub-category "Cereals to be reconstituted" in Appendix I, Table A1-1).

In this opinion, VKM has calculated exposure to acrylamide based on food consumption in Norwegian 1-year-olds using two different approaches (Table 2.5-1) in order to illustrate the difference in exposure when using:
I) EFSA acrylamide concentration data only, or;
II) Norwegian acrylamide concentration data for food categories including 16 samples or more, and EFSA data for the remaining categories.

All estimates were calculated using middle bound (MB) concentration values. For both the Norwegian and EFSA data, there were few differences between lower bound (LB) and upper bound (UB) values in food items relevant for toddlers (Table 2.3.1-1). For a more detailed overview of concentrations used for calculating acrylamide exposure, see Appendix II, Table A2-1.

Table 2.5-1 Calculated dietary acrylamide exposure (µg/kg bw per day) in Norwegian 1-year-olds based on their food consumption (Spedkost-07, n = 1635)

Approach	Source of concentration data	Mean	Median	P95
I	EFSA acrylamide concentration data[1]	1.6	1.5	3.2
II	Norwegian acrylamide concentration data for food categories including 16 samples or more, and EFSA[1] data for the remaining categories	0.9	0.8	1.6

[1] EFSA, 2015

In approach I, when using EFSA occurrence values only, the calculated mean (P95) exposure in Norwegian 1-year-olds was 1.6 (3.2) µg/kg bw per day, which was in the upper range of what EFSA has calculated for the same age group, both for the mean and P95-exposure (EFSA mean range 0.9-1.9 µg/kg bw per day and P95-exposure range 1.4–3.4 µg/kg bw per day).

In approach II, when using Norwegian acrylamide concentration data for food categories including 16 samples or more and EFSA data for the remaining categories, the mean (P95) exposure in Norwegian 1-year-olds was 0.9 (1.6) µg/kg bw per day, which is in the lower range of what EFSA has calculated for the same age group.

The main reason for the difference between the two exposure estimates was the lower acrylamide concentrations in Norwegian infant porridge. In both approaches, 'Baby food' and 'Soft bread' were the food groups contributing the most to the estimated acrylamide exposure (Table 2.3.5-2). Within the 'Baby food'-category, in approach I 'Cereals to be reconstituted' was the main contributor, while in approach II it was 'fruit purée'. In contrast to results for adult populations, fried potato products were a minor contributor to dietary acrylamide exposure in the 1-year olds.

Table 2.5-2 Contribution by food groups (percent) to the calculated acrylamide exposure given in Table 2.5-1 (mean acrylamide exposures by approach I and II were 1.6 and 0.9 µg/kg bw per day, respectively)

Food groups	Approach I[1] % contribution	Approach II[2] % contribution
Baby food (processed cereal-based, and other than cereal based)	71	43
Infant formula	2	3
Fruit purée	8	15
Ready-to-eat meal and dessert	14	13
Cereals to be reconstituted	46	10
Soft bread	24	47
Breakfast cereals	1	2
Cakes	2	4
Potato fried products	1	2

[1] EFSA acrylamide concentration data (EFSA, 2015)
[2] Norwegian acrylamide concentration data for food categories including 16 samples or more, and EFSA data for the remaining categories.

The consumption of infant porridge in Norwegian 1-year-olds is higher than in other European toddlers and the measured concentration of acrylamide in infant porridge on the Norwegian market is lower than the value used by EFSA. VKM is of the opinion that the exposure calculation in Approach II gives the best estimate for the 1-year-old children. However, the exposure calculations by the two approaches were both within the exposure range reported in EFSA 2015.

2.6 Food categories with high potential to increase acrylamide exposure

VKM considered both the specific exposure scenarios included in the EFSA Scientific Opinion (2015) for Norwegian conditions, and some of the food items with high potential to increase acrylamide exposure.

Acrylamide levels in food depend on the way food is processed and prepared. The background for the scenarios included in the EFSA 2015 Scientific Opinion is that questions about food preparation are normally not part of a dietary assessment, e.g. whether people like their French fries yellow or golden brown.

In order to evaluate the influence of specific behaviours on the total dietary exposure to acrylamide, the risk assessors in EFSA have considered several scenarios. The scenarios addressed the potential impact of home-cooking habits (according to instructions on food packaging or consumer preferences), location of consumption of the products, and preferences for particular food products.

Three scenarios for the food group 'French fries and fried potatoes' addressed the impact of home-cooking habits and location of consumption on acrylamide concentrations and exposure (EFSA, 2015). The first scenario simulated a situation where all French fries and fried potatoes, consumed at home or in restaurants, were cooked according to the cooking instructions on the packaging of pre-cooked products. In comparison with the baseline exposure (Table 2.1-1), this resulted in a **decrease** in the mean and P95 acrylamide exposure (up to 16 and 22%, respectively). The second scenario simulated a situation where all the French fries and fried potatoes were consumed in restaurants, and used sample concentrations from official monitoring programs. In comparison with the baseline exposure (Table 2.1-1), this resulted in an **increase** in the mean and P95 acrylamide exposure (up to 3.1 and 4.8%, respectively). The third scenario simulated consumption of crispy brown and brown 'French fries and fried potatoes', using the P95 of the acrylamide concentration observed for this food group (656 µg/kg). In comparison with the baseline exposure (Table 2.1-1), this resulted in an **increase** in the mean and 95th percentile exposure levels (up to 64 and 80%, respectively) (EFSA, 2015).

A separate scenario simulated the consumption of 'toasted bread' with a fixed high degree of browning. In this scenario, a value close to the highest value of acrylamide measured in toasted bread was used (100 µg/kg). This resulted in an **increase** in the mean and P95 levels of the total acrylamide exposure (up to 2.4 and 7.6%, respectively) (EFSA, 2015).

