Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Risk assessment of the exposure to aluminium through food and the use of cosmetic products in the Norwegian population

Opinion of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics and of the Panel on Contaminants of the Norwegian Scientific Committee for Food Safety

Date: 5.04.2013

Doc. no.: 11-504_final

ISBN: 978-82-8259-088-4

Contributors

Persons working for VKM, either as appointed members of the Committee or as *ad hoc* experts, do this by virtue of their scientific expertise, not as representatives for their employers. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

Acknowledgements

VKM wishes to acknowledge the working group consisting of Heidi Amlund (Chair), Berit Granum, Anders Ruus and Inger-Lise Steffensen for their valuable contributions to this opinion. Inger Therese L. Lillegaard is acknowledged for calculating the dietary exposures.

Assessed by

The report from the working group has been evaluated and approved by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics (Panel 4) and the Panel on Contaminants (Panel 5) of the VKM.

Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics (Panel 4):
Inger-Lise Steffensen (Chair), Jan Alexander, Mona-Lise Binderup, Knut Helkås Dahl, Berit Granum, Ragna Bogen Hetland, Trine Husøy, Jan Erik Paulsen, Tore Sanner and Vibeke Thrane.

Panel on Contaminants (Panel 5):
Janneche Utne Skåre (Chair), Heidi Amlund, Augustine Arukwe, Anne Lise Brantsæter, Gunnar Sundstøl Eriksen, Christiane Kruse Fæste, Helle Katrine Knutsen, Anders Ruus and Cathrine Thomsen.

Scientific coordinators from the secretariat:

Edel Holene and Inger Therese L. Lillegaard.

Summary

The Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) has on request of the Norwegian Food Safety Authority performed a risk assessment of aluminium exposure though food and the use of cosmetic products in the Norwegian population. The assessment was performed by the VKM Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics, and the VKM Panel on Contaminants.

The Norwegian Food Safety Authority asked VKM to calculate the aluminium exposure through food and the use of cosmetic products in the Norwegian population, and to compare this exposure with the tolerable weekly intake (TWI) of 1 mg Al/kg bw/week established by EFSA (2008) and the provisional tolerable weekly intake (PTWI) of 2 mg Al/kg bw/week established by JECFA (2012). The TWI and PTWI are based on studies of developmental neurotoxicity in laboratory animals.

Aluminium is a commonly occurring metal in the earth's crust and occurs, therefore, naturally in drinking water and agricultural products. Humans are exposed to aluminium through food, drinking water and the use of cosmetic products and pharmaceuticals. Other sources of aluminium in food are the use of food additives containing aluminium and migration of aluminium from food contact materials to food.

The acute oral toxicity of aluminium compounds is low. There is no indication of carcinogenicity. Reproductive toxicity of aluminium has been observed in male mice, rabbits and dogs. In addition, aluminium compounds may cause embryotoxicity in mice and neurotoxicity in adult mice and rats and their offspring.

In 2010, the Norwegian Food Safety Authority commissioned the Norwegian Institute for Air Pollution (NILU) to conduct a survey of aluminium in food and cosmetic products on the Norwegian market (NILU, 2011). Products expected to contain high levels of aluminium were selected and included in the survey. Lipstick/lip gloss, antiperspirants and a few brands of whitening toothpaste were considered the relevant sources of exposure to aluminium through cosmetics. The occurrence data in the NILU report were used in the estimations of exposure to aluminium in the Norwegian population.

The total exposure to aluminium is a summation of the estimated dietary exposure and the estimated exposure through the use of cosmetic products. The estimated dietary exposure to aluminium is based on national food consumption surveys for various age groups and the aluminium concentration in food on the Norwegian market. The additional contribution from the use of cosmetics was estimated as the systemic exposure dose (SED) from topical application of cosmetic products in different age groups. As the aluminium exposures from food and from the use of cosmetic products were estimated using different approaches the two estimates cannot be directly compared. To sum up the two routes of exposures as total exposure, the dietary exposure was converted to a systemic exposure taking into account the low oral bioavailability (0.1%) of aluminium. Also, for comparison, the TWI set by EFSA (2008) was recalculated to a systemic TWI of 1 µg Al/kg bw/week, while the PTWI set by JECFA (2012) was converted to a systemic PTWI of to 2 µg Al/kg bw/week, taking into account the low oral bioavailability and assuming similar toxicity following oral and dermal exposure to aluminium.

The mean dietary exposure to aluminium in the Norwegian population varied from 0.22 to 0.89 mg/kg bw/week, depending on the age group. None of the estimated mean exposures exceeded the TWI of 1 mg Al/kg bw/week set by EFSA (2008) or the PTWI of 2 mg Al/kg bw/week set by JECFA (2012). The estimated mean dietary exposures to aluminium are

comparable to estimated dietary exposure for populations in other European countries. The high exposure (95-percentile) to aluminium in the Norwegian population varied from 0.5 to 1.9 mg/kg bw/week, depending on the age group. After high dietary exposure, 1-year-old infants and 2-year-old children exceeded the TWI of 1 mg Al/kg bw/week, but were below the PTWI of 2 mg Al/kg bw/week.

Nine-year-old children, 13-year-old adolescents and adults may have an additional exposure to aluminium though the use of cosmetic products (lipstick/lip gloss, antiperspirants and/or whitening toothpaste). The use of cosmetic products, in particular antiperspirants, contributed substantially to the total systemic exposure to aluminium. High systemic exposures were estimated in the worst case scenarios. These estimations are based on skin absorption values derived from skin biopsies after tape-stripping that mimics shaving or waxing of the armpit, or impaired skin caused by skin conditions such as eczema.

For persons using lipstick/lip gloss daily, the mean and high total systemic exposures varied from 0.51 to 1.4 µg Al/kg bw/week, depending on age group, in a standard scenario (0.6% skin absorption, normal skin). Only the total systemic exposure for 9-year-old children equalled (mean exposure) or exceeded (high exposure) the systemic TWI of 1 µg Al/kg bw/week. None of the estimated exposures exceeded the systemic PTWI of 2 µg Al/kg bw/week. In a worst case scenario (10.7% skin absorption, stripped skin), the mean and high total systemic exposures ranged from 4.5 to 14 µg Al/kg bw/week, depending on age group. The estimates exceeded both the systemic TWI and the systemic PTWI.

Adolescents and adults are assumed to use lipstick/lip gloss and/or antiperspirants on a daily basis. With the additional contribution from the use of lipstick/lip gloss and antiperspirants, the mean and high total systemic exposures varied from 30 to 50 µg Al/kg bw/week, depending on age group, in a standard scenario (0.6% skin absorption, normal skin). In a worst case scenario (10.7% skin absorption, stripped skin), the mean and high total systemic exposures ranged from 600 to 940 µg Al/kg bw/week, depending on age group. All the estimates exceeded the systemic TWI and the systemic PTWI. The additional use of whitening toothpaste containing aluminium did not contribute much to the total systemic exposure to aluminium in adults.

Exposure above the TWI/PTWI value is not desirable. A small exceedance of these values represents a reduced safety margin. However, the large exceedance (15-50 folds) of the TWI/PTWI, which was seen for consumers using several cosmetic products in addition to the dietary exposure, will reduce the safety margin further and increase the risk of adverse effects. The exposure situation is even more of concern for individuals shaving their armpits often or having impaired skin, where the exceedance of TWI/PTWI was 300-940 folds.

This risk assessment shows that cosmetic products, and in particular antiperspirants, contribute considerably more than diet to the total systemic aluminium exposure in persons using such products.

Norsk sammendrag

Vitenskapskomiteen for mattrygghet (VKM) har på oppdrag fra Mattilsynet gjennomført en risikovurdering av aluminiumeksponering gjennom mat og bruk av kosmetikk hos den norske befolkningen. Vurderingen er gjennomført av Faggruppen for forurensninger, naturlige toksiner og medisinrester og Faggruppen for tilsetningsstoffer, aroma, matemballasje og kosmetikk.

Mattilsynet ba VKM om å beregne hvor mye den norske befolkningen får i seg av aluminium (Al) gjennom mat og bruk av kosmetiske produkter, og å sammenligne denne eksponeringen med verdier som er fastsatt for mengden av aluminium som en person kan få i seg hver uke hele livet uten vesentlig helserisiko. To slike verdier er fastsatt: det tolerable ukentlige inntaket (TWI) på 1 mg Al/kg kroppsvekt/uke som ble etablert av EUs mattrygghetsorgan (EFSA, 2008), og det foreløpig tolerable ukentlige inntaket (PTWI) på 2 mg Al/kg kroppsvekt/uke som ble etablert av FAO/WHOs ekspertkomité for tilsetningsstoffer (JECFA, 2012). Både TWI og PTWI er basert på studier av toksiske effekter på utvikling av nervesystemet i forsøksdyr.

Aluminium er et vanlig forekommende metall i jordskorpen og finnes derfor naturlig i drikkevann og landbruksprodukter. Mennesker eksponeres for aluminium gjennom mat, drikkevann og ved bruk av kosmetiske produkter og legemidler. Andre kilder til aluminium i mat er aluminiumholdige tilsetningsstoffer og migrasjon av aluminium fra matkontaktmateriale over i maten.

Den akutte toksisiteten til aluminiumforbindelser ved inntak via munn (oralt) er lav, og det er ingen indikasjoner på at de fører til utvikling av kreft. I hanndyr av mus, kaniner og hunder er det observert negative effekter av aluminium på reproduksjon. Aluminium kan forårsake fosterskader hos mus og skader på nervesystemet både i avkom og voksne mus og rotter.

I 2010 ga Mattilsynet Norsk institutt for luftforskning (NILU) i oppdrag å kartlegge innholdet av aluminium i matvarer og kosmetiske produkter på det norske markedet. Produkter med forventede høye nivåer av aluminium ble valgt ut og inkludert i undersøkelsen. Leppestift/lipgloss, antiperspiranter og noen få merker av tannkrem for fjerning av misfarging på tennene, ble ansett som relevante kilder for eksponering for aluminium gjennom kosmetikk. Forekomstdataene i NILU-rapporten er brukt i beregningene av hvor mye den norske befolkningen får i seg av aluminium.

Den totale eksponeringen for aluminium er en summering av det beregnede inntaket via kosten og den beregnede eksponeringen gjennom bruk av kosmetiske produkter. Eksponeringen gjennom kosten er basert på nasjonale kostholdsundersøkelser for ulike aldersgrupper og konsentrasjonen av aluminium i matvarer på det norske markedet. Det ekstra bidraget fra bruk av kosmetikk i ulike aldersgrupper ble beregnet som systemisk eksponeringsdose (SED) etter lokal påføring av kosmetikk på huden. Siden eksponeringen for aluminium gjennom kost og gjennom bruk av kosmetikk ble beregnet på ulike måter, kan ikke estimatene sammenlignes direkte. For å summere de to eksponeringsveiene som en total eksponering, ble eksponeringen gjennom kosten omregnet til en systemisk eksponering, dvs. dosen i kroppen som helhet, hvor det ble tatt hensyn til det lave opptaket (0,1 %) av aluminium over mage/tarm. For å muliggjøre sammenligning med TWI-verdien fra EFSA (2008) og PTWI-verdien fra JECFA (2012), ble i tillegg disse omgjort til en systemisk TWI på 1 µg Al/kg kroppsvekt/uke og en systemisk PTWI på 2 µg Al/kg kroppsvekt/uke. Det er antatt at toksisiteten til aluminium er lik etter eksponering via munn (kost) og etter eksponering over huden (kosmetikk).

Hos den norske befolkningen varierte den gjennomsnittlige eksponeringen for aluminium gjennom kosten fra 0,22 til 0,89 mg/kg kroppsvekt/uke, avhengig av aldersgruppe. Ingen av de beregnede gjennomsnittlige eksponeringene oversteg TWI på 1 mg Al/kg kroppsvekt/uke satt av EFSA (2008) eller PTWI på 2 mg Al/kg kroppsvekt/uke satt av JECFA (2012). Den beregnede gjennomsnittlige eksponeringen for aluminium gjennom kosten er sammenlignbar med eksponering av befolkningen i andre europeiske land gjennom kosten. Norske høykonsumenter av aluminiumholdig kost (95-persentilen) hadde en aluminiumseksponering som varierte fra 0,5 til 1,9 mg/kg kroppsvekt/uke, avhengig av aldersgruppe. Høykonsumentene blant 1 og 2 åringer hadde en eksponering via kosten som oversteg TWI på 1 mg Al/kg kroppsvekt/uke, men var under PTWI på 2 mg Al/kg kroppsvekt/uke.

Niåringer, trettenåringer og voksne kan i tillegg til kosten bli eksponert for aluminium gjennom bruk av kosmetiske produkter (leppestift/lipgloss, antiperspiranter og/eller tannkremer for fjerning av misfarging på tennene). Bruk av kosmetikk, og da spesielt antiperspiranter, bidro vesentlig til den totale systemiske eksponeringen for aluminium. Ved verste-fall-scenarioer ble høy systemisk eksponering beregnet. Disse beregningene er basert på absorpsjonsverdier fra tape-strippet hud som etterligner barbering eller voksing av armhulen, eller hud som er svekket for eksempel av eksem, og dermed har en høyere absorpsjon av stoffer.

For personer som bruker leppestift/lipgloss hver dag varierte den gjennomsnittlige og høye totale systemiske eksponeringen fra 0,51 til 1,4 µg Al/kg kroppsvekt/uke ved standard eksponeringsscenario (0,6 % hudabsorpsjon, normal hud) avhengig av aldersgruppe. Kun den totale systemiske eksponeringen for niåringer tangerte (gjennomsnittlig eksponering) eller oversteg (høy eksponering) den systemiske TWI-verdien på 1 µg Al/kg kroppsvekt/uke. Ingen av de beregnede eksponeringene oversteg den systemiske PTWI-verdien på 2 µg Al/kg kroppsvekt/uke. Ved et verste-fall-scenario (10,7 % hudabsorpsjon, strippet hud) varierte gjennomsnittlig og høy total systemisk eksponering fra 4,5 til 14 µg Al/kg kroppsvekt/uke, avhengig av aldersgruppe. Disse estimatene oversteg både systemisk TWI og systemisk PTWI.

Det er forutsatt daglig bruk av leppestift/lipgloss og/eller antiperspirant blant ungdom og voksne. Med det ekstra bidraget fra daglig bruk av leppestift/lipgloss og antiperspirant, varierte den gjennomsnittlige og den høye totale eksponeringen fra 30 til 50 µg Al/kg kroppsvekt/uke ved standard eksponeringsscenario (0,6 % hudabsorpsjon, normal hud), avhengig av aldersgruppe. Ved et verste-fall-scenario (10,7 % hudabsorpsjon, strippet hud), varierte den gjennomsnittlige og den høye totale systemiske eksponeringen fra 600 til 940 µg Al/kg kroppsvekt/uke, avhengig av aldersgruppe. Disse estimatene oversteg både systemisk TWI og systemisk PTWI. Bruk av aluminiumholdig tannkrem for fjerning av misfarging på tennene bidro i liten grad til den totale systemiske aluminiumeksponeringen hos voksne.

Det er ikke ønskelig at eksponeringen overskrider TWI/PTWI-verdiene. En liten overskridelse av disse verdiene innebærer en redusert sikkerhetsmargin, dvs. en redusert avstand mellom beregnet eksponering og nivåer av aluminium som er vist å gi negative helseeffekter i forsøksdyr. De store overskridelsene (15 – 50 ganger) av TWI/PTWI som ble funnet hos personer som bruker flere kosmetikkprodukter i tillegg til det de eksponeres for gjennom kosten, vil imidlertid gi ytterligere reduksjoner i sikkerhetsmarginene og øke risikoen for negative helseeffekter. Eksponeringssituasjonen er enda mer til bekymring for personer som barberer armhulene ofte eller har svekket hud, ettersom overskridelsen av TWI/PTWI da var 300 – 940 ganger.

Denne risikovurderingen viser at kosmetiske produkter, og særlig antiperspiranter, bidrar mye mer enn kosten til den totale systemiske eksponeringen for aluminium blant de som bruker slike produkter.

Abbreviations

Al – aluminium

AFSSAPS – Agence Francaise de Sécurité Sanitaire des Produits de Santé

bw – body weight

EFSA – European Food Safety Authority

IAI – International Aluminium Institute

FFQ – food frequency questionnaire

JEFCA – Joint FAO/WHO Expert Committee on Food Additives

LOQ – limit of quantification

LOAEL – lowest observed adverse effect level

NOAEL – no observed adverse effect level

NILU – Norwegian Institute for Air Research

MoS – margin of safety

OECD –Organization for Economic Cooperation and Development

PTWI – Provisional tolerable weekly intake

SED – systemic exposure dose

SCCS –Scientific Committee on Consumer Safety

SCCNFP – Scientific Committee on Non-Food Products

SSA – skin surface area

TWI – tolerable weekly intake

Contents

Background

The safety of aluminium from dietary intake was reviewed in 2008 by the European Food Safety Authority (EFSA). The report concluded that a significant part of the European population exceeds the tolerable weekly intake (TWI) of 1 mg aluminium per kg body weight (1 mg Al/kg bw). In 2012, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a provisional tolerable weekly intake (PTWI) of 2 mg Al/kg bw based on new animal data. Aluminium has no physiological function in the human body and may accumulate in various tissues, in particular bone, upon exposure.

According to reports from EFSA (2008) and JECFA (2012), the main source of exposure to aluminium is through the diet. The EFSA report, however, points out that the use of aluminium-containing cosmetics may be another important source of aluminium exposure in the population since most antiperspirants and many lipsticks contain aluminium compounds. The contribution of cosmetic products to the aluminium exposure was not included in the two risk assessments (EFSA, 2008 and JECFA, 2012) since cosmetics are not covered by their remits.

There is no regulation of aluminium as a food contaminant in the EU or in Norway. There are, however, limits for aluminium when used as food additive. Concerning use of aluminium in cosmetics, certain colorants and active ingredients are regulated by the EU cosmetic directive. About 90% of the antiperspirants on the Norwegian market contain the active ingredient aluminium chlorohydrate in concentrations up to 25%, but aluminium chlorohydrate is not regulated specifically in the EU cosmetic directive. In lipsticks, so-called aluminium lakes are part of some of the colorants. Whitening toothpastes may contain high concentrations of aluminium oxides as a polishing agent.

In 2010, the Norwegian Food Safety Authority commissioned the Norwegian Institute for Air Pollution (NILU) to conduct a survey of aluminium in food and cosmetic products on the Norwegian market in order to get better knowledge about their content of aluminium.

The Norwegian Food Safety Authority requested VKM to estimate the total aluminium exposure of the Norwegian population through consumption of food and the use of cosmetic products, and to perform a health risk assessment. VKMs Panel of Contaminants and Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics were responsible for performing the risk assessment. A working group consisting of two persons from each Panel was established.

Terms of reference

The Norwegian Food Safety Authority requests the Norwegian Scientific Committee for Food Safety (VKM) to perform the following tasks based on previous risk assessments from EFSA (2008) and JECFA (2006 and 2012):

- to calculate the total intake of aluminium in the Norwegian population based on the levels found in food and cosmetic products on the Norwegian market and compare this with EFSA's adopted tolerable weekly intake (TWI) of 1 mg/kg bw/week for aluminium and JECFA's provisional tolerable weekly intake (PTWI) on 2 mg Al/kg bw/week. As concerns the foodstuffs, the most recent food consumption surveys for infants, small children, youths and adults should be applied (Spedkost, Småbarnskost, Ungkost, Norkost 3). SCCS "Notes of Guidance for testing of Cosmetic Ingredients and Their Safety Evaluation" should be used to estimate the exposure to cosmetics. A report produced September 2011 from the French agency AFSSAPS should also be taken into account.
- where relevant, VKM is to take into consideration occurrence data for levels of aluminium in food from other countries in addition to the Norwegian data, where the food in question may contribute considerably to the intake of aluminium in the Norwegian population.
- to assess the significance of the total intake of aluminium and whether there is reason for concern regarding exceedance of TWI/PTWI, and to identify any subpopulations that may be especially at risk.

Assessment

The present opinion on the exposure to aluminium in the Norwegian population covers different sources of aluminium in the diet and in cosmetic products[1]. Exposure to aluminium by inhalation is considered related to occupational exposure and is not included. The additional contribution of aluminium from the use of pharmaceuticals is also not included.