Scenarios addressing the preference for particular products were evaluated for potato crisps (made from fresh potatoes vs. potato dough) and coffee products (light versus medium or dark roasted). Fried products made from fresh potato, including potato crisps and snacks, had higher acrylamide levels than those made from potato dough, but the scenario showed that this had very little impact on the total exposure. The low impact was explained by the fact that potato crisps were not a major contributor to total acrylamide exposure (see Chapter 2.1). Contrary to what is found for potato products, acrylamide concentrations are found to be higher in light roasted coffee (374 µg/kg) than in medium (266 µg/kg) and dark (187 µg/kg) roasted coffee (Appendix B1 in EFSA 2015). The explanation is that acrylamide is formed during the beginning of the roasting process and declines with longer roasting time (EFSA, 2015). In comparison with the baseline estimate (Table 2.1-1), where all types of roasted coffee were considered, using values for light-roasted coffee for all consumed coffee resulted in an increase of the mean and P95 exposure levels (up to 14% in adults, elderly and very elderly age groups, and minor impact on the exposure levels in children and adolescents) (EFSA, 2015).

EFSA also considered how the interpretation of 'unspecified' potato consumption as fried or not fried influenced the exposure estimates. Estimates based on the assumption that all consumed potatoes were not fried resulted in a decrease of the mean and P95-exposure with up to 31 and 33% in comparison with the baseline estimates, while estimates based on the assumption that all consumed potatoes were fried resulted in an increase of the mean and P95-exposure with up to 49 and 78% in comparison with the baseline estimates (EFSA, 2015).

These scenarios showed that food preparation, and particularly conditions of potato frying, resulted in large variations and a possible increase of acrylamide exposure with as much as 80%. VKM considers that these scenarios carried out by EFSA (EFSA, 2015) are equally relevant for the Norwegian population. The temperature and browning of fried potato products will have a considerable impact on the exposure to acrylamide (see Figure 2.6-1).

In the last decade, food manufacturers, researchers and national food safety authorities have conducted significant research to identify and apply methods to reduce acrylamide in food products. Efforts have been made by food manufacturers to modify recipes and processes to reduce acrylamide occurrence in foods such as French fries, snacks and crisps. Strategies suggested for the reduction of acrylamide in potato crisps and French fries include e.g. the selection of potato cultivars with a low content of reducing sugars and asparagine, shifting the harvesting time to the end of the growing season when the concentration of sugars are at a minimum, storage of potato tubers at temperatures not lower than 8-12 °C, avoidance of high (>180-190 °C) frying and baking (>250 °C) temperatures, avoidance of long frying and baking times, and the soaking of peeled potatoes, preferably in an acidic environment to remove acrylamide precursors (EFSA, 2015).

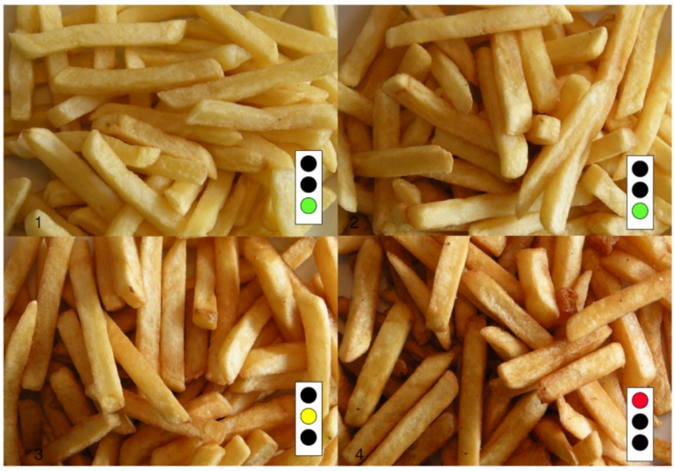

Figure 2.6-1 Potatoes fried at 185 °C and differing cooking times resulted in the following acrylamide concentrations: upper left 24 µg/kg, upper right 130 µg/kg, lower left 690 µg/kg and lower right 1590 µg/kg. For comparison, the EU guidance level is 600 µg/kg. The Norwegian Food Safety Authority advises eateries and the general public to prepare fried potatoes light brown (green light) and to avoid dark brown (red light) due to increased acrylamide levels in the latter. (Source: Fødevarestyrelsen in Denmark.)

It is not possible to avoid exposure to acrylamide, but the exposure will vary depending on e.g. diet, lifestyle and cooking preferences. Advice for minimising acrylamide formation during home preparation has been proposed for consumers by food authorities. This includes recommendations to fry foods at lower temperatures and to choose the golden-yellow rather than golden-brown degree of browning, and to toast bread to the lightest colour acceptable (EFSA, 2015). The UK Food Standards Agency recently published a report focusing on acrylamide, advising people to follow the general dietary recommendation of eating a healthy, balanced diet, to cook home-made chips to a light-golden colour, to toast bread to the lightest acceptable colour, and to carefully follow manufacturers' instructions for frying or oven-heating of food products (Food Standards Agency, 2015).

In Norway, monitoring of acrylamide in food has been carried out every few years by the Norwegian Food Safety Authority. From 2008/2009 to 2011, significant decreases in acrylamide concentrations were found in the following food groups: potato chips, pre-cooked fried potato products for home-cooking, crackers, and infant porridge. From 2011 to 2014, the acrylamide levels remained largely unchanged in these food groups in spite of continuing attempts by the food manufacturing industry to lower the acrylamide content (Norwegian Food Safety Authority, 2014).

According to previous Norwegian exposure estimates and estimates in European populations (EFSA, 2015), the food items contributing the most to acrylamide exposure in adults are fried potato products, coffee, biscuits, crackers and crisp breads, and soft bread. The fact that commonly consumed food items such as coffee and bread are important sources of acrylamide exposure is of concern in Norway as well as in the rest of Europe.