1 Introduction

1.1 Aluminium – general background

Aluminium is a commonly occurring metal in the earth's crust and therefore occurs naturally in drinking water and agricultural products such as fruits, vegetables, grains, seeds and meat. Additionally, environmental contamination of aluminium is caused by anthropogenic activities such as mining and industrial uses.

Humans are mainly exposed to aluminium through food, drinking water and the use of cosmetic products and pharmaceuticals. Aluminium may occur naturally in food or as a contaminant. Other sources of aluminium in food are the use of food additives containing aluminium and migration of aluminium from food contact materials and cookware to food.

Aluminium occurs in the environment in the form of silicates, oxides and hydroxides, combined with other elements such as sodium and fluorine and as complexes with organic matter. Due to its reactivity, aluminium is not found as a free metal in the environment. At pH values greater than 5.5, naturally occurring aluminium compounds exist predominantly in an undissolved form such as $Al(OH)_3$ (gibbsite) or as aluminosilicates. The solubility of aluminium in equilibrium with solid phase $Al(OH)_3$ is highly dependent on pH and on complexing agents such as fluoride, silicate, phosphate and organic matter (WHO, 1997).

1.2 Use and regulation/legislation of aluminium

The use of aluminium as a food additive, food contact materials and in cosmetic products is regulated through the European legislation, which also applies for Norway.

1.3 Recent assessments of aluminium

1.3.1 Recent risk assessments on food

1.3.1.1 EFSA: European Food Safety Authority, 2008

In 2008, on request from the European Commission, the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials of the European Food Safety Authority (EFSA) provided a scientific opinion on the safety of aluminium from dietary intake (EFSA, 2008).

[1]Cosmetic products include all products applied to the external part of the body, teeth, mucous membranes in the oral cavity and are intended to affect body odour, to clean, to perfume, to protect, to preserve or to alter the appearance.

For the general European population the major source of exposure to aluminium is dietary. Drinking water represents only a minor source of aluminium exposure, whereas additional, but unknown, exposures are through the use of pharmaceuticals and consumer products. The main contributors to the dietary aluminium exposure were found to be cereals and cereal products, vegetables, beverages and certain infant formulae.

Based on combined findings from several animal studies (mice, rats and dogs) where adverse effects on testes, embryos and the developing and mature nervous system were taken into account, a tolerable weekly intake (TWI) of 1 mg Al/kg bw/week was established (see 2.3 and Table 3).

In non-occupationally exposed adults there are large variations in mean dietary exposure within and between surveys and countries. The mean dietary (food and water) exposure varied from 0.2 to 1.5 mg Al/kg bw/week (60 kg adult) among Europeans. The mean dietary exposure was estimated in eight European countries based on duplicate diet studies or market basket and total diet studies. In infants, the estimated exposure ranged from 0.1 to 1.1 mg Al/kg bw/week, depending on age and type of infant formula. Children, who generally have higher food intake than adults when expressed on a body weight basis, were identified as the population group with the highest potential aluminium exposure (based on body weight). In general, the Panel concludes that significant parts of the European population are likely to have an intake of aluminium exceeding the TWI.

1.3.1.2 JECFA: Joint FAO/WHO Expert Committee on Food Additives, 2007

Aluminium was reviewed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2007 on request from the Codex Commission on Food Additives and Contaminants (CCFAC).

All available data of toxicity and exposure (including bioavailability) of aluminium-containing food additives as well as other sources of aluminium exposure were taken into consideration during the evaluation. The exposure assessment covered the aluminium compounds included in the Codex General Standard for Food Additives (GSFA). Based on the inherent potential of aluminium compounds to affect the reproductive system and the developing nervous system in animals, the previous established acceptable daily intake (ADI) of 0–0.6 mg/kg bw/day and provisional tolerable weekly intake (PTWI) of 0-7 mg/kg bw/week for aluminium compounds were withdrawn. A new PTWI of 1 mg Al/kg bw/week, which applies to all aluminium compounds in food, including additives, was established.

Population groups likely to exceed the new PTWI for aluminium were identified as those who regularly consume foods added aluminium-containing food additives. Infants fed soya-based formulae were identified as a population group with a high intake of aluminium.

1.3.1.3 JECFA: Joint FAO/WHO Expert Committee on Food Additives, 2012

Aluminium was recently reviewed by JECFA (2012) on request from the CCFAC. The Committee was asked to re-evaluate the PTWI of 1 mg Al/kg bw established in 2007 in light of new toxicological studies.

One of the new animal studies submitted to the Committee provided a no observed adverse effect level (NOAEL). In this study, rats were exposed to aluminium citrate, one of the more soluble aluminium compounds, in drinking water. Based on the NOAEL of 30 mg/kg bw/day and an uncertainty factor of 100, a new PTWI of 2 mg/kg bw/week was established (see 2.3 and Table 3). The previous PTWI of 1 mg/kg bw/week for aluminium compounds was

withdrawn. The PTWI 2 mg Al/kg bw/week applies to all aluminium compounds in food including additives.

The Committee also concluded that children's dietary exposure to aluminium-containing food additives are likely to exceed the PTWI of 2 mg Al/kg bw/week, and adults consuming cereals and cereal-based products added aluminium-containing food additives have a dietary aluminium exposure close to the PTWI.

1.3.1.4 BfR: German Federal Institute for Risk Assessment, 2012

In 2012, the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) performed a health risk assessment of the aluminium content in food for infants.

The exposure to aluminium from infant and follow-on formula was estimated in various scenarios based on age of the infant, volume or amount of formula consumed, form (powder or liquid) of the formula, and aluminium concentration in the formula. For some of the scenarios (high aluminium concentration) the intake was close to or exceeded the TWI of 1 mg Al/kg bw/week set by EFSA (2008). Since infants and premature babies are especially vulnerable groups, the BfR recommended that the aluminium content in infant food should be kept at a level so low that the consumption does not result in an intake of aluminium exceeding the TWI.

1.3.2 Recent risk assessments on cosmetics

1.3.2.1 AFSSAPS: Agence Francaise de Sécurité Sanitaire des Produits de Santé, 2011

In 2011, the French Agency for the safety of sanitary and health products published a scientific opinion on the safety of aluminium from cosmetic sources (AFSSAPS, 2011). The report recommends that the concentration of aluminium in cosmetic products should be restricted to 0.6% and that aluminium-containing cosmetics should not be used on impaired skin. Due to lack of adequate studies on dermal absorption, i.e. studies which follows current requirements/guidelines, the evaluation was based on an *in vitro* study on human skin (unpublished study conducted at the request of AFSSAPS by PMIC (Podesta Marty International Consultants, France). Dermal absorption of aluminium after daily exposure to an antiperspirant containing 20% of aluminium chlorohydrate (5% aluminium) was estimated to be 0.5% and 18% on intact and impaired skin, respectively. The resulting systemic exposures to aluminium were 2.1 µg/kg bw/day and 75 µg/kg bw/day, respectively. The report concludes that additional data concerning the potential irritation of aluminium containing cosmetics are needed, but that human cases of sensitization are rare.

2 Hazard identification and characterisation

2.1 Toxicokinetics

This section is mainly based on recent major reviews on aluminium by the US Agency for Toxic Substances and Disease Registry, International Aluminium Institute and EFSA (ATSDR, 2008; IAI, 2007; EFSA, 2008).

2.1.1 Oral

2.1.1.1 Absorption

Aluminium is poorly absorbed after oral intake. Approximately 0.1-0.8% of ingested aluminium is usually absorbed, whereas absorption of less bioavailable forms of aluminium can be in the order of 0.1% (ATSDR, 2008; EFSA, 2008). The absorption of aluminium depends on many factors, e.g. type of aluminium compound, solubility and co-administration with water or food. In acidic aqueous solutions with pH<5, such as in the gut lumen, aluminium ions exist mainly as $[Al(H_2O)_6]^{3+}$ (usually abbreviated as Al^{3+}). When the gut content passes from the stomach to the intestine, there is an increase in pH to neutral level that results in the formation of insoluble complexes of aluminium with hydroxide. Thus, in the intestine the majority of the aluminium ions are converted to aluminium hydroxide, precipitated and subsequently excreted via the faeces. Only a minor fraction of aluminium in the intestine is expected to be available for absorption (ATSDR, 2008; EFSA, 2008).

The solubility of aluminium compounds above pH 4 is strongly dependent on the presence of ligand species. Thus, the toxicokinetics of aluminium depend on the properties of the complexes formed between Al^{3+} and dietary or biological ligands. Dietary ligands as citrate, lactate and other carboxylic acids and fluoride may increase the absorption, whereas phosphate, silicon and polyphenols may decrease the absorption. The bioavailability of aluminium compounds can, therefore, differ depending on the foods and beverages present in the intestines (ATSDR, 2008; EFSA, 2008).

In humans, the oral bioavailability from drinking water is in the range of 0.1 to 0.4%, whereas the bioavailability from food and beverages has been reported to be 0.1-0.8% in various studies. Depending on the type of food and the chemical forms present in the intestine, it is likely that the oral absorption of aluminium from food can vary at least 10-fold (EFSA, 2008). Bioavailability appears to generally parallel water solubility. However, insufficient data are available to directly extrapolate from solubility in water to bioavailability of aluminium (IAI, 2007; EFSA, 2008).

2.1.1.2 Distribution

There are limited data on distribution of aluminium in humans, but several animal studies have been performed.

Transferrin is the main carrier of Al^{3+} in plasma (ca. 89%), whereas around 11% are bound to citrate (EFSA, 2008). In tissues and organs, cellular uptake is probably relatively slow. Most likely, the uptake occurs from the aluminium bound to transferrin by transferrin receptor-mediated endocytosis. Aluminium may enter the brain from the blood through the blood brain barrier or through the choroid plexus into the cerebrospinal fluid of the ventricles within the brain and then into the brain. In cells, Al^{3+} accumulates in the lysosomes, cell nucleus and chromatin.

In healthy persons, the total body burden of aluminium is reported to be around 30-50 mg/kg bw. Aluminium distributes unequally to all tissues, where about 1/2 of the total body burden is in the skeleton and 1/4 in the lungs (accumulation of inhaled insoluble aluminium compounds). Reported normal levels in human tissues range from 5 to 10 mg/kg in bone, around 20 mg/kg wet weight in lungs, from 0.25 to 0.75 mg/kg wet weight in the brain and from 1 µg/l to 2 µg/l in plasma. Aluminium has also been found in skin, lower gastrointestinal tract, lymph nodes, adrenals, parathyroid glands and in most soft tissue organs. Aluminium has been reported to be transferred to the placenta and foetus, and to some extent distributed to breast milk (ATSDR, 2008).

Several factors may modulate the distribution of aluminium. In animal experiments, calcium and magnesium deficiency have been shown to contribute to an accumulation of aluminium in brain and bone. There is a negative correlation between the iron status and aluminium accumulation in tissues. In addition, citrate and fluoride may reduce tissue accumulation and increase the renal excretion in experimental animals. However, this occurs when the aluminium concentration exceeds the metal binding capacity of transferrin and this seldom happens in humans (EFSA, 2008).

2.1.1.3 Metabolism

It is believed that aluminium is present in four different forms in the body: free ions, low-molecular-weight complexes, physically bound macromolecular complexes and covalently bound macromolecular complexes. Free Al^{3+} binds easily to many substances and structures and its metabolism is determined by its affinity to each of the ligands and their relative amounts and metabolism. Aluminium can form low-molecular-weight complexes with organic acids, amino acids, nucleotides, phosphates and carbohydrates. These complexes are often chelates and may be very stable. They are metabolic active, particularly the nonpolar ones. Much of the aluminium in the body may exist as physically bound macromolecular substances such as proteins, polynucleotides and glycosaminoglycans. However, metabolically, these macromolecular complexes are expected to be less active than the smaller low-molecular-weight complexes. Aluminium bound covalently to macromolecules form stable complexes that are essentially irreversible (ATSDR, 2008; EFSA, 2008).

2.1.1.4 Elimination and excretion

In humans, absorbed aluminium from the blood is primarily eliminated by the kidneys (presumably as Al-citrate) and excreted in the urine. A minor, secondary route is excretion via the bile (EFSA, 2008). Based on studies published over 30 years a reference value of 2.3 µg/l to 110 µg/l in urine has been established (Caroli et al., 1994).

Multiple half-lives of elimination (from hours to years) have been reported for experimental animals and humans suggesting that there are several compartments of aluminium storage from which aluminium is eliminated. The retention times appear to be longer in humans compared to rodents. However, the available information on allometric scaling of aluminium elimination rates does not permit a direct extrapolation of findings from rodents to humans (EFSA, 2008; IAI, 2007).

In a human study, six subjects received a single injection of ^{26}Al citrate. During the first 5 days, 72% and 1.2% was excreted in the urine and faeces, respectively, whereas 27% was estimated to remain in the body. In a re-examination in one of the subjects around three and 10 years after the injection, half-lives of 7 and 50 years, respectively, were calculated (Priest et al., 1995; Priest, 2004; Talbot et al., 1995).

There is evidence that the concentration of aluminium increases with increasing age which may be explained by slow elimination in combination with continued exposure, but also by accumulation of insoluble aluminium compounds.

2.1.2 Dermal

2.1.2.1 Animal – in vitro

Full-thickness viable skin discs (4 cm^2) from Swiss male mice (shaved 24 hours before preparation) were used for permeation studies conducted in a "static" culture system. One topical application of 0.1 ml of 0, 50 or 100 nanogram aluminium chloride/ml solutions was applied (0, 1.25 and 2.5 ng/cm^2, respectively) (n=3 for each dose) (Anane et al., 1995). Aluminium uptake through mouse skin from the medium was measured after 24 hours incubation. The concentration of aluminium in the "subdermal" fluid after 24 hours was 2.1±1.3, 24.6±1.2 and 22.6±3.0 ng/ml for the 0, 50 and 100 ng/ml dose, respectively.

2.1.2.2 Animal – in vivo

Swiss male mice (24±2 g, 56 days) were treated daily with 0.025 or 0.1 µg/cm^2 aluminium chloride solution to 4 cm^2 of skin on the shaved dorsal surface for 130 days (Anane et al., 1995). The total aluminium applied during the study period was 0.5 mg/kg bw and 2 mg/kg bw, respectively. Twenty-four hours after the end of the study period, 24-hour urine and blood samples were collected. The brain was removed and hippocampus dissected. The aluminium concentration in urine and blood was monitored by graphite furnace atomic absorption, whereas aluminium in tissue samples was quantified using a wet digestion method. The aluminium concentrations in urine, serum and brain are shown in Table 1. The concentration of aluminium in urine, serum and brain was significantly increased compared to young (56 days) and aged controls (186 days). Some concerns about this study have been raised: 1) the aluminium solution was applied on a large area on the back and it is possible that grooming produce oral aluminium exposure (the authors do not mention if methods to prevent absorption by non-transcutaneous routes were applied), and 2) the reported increase of brain aluminium suggests >100% bioavailability, and therefore casts further doubts on the validity of these findings (IAI, 2007).

Table 1: Aluminium concentration in control and treated mice after 130 days of dermal exposure to aluminium chloride (modified from Anane et al., 1995).

Animal/treatment	Urine (ng/ml)	Serum (ng/ml)	ng/hippocampus	ng/rest of brain
Young control (56 days)	115.0±19.0	125.0±33.1	11.0±3.1	39.8±9.0
Aged control (186 days)	198.6±23.8	227.5±47.3	19.3±4.1	117.0±15.0
0.1 µg/day (186 days)	211.1±34.0	317.5±63.7	31.5±4.0	141.4±19.6
0.4 µg/day (186 days)	221.0±28.0	380.0±84.6	43.2±4.9	186.7±22.7

2.1.2.3 Human – in vitro

Dermal absorption of aluminium from three cosmetic formulations of antiperspirant was studied by Pineau et al. (2012) using human full skin biopsies mounted in Franz™ diffusion cell. The three formulations tested were an "aerosol" (9.59% Al^{3+}), a "roll-on" emulsion (3.61% Al^{3+}) and a "stick" (5.28% Al^{3+}). For each formulation, 10 diffusion cells (two cells per donor, five donors for all tests) were prepared. Skin biopsies were obtained from the abdominal skin of a biobank of Caucasian humans (age 29-52 years). Tests were performed on both intact and tape-stripped skin ("stick" formulation only). For normal skin, 2.59±0.28,

4.55±0.28 and 3.10±0.64 mg/cm^2 of the "aerosol", "roll-on" and "stick" formulations was applied, respectively. For the stripped skin, 3.61±0.72 mg/cm² of the "stick" formulation was applied. This correspond to 248.47±27.09, 164.47±10.21, 163.80±33.77 and 192.19±47.46 µg/cm^2 of Al^{3+} for "aerosol", "roll-on" and "stick" (normal and stripped skin), respectively. The normal skin samples were non-occluded, whereas the stripped skin was occluded with Parafilm® "M". Samples of the receptor fluid were collected at 6, 12 and 24 hours. After 24 hours, excess of the formulation was removed by washing and the aluminium concentration in the washing liquids was measured. The stratum corneum was thereafter removed by tape-stripping before mechanically separation of epidermis and dermis. The aluminium concentration was measured using Zeeman Electrothermal Atomic Absorption Spectrophotometry (ZEAAS). The percutaneous absorption of aluminium as recovered in the stratum corneum, viable epidermis, dermis and receptor fluid is shown in Table 2. The measured amounts of aluminium in the receptor fluid are negligible and close to the figures recorded with blank samples. Except for the stratum corneum, there are no significant differences concerning the quantities of aluminium between the different formulations (normal skin). However, in viable epidermis and dermis, stripped skin retained more aluminium compared to normal skin (epidermis: 9.42±7.82 vs 1.30±1.25; dermis: 2.01±1.14 vs. 0.41±0.27). Furthermore, in normal skin the aluminium quantities in the stratum corneum invariably exceed those observed in epidermis and dermis. The authors hypothesise that the presence of the stratum corneum diminishes the quantity of aluminium immediately diffusible at the levels of the epidermis and the dermis. It should be noted that the kinetics of aluminium transfer from percutaneous application towards the blood pool is conditioned by parameters that may be cosmetic-dependent (pH, pKa, formulation, size-grading or granulometry) and tissue-dependent (thickness, integrity, vascularisation, temperature).

Table 2: Total amounts of aluminium (µg/cm^2) recovered (mean±SD) (modified from Pineau et al., 2012).

	Amount of Al applied on skin	Stratum corneum (S)	Viable epidermis (E)	Dermis (D)	Receptor fluid (RF) 24 h	Total skin absorption (E+D+RF)
Normal skin						
"Aerosol" base	248.47±27.09	3.98±3.89	1.49±2.09	0.28±0.18	0.07±0.01	1.84±2.23
"Roll-on" emulsion	164.30±10.21	2.24±1.87	0.30±0.36	0.16±0.05	0.07±0.01	0.53±0.38
"Stick"	163.80±33.77	4.43±1.79*	1.30±1.25	0.41±0.27	0.10±0.05	1.81±1.45
Stripped skin						
"Stick"	190.19±47.46	-	9.42±7.82**	2.01±1.14**	0.07±0.03**	11.50±8.90**

*p<0.05 compared to "roll-on" emulsion, **p<0.01 compared to "stick" normal skin.

2.1.2.4 Human - in vivo

Flarend et al. (2001) applied 0.4 ml of a solution containing 21% aluminium chlorohydrate, labelled with the radioisotype ^{26}Al, once to the left axilla surface (3x4 inches) of one male and one female subject. The application area was shaved with an electric razor two days prior to the application. After adjusting for loss of material during the application process, the male and female had 13.3 and 12.4 mg aluminium applied, respectively. The area was covered with an occlusive-type bandage. The next six days, tape-stripping was performed and the area was washed with pre-wetted towelettes and bandaged changed. Blood samples and 24-hour urine were collected before application and periodically for the following 7 weeks. ^{26}Al was detected in the blood at least 15 days after the application. The concentrations were, however, too low for reliable quantitative determinations to be made. In urine, ^{26}Al was detected the

first day and continued for at least 44 days. Of the applied aluminium, 0.0082 and 0.016% was eliminated in urine from the male and female subject, respectively. Of the 12.9 mg aluminium applied (average), 5.1 mg (39.5%) was recovered from the skin and 1.5 µg (0.012%) eliminated in urine. The estimated amount of aluminium absorbed through the skin was 3.6 µg (0.028%) (absorption corrected for 85% complete renal elimination and application of aluminium chlorohydrate to both underarms). The remaining aluminium was either lost into the environment when the bandages came loose, or was retained as precipitating plugs in the sweat ducts. The authors, however, do not believe that it is possible to use the data from this study to project the steady-state absorption of aluminium since only one application of aluminium chlorohydrate was utilised. A similar study using daily applications of ^{26}Al-labeled aluminium should be performed before conclusions on aluminium absorption from daily use of antiperspirants can be drawn.