As a supplement to the scenarios calculated by EFSA, and in order to illustrate the influence of consumption of particular food items on acrylamide exposure in Norway, VKM calculated three simplified scenarios:

I. The first scenario addresses potato crisps. This is a snack that has low mean consumption in the general population (Norkost 3), reflecting occasional consumption or high consumption in only a subgroup of the population. A large bag of potato crisps on the Norwegian market weighs around 300 grams, and the mean acrylamide concentration measured in potato crisps in Norway is 791 µg/kg (Table 2.3.1-1). If a person with a body weight of 70 kg consumed one third of the bag (=100 g potato crisps), this would result in an acrylamide exposure of 1.1 µg/kg bw, which is more than two times the estimated average daily exposure in adolescents and adults. Given a lower body weight (e.g. in a child), the exposure per kg body weight will be higher.

II. The second scenario addresses French Fries. The mean consumption in the general Norwegian population is low, probably reflecting occasional consumption, but subgroups of the population may have frequent consumption. An average portion of French Fries weighs approximately 135 grams (page 35 in Dalane et al., 2015). The mean acrylamide concentration measured in fried potato products in Norway is 296 µg/kg (Table 2.3.1-1). If a person with a body weight of 70 kg consumed one average portion, this would give an acrylamide exposure of 0.6 µg/kg bw, which is above the estimated daily average exposure in adolescents and adults (0.3-0.5 µg/kg bw, see Chapter 2.2.7). Given a lower body weight (e.g. in a child), the exposure per kg body weight will be higher.

III. The third scenario addresses coffee. Coffee is consumed by a large part of the adult Norwegian population. According to the most recent (2010/2011) national dietary survey in adults (Norkost 3), the mean coffee intake is 5 dl/day (P95-intake 14 dl/day). The acrylamide concentration measured in ready-to-drink coffee is 19 µg/L (Table A1-1). An average cup of coffee in Norway contains around 2 dl and would contribute 0.05 µg acrylamide per kg bw in a person with a body weight of 70 kg. Two cups would contribute 0.10 µg/kg bw, and so on. An intake of 5 dl coffee would give an acrylamide exposure of 0.13 µg/kg bw, which constitutes about one third of the estimated daily average exposure in adults (0.3-0.5 µg/kg bw, see Chapter 2.2.7).

The Norwegian Food Safety Authority has issued dietary advices about limiting the consumption of food items associated with high acrylamide exposure, particularly fried potato products and snacks, including crisps, and coffee (Matportalen, 2015). The scenarios described above confirm that potato crisps, French Fries and coffee are food items with a high potential to increase acrylamide exposure and that the dietary advices to limit the consumption of these items are important and can contribute to lower acrylamide exposure. Additionally, further efforts by the food industry to reduce acrylamide concentrations in ready-to-eat baby food and different types of bread could also contribute to reduce acrylamide exposure.

2.7 Summary of exposure

The comparison of data on acrylamide occurrence in food reported in the EFSA Scientific Opinion (2015) and in foods sampled in Norway showed that acrylamide concentrations in the main food categories do not differ substantially, with the exception of three categories. The group "potato crisps and snacks" have higher acrylamide concentrations in Norwegian samples than in those reported by EFSA, while the groups "Baby foods, other than cereal-based" and "Processed cereal-based baby food" have lower concentrations in Norwegian samples than in those reported by EFSA. The baby food categories are only consumed by infants and toddlers.

A summary of previous estimates of acrylamide exposure in Norwegian adults and adolescents showed that the estimated average exposure ranged from 0.3 to 0.5 µg/kg bw. This is within the exposure range reported by EFSA (EFSA 2015).

No previous studies in Norway have assessed acrylamide exposure in infants and children less than three years of age. Information from national dietary surveys shows that Norwegian 1-year-olds have higher consumption of infant porridge than other European toddlers and VKM decided to conduct a full exposure estimate in 1-year-old toddlers.

VKM calculated acrylamide exposure based on food consumption in Norwegian 1-year-olds by two approaches; one using EFSA concentration data only, and the other using Norwegian concentration data for food categories including 16 samples or more and EFSA data for the remaining. When using EFSA concentration data only, the calculated daily exposure (mean: 1.6 µg/kg bw and P95: 3.2 µg/kg bw) is in the upper range calculated by EFSA for toddlers (mean range: 0.9-1.9 µg/kg bw, P95 range: 1.2-3.4 µg/kg bw). When using Norwegian concentration data for food categories including 16 Norwegian samples or more, and EFSA data for the remaining categories, the calculated exposure (mean: 0.9 µg/kg bw, P95: 1.6 µg/kg bw) is in the lower range of what EFSA has calculated for the same age group. Although Norwegian 1-year-olds have higher consumption of infant porridge than European toddlers and the acrylamide concentrations were lower in Norwegian samples, both approaches resulted in acrylamide exposures within the exposure range for toddlers reported by EFSA (2015). In Norway as well as in other European population groups, toddlers had the highest exposure on a body weight basis.

Baby food and soft bread contributed most to acrylamide exposure in the 1-year-old children, while food items contributing the most to acrylamide exposure in adults are fried potato products, coffee, biscuits, crackers and crisp breads, and soft bread.

Previous Norwegian studies of acrylamide exposure as well as acrylamide exposure reported in the EFSA Scientific Opinion (2015) showed that 'fried potato products' is a food group with high potential to increase acrylamide exposure in all population groups except infants and toddlers. Commonly consumed food items such as coffee and bread are also important sources of acrylamide exposure, which is of concern in Norway as in the rest of Europe.

VKM calculated three simplified scenarios to illustrate the influence of consumption of particular food items on acrylamide exposure. These scenarios confirmed that potato crisps, French Fries and coffee are food items with high potential to increase acrylamide exposure.