2.1.2.5 Dermal absorption and systemic availability of aluminium

There are several uncertainties regarding the animal and human *in vivo* studies (Anane et al., 1995; Flarend et al., 2001), therefore these studies were not used for the estimation of the systemic exposure dose (SED) of aluminium.

SCCS has in the Notes of Guidance for the Testing of Cosmetic Ingredients (SCCS, 2010) provided general guidelines to estimate the systemic availability (SED) of a cosmetic ingredient by taking into account the daily amount of finished cosmetic product applied, the concentration of the ingredient, the dermal absorption of that particular ingredient and a mean human body weight value. According to the SCCS' Notes of Guidance for the Testing of Cosmetic Ingredients, dermal absorption is defined as the amount measured in the dermis, epidermis (without stratum corneum) and the receptor fluid (SCCS, 2010). When studies fulfil the SCCS basic requirements for *in vitro* dermal absorption studies (see Appendix 1), the mean+1SD should be used when calculating the margin of safety (MoS). However, in case of significant deviations from the protocol and/or very high variability, the mean+2SD should be used.

The animal *in vitro* study by Anane et al. (1995) does not fulfil the SCCS's requirements. The study by Pineau et al. (2012) fulfils most of the SCCS's requirements and was therefore chosen for the estimations of SED in this opinion. Since this study does not significantly deviate from the protocol, the mean+1SD was used. Three different formulations were tested on normal skin. However, the antiperspirants analysed by the Norwegian Institute of Air Research (NILU) were roll-on types (see 3.1.1.2), thus the absorption value for "roll-on" emulsion was chosen. The total absorption (viable epidermis, dermis, receptor fluid) after 24 hours was 0.53 µg/cm^2 ± 0.38 for normal skin ("roll-on") and 11.50 µg/cm^2 ± 8.90 for stripped skin ("stick") (Table 2). The value of dermally absorbed aluminium in agreement with the SCCS's guideline was estimated by VKM to be 0.91 µg/cm^2 for normal skin (standard scenario) and 20.40 µg/cm^2 for stripped skin (worst case scenario). The total applied amount of aluminium for "roll-on" emulsion and "stick" were 164.30±10.21 and 190.50±37.95 µg/cm^2, respectively (Table 2). Thus, the estimated percentages of absorbed aluminium were 0.6% for normal skin and 10.7% for stripped skin.

2.2 Toxicity of aluminium

The toxicity of aluminium has been thoroughly reviewed in recent risk assessments by EFSA (2008) and JECFA (2012). Below a brief summary is given. Please refer to the risk assessments of EFSA and JECFA for details. As mentioned above, both EFSA (2008) and

JECFA (2012) commented on the lack of specific toxicological data for food additives containing aluminium and on the limitations of the available animal studies.

The acute oral toxicity of aluminium compounds is low; with LD_{50} values ranging from 162 to 750 mg Al/kg bw in rats, and from 164 to 980 mg Al/kg bw in mice, depending on the aluminium compound. Aluminium compounds can lead to histopathological changes in liver and kidney of rats (104 mg Al/kg bw/day) and dogs (88-93 mg Al/kg bw/day) during sub-chronic exposure. Aluminium compounds may cause DNA damage *in vitro* and *in vivo* through indirect mechanisms. This was, however, observed at high levels of exposure, and EFSA concluded that the observation of damage on DNA is "unlikely to be of relevance for humans exposed to aluminium via the diet" (EFSA, 2008). There was no indication of carcinogenicity at high dietary doses (up to 850 mg Al/kg bw/day) in animals studies, and EFSA concluded that "aluminium is unlikely to be a human carcinogen at exposures relevant to dietary intake" (EFSA, 2008). Aluminium compounds did not affect the fertility of female or male rats (at doses up to 100 mg Al/kg bw/day), while reduced fertility, decreased sperm quality and testicular toxicity was seen in male mice (at 100 and 200 mg Al/kg bw/day). Reproductive toxicity has also been observed in male rabbits and male dogs. In addition, aluminium compounds cause embryotoxicity in mice and neurotoxicity in offspring of mice and rats (at 50 mg Al/kg bw/day). Neurotoxicity has also been observed in adult mice and rats.

2.3 Tolerable weekly intake level of aluminium

EFSA established TWI for aluminium of 1 mg/kg bw/week in 2008 based on combined findings from several dietary animal studies (mice, rats and dogs). Due to the lack of a clear dose-response relationship in the available animal studies and hence an uncertainty in the definition of reliable no observed adverse effect levels (NOAELs) and lowest observed adverse effect levels (LOAELs), the TWI is a rounded value of the TWIs established by the NOAEL and LOAEL approaches, respectively (EFSA, 2008). Using the lower end of the LOAELs (50 mg Al/kg bw/day for neurodevelopmental toxicity in mice) and applying an uncertainty factor of 100 for intra- and interspecies variation and a factor of 3 for using a LOAEL and not a NOAEL, a TWI of 1.2 mg Al/kg bw/week was set (EFSA, 2008). Similarly, using the lowest NOAEL (10 mg Al/kg bw/day for neurodevelopmental toxicity in mice) and a applying an uncertainty factor of 100 for intra- and interspecies variation, a TWI of 0.7 mg Al/kg bw/week was set (EFSA, 2008). The established TWI of 1 mg Al/kg bw/week is a rounded value of the two TWIs.

The TWI established by EFSA is equal to the provisional tolerable weekly intake (PTWI) of 1 mg Al/kg bw/week established by JECFA in 2007. JECFA also based the PTWI on several studies due to their limitations and inadequacy to define dose-response relationships (JECFA, 2007).

In 2012, JECFA withdrew the PTWI of 1 mg Al/kg bw/week. New animal studies had become available and JECFA found that one study of developmental and neurotoxicity provided an appropriate NOAEL for the establishment of a PTWI (JECFA, 2012). In this study, rats were exposed to aluminium citrate, one of the more soluble aluminium compounds, in drinking water. Based on the NOAEL of 30 mg/kg bw/day, and applying an uncertainty factor of 100 for inter- and intra-species variation a new PTWI of 2 mg/kg bw/week was established, applying to all aluminium compounds in food, including additives.

An overview of the above referred NOAELs/LOAELs and TWIs is given in Table 3.

Table 3: Overview of the no observed adverse effect levels (NOAELs) and lowest observed adverse effect levels (LOAELs) underlying the tolerable weekly intakes established by different authorities.

	Animal study	NOAEL/LOAEL[1] mg Al/kg bw/day	Uncertainty factor[2]	Additional uncertainty factor[3]	TWI[4] / PTWI[5] mg Al/kg bw/week	Comments
EFSA, 2008	Neurodevelop-mental toxicity in mice	NOAEL 10 LOAEL 50	100 100	- 3	1	The TWI is a rounded value of the TWI provided by the NOAEL approach (0.7 mg Al/kg bw/week) and the TWI provided by the LOAEL approach (1.2 mg Al/kg bw/week) from several studies.
JECFA, 2007	Various dietary studies in mice, rats and dogs	LOAELs 50–75	100	3	1	The lowest LOAELs were used as basis for the estimation of the PTWI due to the lack of an appropriate NOAEL.
JECFA, 2012	Developmental and chronic neurotoxicity in rats	NOAEL 30 LOAEL 100	100	-	2	The NOAEL of 30 mg/kg bw/day was considered an appropriate basis for establishing a PTWI.

[1]NOAEL – no observed adverse effect level, LOAEL – lowest observed adverse effect level.
[2]Uncertainty factor due to interspecies and intraspecies differences.
[3]Additional safety factor due to the use of LOAEL.
[4]TWI – tolerable weekly intake, term used by EFSA.
[5]PTWI – provisional tolerable weekly intake, term used by JECFA.

3 Aluminium concentration in food and cosmetics

In 2010, the Norwegian Food Safety Authority commissioned the Norwegian Institute for Air Pollution (NILU) to conduct a survey of aluminium in food and cosmetic products on the Norwegian market (NILU, 2011). Products expected to contain high levels of aluminium were selected and included in the survey. A summary of the occurrence data is given below and tables compiling them can be found in Appendices 2 and 3.

Due to limited number of samples analysed within each food group and a large variation within food groups the median was calculated for all food groups (see 4.1.2).

The data set contained a number of samples with aluminium levels below the limit of detection (LOD) and the limit of quantification (LOQ), and the VKM therefore chose to use the middle bound approach.

The middle bound approach was applied in the following manner: In cases where the analysed aluminium value in food was below the LOD, half of the LOD value was used. Correspondingly, when the analysed aluminium value was below the LOQ, but above LOD, half of the LOQ value was used (see Table 4).

Table 4: The limit of detection and the limit of quantification for analyses of aluminium concentration in solid and liquid samples (NILU, 2011).

	Limit of detection (LOD)	Limit of quantification (LOQ)
Solid sample	0.35 mg Al/kg	1.2 mg Al/kg
Liquid sample	0.001 mg Al/L	0.004 mg Al/L

3.1 Food including drinking water

An overview of the aluminium concentrations in various food groups on the Norwegian market is given in Table 5. Due to limited number of samples analysed within each food group (Table 5) and a large variation within food groups the median aluminium concentration was calculated for all food groups (see also 4.1.2).

Bread had a median aluminium concentration of 1.5 mg/kg (n = 14), while flat bread and potato cake had a median of 1.8 mg Al/kg (n = 4) and crisp bread contained a median level of 0.6 mg/kg (n = 4).

Low levels of aluminium was found in flour (median 0.6 mg/kg, n = 3) and rice (median 0.18 mg/kg, n = 2), compared to levels found in pasta (median 3.7 mg/kg, n = 5).

Breakfast cereals may contain high levels of aluminium; the level ranged from levels below LOD to 26 mg/kg, with a median aluminium concentration of 2.2 mg/kg (n = 7). Biscuits may also contain high levels of aluminium (<LOD – 16 mg/kg, median of 1.5 mg/kg, n = 10), while cakes contained lower levels of aluminium (median of 0.6 mg/kg, n = 7).

Dairy products contain low levels of aluminium; both milk (n = 2) and cheese (n = 5) contained levels below LOQ, with a median concentration of 0.18 mg/kg.

Potatoes contained a median concentration of 1.9 mg Al/kg (n = 2). Vegetables (fresh and canned) contained <LOD – 23 mg Al/kg (median of 0.6 mg Al/kg, n = 16), with the highest levels seen in tomatoes (fresh and canned), broccoli and spinach. Fruit contained <LOD – 13 mg Al/kg (median of 7.9 mg Al/kg, n = 5), with the highest levels seen in apples and canned pineapple. Seeds contain high levels of aluminium; the level ranged from 5.1 to 1224 mg/kg, with a median aluminium concentration of 26 mg/kg (n = 4). The highest level of aluminium

was found in sesame seeds. High levels of aluminium were also found in spices, ranging from 125 to 1005 mg/kg, with a median of 671 mg/kg (n = 4).

The aluminium concentration in meat and meat products had a median concentration of 1.0 mg Al/kg (n = 10). In fish and fish products the aluminium concentration ranged from below LOD to 12 mg/kg with a median concentration of 0.6 mg/kg (n = 18). The highest level of aluminium was found in salmon prepared in aluminium foil with salt and lemon.

Tea contains higher levels of aluminium than coffee; in tea the median was 4 mg/L (n = 5), while in coffee the median was 0.03 mg/L (n = 6). Coffee white may contain elevated levels of aluminium; the median was 2.3 mg Al/L (n = 3).

Water (from tap and bottled) contained low levels of aluminium, with a median concentration of 0.002 mg/L (n = 4). Soft drinks also contained low levels of aluminium (median of 0.036 mg/L, n = 4). "Saft" (fruit concentrate which is mixed with water before consumption) contained 1.3 mg/L, (median, n = 2), while cacao (prepared) contained 0.13 mg Al/L, (median, n = 2).

The aluminium concentration in porridges (powder based) had a median of 0.6 mg/kg (n = 4), while canned baby foods contained 0.18 mg Al/kg (median, n = 4) and infant formula contained 0.6 mg Al/kg (median, n = 3).

Chocolate may contain high levels of aluminium ranging from 3.6 to 32 mg/kg (median of 6.8 mg/kg, n = 6). Cake mixes contained 1.3 – 13 mg Al/kg (median of 3.5 mg Al/kg, n =7), with the highest levels found in chocolate cake mixes. Similar for desserts; the desserts contained <LOD – 4.6 mg Al/kg (median of 0.6 mg Al/kg, n = 5), with the highest levels found in chocolate pudding. Sweets contained 0.6 mg Al/kg (median, n = 7).

In ready-to-cook food products the aluminium concentration ranged from 0.5 to 11 mg Al/kg (median concentration of 2.0 mg Al/kg, n = 8), with the highest level found in fresh tortellini. In ready-to-cook potato products the aluminium concentration was 0.6 mg Al/kg (median, n = 4), while snacks contained 0.6 – 6.1 mg Al/kg (median of 1.2 mg Al/kg, n = 6), with the highest level found in a potato-based product.

Table 5: Summary of aluminium concentration (mg/kg or mg/L) in various food groups on the Norwegian market (modified from NILU, 2011).

Food groups	Number of samples (samples with Al concentration below LOQ and LOD)	Minimum	Middle bound, median	Maximum
Crisp bread	4 (2,1)	< LOD [a]	0.60 [c]	1.7
Bread	14 (1,0)	1.1 [b]	1.5 [c]	7.3
Flatbread and potato cake	4 (0,0)	1.7	1.8	6.2
Flour	3 (2,0)	0.9 [b]	0.60 [c]	1.2
Rice	2 (0,2)	< LOD [a]	0.18 [c]	<LOD [a]
Breakfast cereals	7 (1,2)	< LOD [a]	2.2 [c]	26
Biscuits	10 (3,1)	< LOD [a]	1.5 [c]	16
Cakes	7 (4,1)	< LOD [a]	0.6 [c]	2.2
Pasta	5 (1,0)	1.1 [b]	3.7 [c]	5.6
Milk	2 (0,2)	< LOD [a]	0.18 [c]	<LOD [a]
Cheese	6 (1,5)	< LOD [a]	0.18 [c]	0.7 [b]
Potatoes	2 (1,0)	1.1 [b]	1.9 [c]	3.1
Vegetables	16 (2,7)	< LOD [a]	0.60 [c]	23
Fresh and canned fruit	5 (0,2)	< LOD [a]	7.9 [c]	13
Seeds	4 (0,0)	5.1	26	1224
Meat and meat products	10 (3,2)	< LOD [a]	1.0 [c]	3.6

Fish and fish products	18 (6,6)	< LOD [a]	0.60 [c]	12
Powder-based porridges	4 (2,1)	< LOD [a]	0.60 [c]	2
Canned baby food	4 (1,3)	< LOD [a]	0.18 [c]	0.4 [b]
Infant formula	3 (2,0)	0.5 [b]	0.60 [c]	1.4
Cake mixes	7 (0,0)	1.3	3.5	13
Sweets	7 (4,1)	< LOD[a]	0.60 [c]	1.9
Chocolate/chocolate products	6 (0,0)	3.6	6.8	32
Dessert	5 (1,2)	< LOD [a]	0.60 [c]	4.6
Ready-to-cook food	8 (4,0)	0.5 [b]	2.0 [c]	11
Ready-to-cook potato products	4 (2,1)	< LOD [a]	0.6 [c]	1.6
Coffee white	3 (0,1)	< LOD [a]	2.3	5.4
Snacks in aluminium bags	6 (2,0)	0.6 [b]	1.2 [c]	6.1
Spices	4 (0,0)	125	671	1005
Water	4 (1,1)	< LOD [d]	0.002 [c]	0.2
Tea	5 (0,0)	0.02	4	5
Coffee	6 (0,0)	0.013	0.03	0.14
"Saft" [e]	2 (0,0)	0.5	1.3	2
Cocoa	2 (1,0)	0.002 [f]	0.13 [c]	0.26
Soft drinks	4 (0,0)	0.018	0.036	0.19

[a] Below the limit of detection (LOD) of 0.35 mg Al/kg.

[b] Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above the LOD of 0.35 mg Al/kg. The actual analysed value is given.

[c] The middle bound approach has been used in calculation of the median.

[d] Below the limit of detection (LOD) of 0.001 mg Al/L

[f] Below the limit of quantification (LOQ) of 0.004 mg Al/L, but above the LOD of 0.001 mg Al/L. The actual analysed value is given.

[e] "Saft" is a traditional Norwegian product subjected to national legislation, and cannot be translated directly into English. 'Saft' is a fruit concentrate which is mixed with water before drinking.

3.2 Cosmetics

Two groups of cosmetics products, antiperspirants and lipstick/lip gloss, were included in the survey (NILU, 2011). Antiperspirants contained 28 – 71 g Al/kg, with a median aluminium concentration of 41 g/kg (n = 8). In lipstick/lip glosses, the aluminium concentration ranged from levels below the LOD to 28 g/kg, with much lower levels found in the lip glosses (<LOD – 0.8 g Al/kg). The overall median aluminium concentration in lipstick/ lip gloss was 7.7 g/kg (n = 11). See Appendix 3 for details. In addition, data on aluminium concentration (4.5%) in toothpaste used for whitening of the teeth was obtained from an earlier study performed by the Norwegian Food Safety Authority (previous SNT, 1997).

4 Exposure characterisation

4.1 Dietary exposure to aluminium

Aluminium may occur naturally in food or as a contaminant. Other sources of aluminium in food are the use of food additives containing aluminium and migration of aluminium from food contact materials to food (see Chapter 1.1).

4.1.1 Description of the national dietary surveys

The estimated dietary exposure to aluminium presented in this opinion are based on data from the nationally food consumption surveys for infants, children, adolescents and adults. The food consumption data are the most complete and detailed currently available in Norway. However, it should be pointed out that three different methodologies were used in the different surveys and thus direct comparisons between different age groups (1-year-old

infants and 2-year-old children, 4 to 13-year-old children/adolescents, adults) can be misleading.

A short description of the food consumption surveys and the different methodologies used is given below:

- 1-year-old infants; 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. The study was conducted in 2007, and a total of 1635 1-year-old children participated (participation rate 57%) (Øverby et al., 2009).
- 2-year-old children; Småbarnskost 2007 is based on a semi-quantitative food frequency questionnaire. In addition to predefined household units, food amounts were also estimated from photographs. The study was conducted in 2007, and a total of 1674 2-year-olds participated (participation rate 56%) (Kristiansen et al., 2009).
- 4-, 9-, and 13-year-old children/adolescents; Ungkost 2000 is based on a 4-day food intake registration with a precoded food diary. Food amounts were presented in predefined household units or as portions estimated from photographs. The study among 4-year-olds was conducted in 2001, and 391 4-year-old children participated (participation rate 52%) (Pollestad et al., 2002). The study among 9- and 13-year-olds was conducted in 2000 and 810 9-year-old children and 1005 13-year-old adolescents participated (participation rate 83%) (Øverby and Andersen, 2002).
- Adults; Norkost 3 is based on two 24-hour recalls by telephone at least one month apart. Food amounts were presented in household measures or estimated from photographs (Totland et al., 2012). The study was conducted in 2010/2011 and 925 women and 862 men aged 18-70 years participated (participation rate 37%).

Daily exposure to aluminium was computed by using food databases in the software system (KBS) developed at the Institute of Basic Medical Sciences, Department of Nutrition, at the University of Oslo. The food databases are mainly based on various versions of the official Norwegian food composition table (Rimestad et al., 2000; The Norwegian Food Composition Table, 1995; 2006) and are continuously supplemented with data on new food items.

4.1.1.1 Body weights

The individual body weights (bw) reported in the different dietary surveys have been used to calculate the exposure in mg Al/kg bw. In cases where an individual bw is missing, the mean bw for the age group in question has been used.