3 Risk characterisation in the Norwegian population compared to other European population

VKM bases the hazard characterisation on the reference points derived in the EFSA Scientific Opinion (2015), and calculated the Margin of Exposures (MOEs). MOE is the ratio between a reference value and the estimated dietary exposure. The MOE approach provides an indication of the level of safety but it does not quantify the risk as such. The MOE that indicates a low level of concern depends on the nature of the effects, and the nature and quality of the studies that are basis for the point of departure, considering uncertainty. As in EFSA 2015, VKM evaluated MOEs for non-neoplastic effects (peripheral neuropathy in rats) and for neoplastic effects (tumour incidence in mice) (EFSA 2015).

<u>Non-neoplastic effects:</u>

For non-neoplastic effects, EFSA used a $BMDL_{10}$ value of 0.43 mg/kg bw/day as the reference point based on animal studies of neurotoxicity, and considered a substance-specific MOE of 125 or above as a sufficient safety margin for no health concern (EFSA, 2015).

The MOEs for non-neoplastic effects reported for European adolescents and adults ranged from 478-1075 for mean exposure and from 215-538 for P95-exposure (EFSA, 2015). EFSA concluded that the MOEs across all age groups indicate no health concern for average or P95-exposure. As the reported acrylamide exposures estimates in Norwegian adolescent and adults were within the exposure range for the corresponding European age groups, the resulting MOEs will be above the value of 125.

VKM has calculated MOEs for non-neoplastic effects based on food consumption in 1-year-old Norwegian children. When using EFSA occurrence values only for estimating acrylamide exposure, the MOE is 269: ($MOE = \frac{0.43\frac{mg}{kg\ bw}}{1.6\frac{\mu g}{kg\ bw}} = \frac{430\frac{\mu g}{kg\ bw}}{1.6\frac{\mu g}{kg\ bw}} = 269$). The corresponding P95-exposure results in a MOE of 134.

When using Norwegian concentration data for food categories including 16 Norwegian samples or more, and EFSA data for the remaining categories, the calculated MOE is 478:

($MOE = \frac{0.43\frac{mg}{kg\ bw}}{0.9\frac{\mu g}{kg\ bw}} = \frac{430\frac{\mu g}{kg\ bw}}{0.9\frac{\mu g}{kg\ bw}} = 478$). The corresponding P95-exposure results in a MOE of 269.

The calculated MOEs for 1-year-olds derived from both approaches (i.e. without and with Norwegian concentration data) resulted in MOEs above the value of 125.

For non-neoplastic effects of dietary acrylamide exposure, VKM therefore reached the same conclusion as EFSA, which is that the MOEs across all age groups indicate no health concern for average or P95-exposure. However, in the 1-year-old Norwegian toddlers the P95-exposure is close to the MOE of 125.

Neoplastic effects:

For neoplastic effects, EFSA used a $BMDL_{10}$ value of 0.17 mg/kg bw/day as the reference point based on animal studies, and taking into account overall uncertainties in the interpretation, EFSA concluded that a MOE of 10 000 or higher would be of low concern for public health (EFSA 2015).

The MOEs for neoplastic effects reported for European adolescents and adults ranged from 189-425 for mean exposure and from 85-213 for P95-exposure (EFSA 2015). EFSA concluded that the MOEs across all age groups were substantially lower than 10 000, indicating a health concern.

As the reported acrylamide exposure estimates in Norwegian adolescents and adults were within the exposure range for the corresponding European age groups, the resulting MOEs will be substantially lower than the value of 10 000.

VKM has calculated MOEs for 1-year-old Norwegian children. When only using EFSA occurrence data for estimating acrylamide exposure the MOE is 106:

$(MOE = \frac{0.17 \frac{mg}{kg\ bw}}{1.6 \frac{\mu g}{kg\ bw}} = \frac{170 \frac{\mu g}{kg\ bw}}{1.6 \frac{\mu g}{kg\ bw}} = 106)$. The corresponding P95-exposure results in a MOE of 53.

When using Norwegian occurrence data for food categories including 16 Norwegian samples or more, and EFSA data for the remaining categories, the MOE is 189:

$(MOE = \frac{0.17 \frac{mg}{kg\ bw}}{0.9 \frac{\mu g}{kg\ bw}} = \frac{170 \frac{\mu g}{kg\ bw}}{0.9 \frac{\mu g}{kg\ bw}} = 189)$. The corresponding P95-exposure results in a MOE of 106.

The calculated MOEs for 1-year-olds derived from both approaches (i.e. without and with Norwegian concentration data) resulted in MOEs substantially lower than the value of 10 000.

For neoplastic effects of dietary acrylamide exposure, VKM reached the same conclusion as EFSA, which is that the MOEs across all age groups were lower than 10 000, indicating a health concern.

3.1 Summary of risk characterisation

The acrylamide exposures in Norwegian adolescents and adults were within the range calculated by EFSA for these age groups. VKM therefore concludes that the resulting MOEs for non-neoplastic and neoplastic effects of acrylamide for these groups will be similar to those calculated by EFSA.

VKM calculated acrylamide exposure based on food consumption in Norwegian 1-year-olds by two approaches: one using EFSA concentration data only; and using Norwegian concentration data for food categories including 16 samples or more, and EFSA data for the remaining categories. Both approaches resulted in comparable MOEs.

For both non-neoplastic and neoplastic effects, MOEs for 1-year-olds were similar to those reported in EFSA 2015.

For non-neoplastic effects of dietary acrylamide exposure, VKM reached the same conclusion as EFSA, which is that the MOEs across all age groups indicate no health concern for average or P95-exposure.

For neoplastic effects of dietary acrylamide exposure, VKM reached the same conclusion as EFSA, which is that the MOEs across all age groups were substantially lower than 10 000, indicating a health concern.

VKM is of the opinion that the conclusion reached by EFSA's risk assessment of acrylamide, which states that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups, also applies to Norwegians.

4 Uncertainties

The EFSA (2015) Scientific Opinion on acrylamide in food included 43 419 analytical results of food commodities collected and analysed since 2010, whereas a total of 352 Norwegian food samples were analysed for acrylamide during this time period (Appendix I). There is uncertainty as to what degree the occurrence data cover all relevant food groups and regional and seasonal differences.

The measured acrylamide concentrations within a single food group show large variation e.g. acrylamide concentrations in potato crisps sampled in Norway in 2014 ranged from 190 to 2900 µg/kg. Using a mean value to calculate the dietary exposure can result in both over- and underestimation depending on the "true" concentration in the consumed snack.

Acrylamide levels in food depend on the way food is processed and prepared. Home-cooking methods and preferences represent uncertainties in assessing acrylamide exposure.

As with all dietary assessment, there is uncertainty in the calculation of dietary acrylamide exposure. None of the existing dietary methods is able to capture "true" long-term food consumption in individuals.

Since no previous exposure estimate for Norwegian infants and toddlers existed, a full exposure assessment was carried out for 1-year-old children. The uncertainties regarding this assessment are outlined below.

EFSA use repeated 24-hour recalls for estimating acrylamide exposure in European population groups, while in Norway a food frequency questionnaire was used to assess food consumption and to estimate acrylamide exposure in 1-year-old children. The food frequency method addresses the average intake of predefined food items and does not capture day-to day-variations in consumption. This is, however, of minor importance for calculating chronic exposure.

Many children receive breastmilk in addition to other food at the age of 1 year. The potential additional exposure to acrylamide or its metabolite glycidamide via breastmilk has not been taken into account for the present assessment performed by VKM.

Consumption patterns change rapidly in infants and toddlers during the transition from weaning foods to a more varied diet and eating more of the same food as the rest of the family. The high consumption of infant porridge at this age seems, however, to be a consistent pattern, and was confirmed by earlier dietary surveys in Norwegian children. The survey carried out in 1999 reported that infant porridge was consumed by more than 80% of the 1-year-olds regardless of whether or not they were still breastfed (Lande et al., 2004).

In comparison to the extensive database on acrylamide occurrence in European food products accumulated and used by EFSA, the number of foods analysed in Norway is limited.

However, infant porridge is one of the few food groups for which a considerable number of Norwegian samples has been analysed. For 1-year olds, in order to address uncertainties in the occurrence data VKM calculated the possible range of acrylamide exposure when Norwegian consumption data were combined with both European and national occurrence data in two different approaches. By both approaches, the exposure was within the range for other European toddlers calculated by EFSA.

Although there were differences both in the acrylamide occurrence data and consumption patterns of infant food between European and Norwegian data, the mean and median exposures in 1-year-old Norwegian children were nevertheless quite similar to those calculated in European toddlers. The occurrence data and consumption patterns of foods contributing to acrylamide exposure in adolescents and adults do not differ substantially between Norway and EFSA, and VKM is therefore of the opinion that there is little uncertainty in assuming similar acrylamide exposures in Norwegian and European adolescents and adults.

For more elaborate explanations on the uncertainties related to exposure models, exposure scenarios and other uncertainties relevant for the Scientific Opinion on acrylamide in food by EFSA, see Chapter 9 in the EFSA opinion (2015).

5 Answers to the terms of reference

The Norwegian Food Safety Authority (NFSA) requested VKM to evaluate the dietary exposure to acrylamide in the Norwegian population. The background for the request was that EFSA recently published a scientific opinion confirming that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups.

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

ToR 1: To assess whether the consumption pattern of the Norwegian population or specific groups deviates from the European population in a way which could lead to a different acrylamide exposure through food. If found to be different, calculate the exposure for the identified population groups

VKM concludes it is not likely that Norwegian adults, adolescent and other children have specific eating patterns leading to a different dietary exposure to acrylamide than reported for the corresponding European age groups. A summary of previous estimates of acrylamide exposure in Norwegian adults and adolescents showed that the estimated daily average exposure ranged from 0.3 to 0.5 μg/kg bw. This is within the exposure range reported by EFSA (EFSA, 2015).

No previous studies in Norway have assessed acrylamide exposure in infants (<1-year-old) and toddlers (≥1-year to 3-years-olds). Quantitative food consumption data were available for 1- and 2-year-olds, but not for infants. 1-year-olds have higher consumption of infant porridge than 2-year-olds, and also higher consumption frequency and amount than European toddlers. The number of Norwegian infant porridge samples was considered sufficient (n=52) for exposure calculation, and the brands sampled representative for infant porridge on the Norwegian market. VKM decided to conduct a full exposure estimate for 1-year-old toddlers.

VKM calculated dietary acrylamide exposure based on food consumption in Norwegian 1-year-olds by two approaches: one using EFSA concentration data only; and the other using Norwegian concentration data for food categories including 16 samples or more, and EFSA data for the remaining categories. When using EFSA concentration data only, the calculated daily exposure (mean: 1.6 μg/kg bw and P95: 3.2 μg/kg bw) is in the upper range calculated by EFSA for toddlers (mean range: 0.9-1.9 μg/kg bw, P95 range: 1.2-3.4 μg/kg bw). When using Norwegian concentration data for food categories including 16 Norwegian samples or more, and EFSA data for the remaining categories, the calculated daily exposure (mean: 0.9 μg/kg bw, P95: 1.6 μg/kg bw) is in the lower range of what EFSA has calculated for toddlers. Although Norwegian 1-year-olds have higher consumption of infant porridge than European toddlers and the acrylamide concentrations were lower in Norwegian samples, both approaches resulted in acrylamide exposures within the exposure range for toddlers reported by EFSA (2015). In addition to infant porridge, soft bread is a major source of acrylamide in Norwegian 1-year-olds.