Among the 1-year-old infants, bw data for 6.3% (i.e. 103 individuals) were not reported and thus substituted with the group's mean bw of 9.9 kg. Correspondingly, 37% (620 individuals) of the 2-year-old children were given the group mean bw of 12.8 kg, 23.8% (93 individuals) of the 4-year-old children were given the group's mean bw of 18.0 kg, 14.3% (116 individuals) of the 9-year-olds were given the group mean bw of 32.0 kg, 14.4% (145 individuals) of the 13-year-old adolescents were given the group mean bw of 49.4 kg, and 1.7% (20 individuals) of the adults were given the group mean bw of 77.5 kg.

An overview of the mean bw for the different age groups is given in Table 6.

Table 6: Mean body weight of different age groups in the Norwegian population as reported in the national dietary surveys.

Age	Mean body weight (kg)
1-year-old infants	9.9
2-year-old children	12.8
4-year-old children	18.0
9-year-old children	32.0
13-year-old adolescents	49.5
Adults aged 18-70 years	77.5

4.1.2 Calculation of aluminium concentrations in food groups and estimation of dietary exposure

The data compiled in the survey of aluminium in food and cosmetic products (Appendix 2 and 3, respectively) on the Norwegian market by NILU (2011) was used in the estimations of exposure to aluminium in Norway. The survey included all food groups expected to contain high levels of aluminium (see Table 5 and Appendix 2); hence no occurrence data for aluminium in food from other countries were included in the estimations of dietary exposure.

The data set contained a number of samples with aluminium levels below the limit of detection (LOD) and the limit of quantification (LOQ), and the VKM therefore chose to use the middle bound approach.

The middle bound approach was applied in the following manner: In cases where the analysed aluminium value in food was below the LOD, half of the LOD value was used. Correspondingly, when the analysed aluminium value was below the LOQ, but above LOD, half of the LOQ value was used (see Table 4).

Several approaches for the estimation of dietary exposure were considered. Due to limited number of samples analysed within each food group, the median was calculated for all food groups (termed *middle bound, median*) and used in the estimation of the dietary exposure (see Table 5).

4.1.3 Estimated aluminium exposure in infants, children, adolescents and adults

The exposure calculations are based on consumption data from the National dietary surveys (see Chapter 4.1.1) and aluminium concentration in food as listed in Table 5 with details given in Appendix 2.

The estimated weekly exposure to aluminium through food for infants, children, adolescents and adults are shown in Table 7. The exposure is given as mean and 95-percentile (high) exposure, as all age groups in the dietary surveys are exposed to aluminium through food and there are a high number of participants in all groups. The estimated mean and median exposure were similar (mean data not shown).

Based on the middle bound, median concentration of aluminium in food, the estimated weekly exposures for 1-year-old infants were 0.89 and 1.9 mg Al/kg bw for mean and 95-percentile exposure, respectively. For 2-year-old children the weekly mean exposure to aluminium was 0.88 mg/kg bw, while the 95-percentile exposure was 1.7 mg/kg bw. Four-year-old children have a weekly mean exposure of 0.53 mg Al/kg bw and a 95-percentile exposure of 0.90 mg Al/kg bw. The estimated weekly exposure for 9-year-old children was 0.35 and 0.66 mg Al/kg bw for mean and 95-percentile exposure, respectively.

Based on the middle bound, median concentration of aluminium in food, the estimated weekly exposure to aluminium for 13-year-old adolescents was 0.22 and 0.49 mg Al/kg bw for mean and 95-percentile exposure, respectively. In adults, the weekly mean aluminium exposure was 0.29 mg/kg bw, while the 95-percentile exposure was 0.67 mg/kg bw (Table 7).

Table 7: Aluminium exposure through food for 1-year-old infants (n=1635), 2-year-old-children (n=1674), 4-year-old children (n=391), 9-year-old children (n=310), 13-year-old adolescents (n=1005) and adults (n=1787) given as mg Al/kg bw/week.

Age groups	Mean exposure (mg Al kg bw/week)	High exposure (95-percentile) (mg Al kg bw/week)
1-year-old infants	0.89	1.9
2-year-old children	0.88	1.7
4-year-old children	0.53	0.90
9-year-old children	0.35	0.66
13-year-old adolescent	0.22	0.49
Adults	0.29	0.67

4.1.4 Comments to the estimated dietary exposure

The estimated mean dietary exposures to aluminium are comparable to estimated dietary exposure for populations in other European countries (EFSA, 2008). In infants, the estimated exposure ranged from 0.1 to 1.1 mg Al/kg bw/week, depending on age and type of infant formula (EFSA, 2008). In comparison, the estimated mean dietary exposure for 1-year-old infants in Norway was 0.89 mg Al/kg bw/week. The mean dietary exposure for toddlers (1.5 – 4.5 years of age), children (3 – 15 year of age) and young people (4 – 18 years of age) ranged from 0.3 to 1.2 mg Al/kg bw/week (EFSA, 2008). For Norwegian children and adolescents the estimated mean dietary exposure ranges from 0.22 to 0.88 mg Al/kg bw/week. The estimated mean dietary exposure for Norwegian adults is 0.29 mg Al/kg bw/week, which is comparable to the mean dietary exposure estimated for adults in other European countries; ranging from 0.2 to 1.5 mg Al/kg bw/week (EFSA, 2008).

4.2 Dermal exposure to aluminium from the use of cosmetics

The aluminium concentration was measured in a selection of antiperspirants and lipsticks/lip glosses found on the Norwegian market (NILU, 2011). The median values were 41 g/kg and 7.7 g/kg, respectively. This corresponds to 4.1% aluminium in antiperspirants and 0.77% in lipstick/lip gloss.

Based on the study by Pineau et al. (2012), VKM estimated an absorption rate of 0.6% in intact (normal) skin and 10.7% for tape-stripped skin (see Chapter 2.1.2.5). Tape-stripping of the skin biopsies mimics shaving or waxing of the arm pit, but may also mimic impaired skin caused by eczema or other skin conditions. When stratum corneum is impaired the permeability to cosmetics may increase (Turner et al., 2007). Absorption rates of 0.6% and 10.7% were used for standard and worst case scenarios, respectively.

In this opinion, VKM assumed that 1-year-old infants, and 2- and 4-year-old children do not use antiperspirant and lipstick/lip gloss on a daily basis. Thus, exposure calculations for

cosmetics for these age groups were not performed. Furthermore, VKM assumed that 9-year-old children do not use antiperspirant on a daily basis. For this age group, only lipstick/lip gloss was included in the cosmetics exposure scenarios. It can be assumed that 9-year old children use lip gloss to a greater extent than lipstick. However, since there were no available consumer data regarding the use of lip gloss versus lipstick, the median aluminium value for both product types were used in the present exposure assessments. Both 13-year old adolescents and adults were assumed to use antiperspirant and lipstick/lip gloss on a daily basis.

With regard to whitening toothpaste only a few products contain aluminium (Storehagen et al., 2003), whereas most contain silica. VKM therefore assumed that only a small part of the adult population is consumers of aluminium containing toothpaste on a daily basis.

4.2.1 Estimation of daily exposure to aluminium from the use of cosmetics

In this opinion, VKM has estimated the systemic exposure dose (SED) to aluminium from topical application of cosmetic products in different age groups of the Norwegian population.

The different exposure scenarios presented in Tables 8 to 11 are based on default values for daily exposure to antiperspirants, lipsticks/lip glosses and/or toothpastes described in the SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (SCCS, 2010):

- Antiperspirant: 1.5 g/day
- Lipstick/lip gloss: 0.057 g/day
- Toothpaste: 0.138 g/day

The daily exposure values represented in Table 3 of the Notes of Guidance are valid for adults. For the 9-year-old children, the daily amount applied was adjusted to the difference in skin surface area over body weight ratio (SSA/BW) between adults and children (1.3 fold at 10 years). The daily exposure to skin care products for 13-year-old adolescents has been assumed to be similar to adults, as there is no correction factor for SSA/BW ratio above 10 years in the Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (SCCS, 2010).

SED for antiperspirant and lipstick/lip gloss was calculated using the same approach as used by Agence Francaise de Sécurite Sanitaire des Produits de Santé (AFSSAPS, 2011):

Equation 1

$$SED = \frac{Daily\ applied\ dose\ (g/day) \times 1 \times 10^6 \times \frac{C\ (\%)}{100} \times \frac{DA_p\ (\%)}{100}}{bw}$$

where C is concentration (%) of aluminium in the product and DA_p is dermal absorption (%) of aluminium.

Study specific body weights were used when calculating SED (see Table 6: 9-year-old children: 32 kg; 13-year-old adolescents: 49.5 kg; adults: 77.5 kg).

The dermal absorption rate for aluminium was based on data for "roll-on" emulsion on normal skin and "stick" formulation on stripped skin in the study by Pineau et al. (2012). Taking into the account the basic criteria for dermal absorption studies described in SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (2010), dermal absorption rates of 0.6% and 10.7% for normal and stripped skin, respectively,

were calculated and used in the exposure scenarios in this opinion from VKM (see Chapter 2.1.2.5).

For cosmetics, SED is typically based on dermal absorption data. However, for toothpaste, oral exposure data are more relevant. In this assessment, an oral absorption of 0.1% is used, which is considered relevant for absorption from food and beverages (EFSA, 2008). SED for toothpaste were therefore calculated using the following equation:

Equation 2

$$SED = \frac{\frac{Bioavailability\ (\%)}{100} \times daily\ applied\ dose\ (g/day) \times 1 \times 10^6 \times RF \times \frac{Amount\ of\ Al\ in\ product\ (\%)}{100}}{bw}$$

where RF is the retention factor (a factor that takes into account rinsing off and dilution of the finished products by application, e.g. shower gels, shampoos).

Estimated concentration of Al in $Al(OH)_3$ used in toothpastes was calculated as: Assumed concentration of $Al(OH)_3$ x (Al atomic weight/$Al(OH)_3$ molar mass)=13% x (27 g/mol/78 g/mol) = 4.5% aluminium.

A similar approach was used in SCCS' opinion on triclosan where oral, and not dermal, absorption of triclosan from toothpastes was used when estimating SED (SCCS, 2011).