ToR 2: To identify food categories with a high potential to increase acrylamide exposure – both for the whole population and specific groups

According to previous Norwegian exposure estimates and estimates in adult European populations, the food items contributing most to acrylamide exposure in adults are fried potato products, coffee, biscuits, crackers and crisp breads, and soft bread.

In Norwegian 1-year-old toddlers, 'Baby food' and 'Soft bread' are the food groups contributing most to the calculated acrylamide exposure. Within the 'Baby food'-category, 'Cereals to be reconstituted' and 'fruit purée' contributed most.

In all populations groups except toddlers, 'fried potato products' is a food group with high potential to increase acrylamide exposure. Acrylamide is also contributed by food items commonly consumed such as coffee and bread, and this is of concern in Norway as well as in the rest of Europe.

The EFSA risk assessment for European populations included exposure scenarios addressing the potential impact of home-cooking habits, location of consumption, and preferences for particular food products. These scenarios showed that food preparation, and particularly conditions of potato frying, resulted in large variations and a potential increase in acrylamide exposure by as much as 80%. VKM considers that these scenarios carried out by EFSA are equally relevant for the Norwegian population. The temperature and browning of fried potato products will have a considerable impact on the exposure to acrylamide.

VKM calculated three simplified scenarios to illustrate the influence of consumption of particular food items on acrylamide exposure. These scenarios confirmed that potato crisps, French Fries and coffee are food items with high potential to increase acrylamide exposure.

ToR 3: To characterise the risk to the Norwegian population compared to the rest of the European population

VKM used the same reference points as EFSA (2015), and calculated Margin of Exposures (MOEs) for assessing health risk. MOE is the ratio between a reference value and the estimated dietary exposure. The MOE approach provides an indication of the level of safety but it does not quantify the risk as such.

For non-neoplastic effects, EFSA used a $BMDL_{10}$ value of 0.43 mg/kg bw/day as the reference point based on animal studies of neurotoxicity, and considered a substance-specific MOE of 125 or above as a sufficient safety margin for no health concern.

For neoplastic effects, EFSA used a $BMDL_{10}$ value of 0.17 mg/kg bw/day as the reference point based on animal studies, and taking into account overall uncertainties in the interpretation, EFSA concluded that a MOE of 10 000 or higher would be of low concern for public health.

The dietary acrylamide exposure in Norwegian adolescent and adults were within the range calculated by EFSA for these age groups. VKM therefore concludes that the resulting MOEs for non-neoplastic and neoplastic effects of acrylamide for adolescent and adults will be similar to those calculated by EFSA.

VKM calculated acrylamide exposure based on food consumption in Norwegian 1-year-olds by two approaches: one using EFSA concentration data only; and the other using Norwegian concentration data for food categories including 16 samples or more, and EFSA data for the remaining categories. Both approaches resulted in comparable MOEs.

For both non-neoplastic and neoplastic effects, MOEs for 1-year-olds were similar to those reported in EFSA 2015.

For non-neoplastic effects of dietary acrylamide exposure, VKM reached the same conclusion as EFSA, which is that the MOEs across all age groups indicate no health concern for average or P95-exposure.

For neoplastic effects of dietary acrylamide exposure, VKM reached the same conclusion as EFSA, which is that the MOEs across all age groups were substantially lower than 10 000, indicating a health concern.

VKM is of the opinion that the conclusion reached by EFSA's risk assessment of acrylamide, which states that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups, also applies to Norwegians.

6 Data gaps

Acrylamide is known to be neurotoxic in humans and is classified as a probable human carcinogen, which is present in numerous baked or fried carbohydrate-rich foods, such as French fries, potato crisps, breads, biscuits, as well as in coffee. The current exposure calculation in Norwegian 1-year-olds also identified baby food as an important contributor to acrylamide exposure. VKM concludes that the dietary acrylamide exposure is of health concern in all age groups. Hence, there is a need for systematic surveillance of acrylamide levels and food consumption data in order to provide a basis for up-to-date exposure estimates.

Acrylamide levels in food depend on the way food is processed and prepared, and more knowledge on how home-cooking practises impact acrylamide exposure is particularly needed.

In order to improve the dietary exposure assessment of acrylamide, duplicate diet studies are recommended, since they provide a more accurate indication of the exposure to acrylamide by food prepared and consumed at home.

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Appendix I

A1-1 Occurrence of acrylamide (µg/kg food) in Europa (EFSA, 2015 table 6) and in Norway

	Food group (as in FoodEx1)	EFSA n	EFSA MB mean (LB-UB)	EFSA P95	Norway n	Norway MB mean (LB-UB)
1	**Potato fried products**	**1694**	**308 (303-313)**	**971**	**33**	**296 [b]**
1.1	French fries and potato fried, fresh or pre-cooked, sold as ready-to-eat	877	308 (302-314)	904	14	353 [b]
1.2	French fries and potato fried, fresh or pre-cooked, sold as fresh or pre-cooked, analysed as sold	74	367 (362-372)	1888	11	300 [b]
1.3	French fries and potato fried, fresh or pre-cooked, sold as fresh or pre-cooked, prepared as consumed	557	239 (236-242)	656	6	228 [b]
1.4	French fries and potato fried, fresh or pre-cooked, Sold as fresh or pre-cooked, preparation unspecified	90	368 (361-375)	1468	na	na
1.5	Other potato fried products	96	606 (606-607)	1549	2	144 [b]
2	**Potato crisp and snacks**	**34501**	**389 (388-389)**	**932**	**58**	**791 [b]**
2.1	Potato crisps made from fresh potatoes	31467	392	949	41	772 [b]
2.2	Potato crisps made form potato dough	2795	338	750	17	758 [b]
2.3	Potato crisps unspecified	216	519 (516-521)	1465	na	na
2.4	Potato snack other than potato crisp	23	283	- [a]	na	na
4	**Soft bread**	**543**	**42 (36-49)**	**156**	**31**	**17 (17-17) [c]**
4.1	Wheat soft bread	302	38 (33-44)	120	22	17 (17-18)
4.2	Other soft bread	107	57 (51-62)	240	4	18 (18-18) [c]
4.3	Soft bread unspecified	134	40 (31-50)	141	5	13 (13-13) [c]
5	**Breakfast cereals**	**1230**	**161 (157-164)**	**552**	**41**	**120 (120-121)**
5.1	Maize, oat, spelt, barley and rice based products	210	102 (96-109)	403	17	110 (110-110) [c]
5.2	Wheat and rye based products	151	170 (169-172)	410	7	267 [b]
5.3	Bran products and whole grains cereals	520	211 (210-211)	716	11	20 (19-21)
5.4	Breakfast cereals, unspecified	349	117 (109-124)	367	6	161 [b]

	Food group (as in FoodEx1)	EFSA n	EFSA MB mean (LB-UB)	EFSA P95	Norway n	Norway MB mean (LB-UB)
6	**Biscuits, crackers, crisp bread and similar**	**2065**	**265 (261-269)**	**1048**	**73**	**205** [b]
6.1	Crackers	162	231 (229-233)	590	15	323 (1)
6.2	Crisp bread	528	171 (166-176)	486	38	169 (169-169) [c]
6.3	Biscuits and wafers	682	201 (197-206)	810	20	185 [b]
6.4	Gingerbread	693	407 (403-412)	1600	na	na
7	**Coffee and coffee substitutes**	**1545**	**578 (577-578)**	**1133**	**17**	**412** [b]
7.1	Roasted coffee (dry)	595	249 (248-251)	543	12	283 [b]
7.2	Instant coffee (dry)	862	710	1122	5	722 [b]
7.3	Substitute coffee (dry), based on cereals	20	510 (509-510)	-[a]	na	na
7.4	Substitute coffee (dry), based on chicory	37	2942	-[a]	na	na
7.5	Substitute coffee (dry), unspecified	31	415 (414-415)	-[a]	na	na
	Ready to drink coffee, only Norwegian data	na	na	na	35	19 (19-20)
8	**Baby foods, other than cereal-based**	**416**	**24 (17-31)**	**72**	**35**	**9 (9-10)**
8.1	Baby food, not containing prunes	357	20 (13-27)	48	35	9 (9-10)
	Infant formulae	33	14 (3-26)	-[a]	3	2 (0-3)
	Fruit purée	24	22 (15-29)	-[a]	na	na
	Juice	3	12 (0-23)	-[a]	na	na
	Ready-to-eat meal and dessert	291	20 (13-26)	51	32	10 (10-10) [c]
8.2	Baby food, containing prunes	13	101	-[a]	na	na
8.3	Baby foods, unspecified regarding prunes content	46	33 (25-40)	-[a]	na	na
9	**Processed cereal-based baby food**	**736**	**73 (70-76)**	**175**	**53**	**10 (10-11)**
9.1	Biscuits and rusks	235	111 (106-115)	287	1	30 [b]
9.2	Other processed cereal-based foods	232	89 (84-95)	60	na	na
	Cereals to be reconstituted	159	125 (119-130)	86	52	10 (9-11)
	Ready-to-eat meal cereal-based	73	13 (8-17)	30	*na*	*na*
9.3	Unspecified processed cereal-based foods	269	26 (25-26)	83	na	na
10	**Other products based on potatoes, cereals and cocoa**	**569**	**97 (92-101)**	**370**	**22**	**65 (65-66)**
10.1	Porridge	9	29 (28-31)	-[a]	na	na
10.2	Cake and pastry	198	66 (61-71)	219	4	2 (2-2) [c]

	Food group (as in FoodEx1)	EFSA n	EFSA MB mean (LB-UB)	EFSA P95	Norway n	Norway MB mean (LB-UB)
10.3	Savoury snacks other than potato-based (mostly maize)	135	171 (168-173)	690	2	19 [b]
10.4	Other products based on cereals	143	68 (61-76)	293	14	60 (60-61)
	Grains for human consumption	73	46 (39-54)	152	na	na
	Grains milling products	17	117 (112-121)	- [a]	na	na
	Pasta	9	13 (0-25)	- [a]	na	na
	Beer	11	14 (0-27)	- [a]	na	na
	Composite dishes containing cereals	25	129 (122-135)	- [a]	na	na
	Fine bakery wares for diabetics	1	139	- [a]	na	na
	Other	7	107 (104-109)	- [a]	na	na
10.5	Other (non-fried) products based on potatoes	40	108 (104-112)	- [a]	2	273 [b]
	Potato bread	3	570	- [a]	na	na
	Other	37	70 (66-74)	- [a]	na	na
10.6	Other products based on cocoa	44	104 (103-105)	- [a]	na	na
	Cocoa powder	13	178 (178-179)	- [a]	na	na
	Other products based on cocoa	31	73 (72-75)	- [a]	na	na
11	**Other products**	**120**	**330 (321-339)**	**1510**	**3**	**6 (5-6)**
11.1	Roasted nuts and seeds	40	93 (82-103)	- [a]	na	na
11.2	Black olives in brine	3	454	- [a]	na	na
11.3	Prunes and dates	18	89 (87-92)	- [a]	1	16 [b]
11.4	Vegetable chips	11	1846 (1843-1848)	- [a]	na	na
11.5	Paprika powder	30	379 (365-393)	- [a]	na	na
11.6	Other	18	68 (59-77)	- [a]	2	1 (0-1)

na: not analysed, MB: middle bound, LB: lower bound, UB: upper bound.

[a] There is no 95-percentile due to fewer than 60 samples.

[b] None of the samples were below the limit of detection (LOD).

[c] Few samples were below the limit of detection, thus lower bound was similar to upper bound.

Appendix II

Table A2-1 Food items in the Food Frequency Questionnaire for 1-year-olds (Spedkost 2007) and acrylamide concentrations (µg/kg food) used in the two approaches described in Chapter 2.5

Food groups and food items in FFQ of Spedkost 2007 English generic name (Norwegian name/product name)	Approach I EFSA values[1] mean µg/kg	Approach II Norwegian and EFSA values[2] mean µg/kg	Reference from EFSA 2015, occurrence table
Infant formulae (NAN/Collet/Hipp/Holle o.l.)	1.8	1.8	8.1 Infant formulae
Milk (Helmelk, Lettmelk, Cultura osv.)	na	na	
Other types of milk/milk substitut(Annen melk/melkeerstatning)	na	na	
Flour, used in porridge, cakes etc. (mel, brukt i grøt, kaker o.l.)	46	46	10.4 Grains for human consumption
Infant porridge (Nestlé/Hipp/Holle spedbarnsgrøter)	125	10	9.2 Cereals to be reconstructed
Breakfast cereals (Cornflakes, puffet ris, havre/hvetenøtter)	102	110	5.1 Maize, oat, spelt, barley and rice based products
Sweet breakfast cereals (Honni korn, Sol Frokost o.l.)	161	120	5 Breakfast cereals
Sugar (Sukker)	na	na	
Rosehip extract (Nypeekstrakt)	na	na	
Fruit purè (Frukt/bærmos)	22	22	8.1 Fruit purée
White bread (Fint brød (loff, fine rundstykker o.l.)	38	17	4.1 Wheat soft bread

Food groups and food items in FFQ of Spedkost 2007 English generic name (Norwegian name/product name)	Approach I EFSA values[1] mean µg/kg	Approach II Norwegian and EFSA values[2] mean µg/kg	Reference from EFSA 2015, occurrence table
Whole meal bread (Mellomgrovt brød, grovbrød)	57	57	4.2 Other soft bread
Crisp bread (Knekkebrød, kavring o.l.)	171	169	6.2 Crisp bread
Butter/Margarine (Smør, Bremykt, Melange, Soft Flora, Vita osv.)	na	na	
Cheese (Hvitost, brunost, smøreost)	na	na	
Meat as bread spread (Leverpostei, servelat, kokt skinke)	na	na	
Fish as bread spread (Svolværpostei, kaviar, makrell i tomat osv.)	na	na	
Egg (Egg (kokt, stekt, eggerøre))	na	na	
Jam (Syltetøy, marmelade)	na	na	
Sweet bread spread (Honning, Hapå, Sunda, nøttepålegg o.l.)	na	na	
Sausages, meat (Pølser , kjøttkaker, kylling osv.)	na	na	
Fish, and fish products (Torsk, fiskekaker osv.)	na	na	
Soup (Tomatsuppe, annen suppe)	na	na	
Rice porridge (Risengrynsgrøt)	na	na	
Pizza	129	129	10.4 Composite dishes containing cereals
Boiled potatoe (Poteter, kokt/most)	na	na	
Mashed potatoes (Potetmos av pulver)	70	108	10.5 Other (non-fried) products based on potatoes
French fries/fried potatoes (Pommes frites, stekte poteter)	308	296	1 Potato fried products

Food groups and food items in FFQ of Spedkost 2007 English generic name (Norwegian name/product name)	Approach I EFSA values[1] mean µg/kg	Approach II Norwegian and EFSA values[2] mean µg/kg	Reference from EFSA 2015, occurrence table
Rice (Ris)	na	na	
Pasta	13	13	10.4 Other products based on cereals Pasta
Long roll (Pølsebrød, lomper)	38	17	4.1 Wheat soft bread
Sauce (Brun og hvit saus)	na	na	
Ketchup	na	na	
Sauer cream (Rømme)	na	na	
Vegetables (Gulrot, spinat, agurk osv.)	na	na	
Ready-to-eat meal (Glass m/pasta, kjøtt, kylling, fisk og ris og grønsaker)	20	10	8.1 Ready-to-eat meal and dessert
Ready-to-eat dessert (Glass m/frukt og bærmos)	20	10	8.1 Ready-to-eat meal and dessert
Icecream, desserts (is, puddinger, fromager)	na	na	
Cakes (Kaker)	66	66	
Buns, waffles (Boller, vafler)	57	57	4.2 Other soft bread
Biscuits (Tom & Jerry, Mumie o.l.)	111	111	9.1 Biscuits and rusks
Biscuits (Mariekjeks o.l.)	201	185	6.3 Biscuits and wafers
Crackers (Smørbrødkjeks)	231	325	6.1 Crackers
Sweets, Chocolate (Barnetimegodt, Sjokolade o.l.)	na	na	
Snacks (potetgull, popcorn, ostepop o.l.)	389	768	2 Potato crisp and snacks
Fruits and berries (bær, druer, epler osv.)	na	na	
Raisin (Rosiner)	na	na	
Children juice (Bringebær, epledrikk)	12	12	

Food groups and food items in FFQ of Spedkost 2007 English generic name (Norwegian name/product name)	Approach I EFSA values[1] mean µg/kg	Approach II Norwegian and EFSA values[2] mean µg/kg	Reference from EFSA 2015, occurrence table
Dried fruit (Annen tørket frukt (aprikoser, svisker o.l.))	89	89	
Water (Vann)	na	na	
Cordial and soft drinks (saft, nektar og brus)	na	na	
Juice	na	na	
Dietary supplement (Diverse kosttilskudd)	na	na	

[1] EFSA, 2015; [2]Norwegian acrylamide concentration data for food categories including 16 samples or more, and EFSA data for the remaining categories,
na: not analysed.