4.2.2 Daily exposures used in the exposure scenarios

The exposure scenarios were based on different absorption values for normal (standard scenario) and stripped skin (worst case) from the study of Pineau et al., 2012 (see Chapter 4.2.1) and the measured concentrations of aluminium in antiperspirants and lipsticks/lip glosses on the Norwegian market (Appendix 3). With regard to toothpaste, an assumed concentration of 13% $Al(OH)_3$, corresponding to 4.5% aluminium was used (personal communication Norwegian Food Safety Authority (previous SNT, 1997)).

The following skin absorption values and aluminium concentrations were used for cosmetic product types in the exposure scenarios:

- Antiperspirant:
  - Standard scenario: 0.6% skin absorption, 4.1% aluminium in the product
  - Worst case scenario: 10.7% skin absorption, 4.1% aluminium in the product
- Lipstick/lip gloss:
  - Standard scenario: 0.6% skin absorption, 0.77% aluminium in the product
  - Worst case scenario: 10.7% skin absorption, 0.77% aluminium in the product
- Toothpaste:
  - Worst case scenario: 0.1% oral absorption, 4.5% aluminium in the product

VKM assumed that only adults used aluminium-containing whitening toothpastes, and that only a small part of the adult population is consumers of aluminium-containing whitening toothpastes on a daily basis, thus toothpastes are only included in the worst case scenario for adults.

4.2.3 Estimated exposure to aluminium in children

The use of lipstick/lip gloss containing aluminium was considered relevant for 9-year-old children. The estimated exposure to aluminium from topical application of cosmetic products for 9-year-old children is shown in Table 8. Two different exposure scenarios are presented; a standard scenario based on 0.6% skin absorption and a worst case scenario based on 10.7% skin absorption.

Table 8: Exposure scenarios for the application of cosmetic products containing aluminium for 9-year-old children – based on two different per cent of dermal absorption.

Cosmetic product type	Estimated daily amount applied (g)[1]	Concentration of Al in the product (%)[2]	Dermal absorption (%)[3]	SSA/ BW[4]	Systemic exposure dose (SED) (µg Al/kg bw/day)[5]	Systemic exposure dose (SED) (µg Al/kg bw/week)
Lipstick/lip gloss	0.057	0.77	0.6	1.3	0.10	0.69
Lipstick/lip gloss	0.057	0.77	10.7	1.3	1.9	13

[1]Based on default exposure levels from Table 3 in SCCS Notes of Guidance. [2]Based on measurements of aluminium in cosmetic products on the Norwegian market (NILU, 2011). [3]The different scenarios are based on absorption values in normal and stripped skin from the study by Pineau et al. (2012). [4]Factor for the difference in skin surface area (SSA) over body weight (bw) ratio between adults and children (SCCS, 2010). [5]Estimated by using equation 1 cited in Chapter 4.2.1, and mean body weight (bw) of 32 kg.

The results in Table 8 show that SED from the use of lipstick/lip gloss containing aluminium in 9-year-old children was estimated to 0.69 and 13 µg Al/kg bw/week for the two scenarios (0.6 and 10.7% dermal absorption).

4.2.4 Estimated exposure to aluminium in adolescents and adults

The estimated exposure to aluminium from topical application of cosmetic products for 13-year-old adolescents and adults are shown in Tables 9 and 10, respectively. Different exposure scenarios for adolescents and adults, taking into account topical application of both lipstick/lip gloss and antiperspirant and a combination of these two cosmetic products are represented. The standard scenario was based on 0.6% skin absorption and the worst case scenario on 10.7% skin absorption.

The results in Table 9 shows that SED from the use of lipstick/lip gloss containing aluminium in 13-year-old adolescents could be estimated to 0.34 and 6.7 µg Al/kg bw/week for the two scenarios (0.6 and 10.7 % dermal absorption). Similarly, SED from the use of antiperspirants could be estimated to 48 and 935 µg Al/kg bw/week.

For the use of both lipstick/lip gloss and antiperspirant in 13-year-old adolescents, SED-values of 49 and 941 µg Al/kg bw/week were estimated for standard and worst case scenarios, respectively.

Table 9: Exposure scenarios for the application of cosmetic products containing aluminium for 13-year-old adolescents – based on two different per cent of dermal absorption for each cosmetic product.

Cosmetic product type	Estimated daily amount applied (g)[1]	Concentration of Al in the product (%)[2]	Dermal absorption (%)[3]	SSA/ BW[4]	Systemic exposure dose (SED) (µg Al/kg bw/day)[5]	Systemic exposure dose (SED) (µg Al/kg bw/week)
Lipstick/lip gloss	0.057	0.77	0.6	1	0.05	0.34
	0.057	0.77	10.7	1	0.95	6.7
Anti-perspirant	1.50	4.11	0.6	1	6.9	48
	1.50	4.11	10.7	1	134	935
Lipstick/lip gloss + anti-perspirant	0.057 1.50	0.77 4.11	0.6	1	7.0	49
	0.057 1.50	0.77 4.11	10.7	1	134	941

[1]Based on default exposure levels from Table 3 in SCCS Notes of Guidance. [2]Based on measurements of aluminium in cosmetic products on the Norwegian market (NILU, 2011). [3]The different scenarios are based on absorption values in normal and stripped skin from the study by Pineau et al. (2012). [4]Factor for the difference in skin surface area (SSA) over body weight (bw) ratio between adults and children (SCCS, 2010). [5]Estimated by using equation 1 cited in Chapter 4.2.1, and mean body weight (bw) of 49.5 kg.

The results for adults presented in Table 10 show that SED from the use of lipstick/lip gloss containing aluminium could be estimated to 0.22 and 4.3 µg Al/kg bw/week for the two scenarios (0.6 and 10.7% dermal absorption). With regard to the use of antiperspirants, SED could be estimated to 31 and 597 µg Al/kg bw/week for the standard and worst case scenario, respectively.

When including both the use of lipstick/lip gloss and antiperspirants for adults, SED values of 31 and 601 µg Al/kg bw/week were estimated for the standard and worst case scenarios respectively.

Table 10: Exposure scenarios for the application of cosmetic products containing aluminium for adults – based on two different per cent of dermal absorption.

Cosmetic product type	Estimated daily amount applied (g)[1]	Concentration of Al in the product (%)[2]	Dermal absorption (%)[3]	SSA/ BW[4]	Systemic exposure dose (SED) (µg Al/kg bw/day) [5]	Systemic exposure dose (SED) (µg Al/kg bw/week)
Lipstick/lip gloss	0.057	0.77	0.6	1	0.03	0.22
	0.057	0.77	10.7	1	0.61	4.3
Anti-perspirant	1.50	4.11	0.6	1	4.4	31
	1.50	4.11	10.7	1	85	597
Lipstick/lip gloss + anti-perspirant	0.057 1.50	0.77 4.11	0.6	1	4.4	31
	0.057 1.50	0.77 4.11	10.7	1	86	601

[1]Based on default exposure levels from Table 3 in SCCS Notes of Guidance. [2]Based on measurements of aluminium in cosmetic products on the Norwegian market (NILU, 2011). [3] The different scenarios are based on absorption values in normal and stripped skin from the study by Pineau et al. (2012). [4] Factor for the difference in skin surface area (SSA) over body weight (bw) ratio between adults and children (SCCS, 2010). [5]Estimated by using equation 1 cited in Chapter 4.2.1, and mean body weight (bw) of 77.5 kg.

The use of aluminium-containing toothpastes was considered only to be relevant for adults, an only for a small part of the adult population. Toothpastes were, therefore, only included in the worst case scenario. The estimated adult exposure to aluminium from the use of toothpastes is shown in Table 11.

Table 11: Exposure scenarios for the use of toothpaste containing aluminium for adults.

Cosmetic product type	Assumed bio-availability (%)[1]	Amount applied (g)[2]	Retention [2]	Calculated daily exposure (g) [3]	Aluminium content (%)	Systemic exposure dose (SED) (µg Al/kg bw/day)[4]	Systemic exposure dose (SED) (µg Al/kg bw/week)
Toothpaste	0.1	2.75	0.05	0.138	4.5	0.080	0.56
Toothpaste + lipstick/lip gloss +antiperspirant[5]	-	-	-	-	-	86	602

[1]Based on values for oral absorption of 0.1% (see Chapter 2.1.1.1). [2]Based on default values from Table 3 in SCCS Notes of Guidance, [3]See Chapter 4.2.1 for calculation, [4]Estimated by use of equation 2 cited in Chapter 4.2.1, and mean body weight of 77.5 kg. [5]SED values for lipstick/lip gloss and antiperspirants are taken from Table 10.

The results in Table 11 show that SED from the use of toothpaste containing aluminium in adults could be estimated to 0.56 µg Al/kg bw/week. A worst case scenario for adults including aluminium-containing lipstick/lip gloss, antiperspirant and toothpaste gives a SED-value of 602 µg Al/kg bw/week.

4.2.5 Summary of dermal exposure

SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (SCCS, 2010) were used to estimate SED for aluminium after the use of

antiperspirant and lipstick/lip gloss, whereas SED after the use of toothpaste was estimated based on oral intake values (see Chapter 4.2.1).

VKM estimated absorption rates of 0.6% and 10.7% for standard and worst case scenarios, respectively, based on the study by Pineau et al. (2012). VKM assumed that 1-year-old infants and 2- and 4-year-old children do not use lipstick/lip gloss and antiperspirant on a daily basis. Furthermore, 9-year-old children where assumed to use lipstick/lip gloss but not antiperspirants. Both 13-year-old adolescents and adults were assumed to use lipstick/lip gloss and antiperspirant on a daily basis. Therefore, exposure scenarios were performed for 9-year-old children, 13-year-old adolescents and adults for the use of lipstick/lip gloss and/or antiperspirants. Due to the low number of aluminium-containing whitening toothpaste available on the Norwegian market, SED were estimated only for the worst case scenario for adults.

SED for 9-year-old children were estimated to be 0.69 and 13 µg Al/kg bw/week for standard and worst case scenario, respectively. For 13-year-old adolescents, total SED for both cosmetic product groups were estimated to be 49 and 941 µg Al/kg bw/week for standard and worst case scenario, respectively. For adults, SED was estimated to be 31 µg Al/kg bw/week for standard scenario (antiperspirant, lipstick/lip gloss) and 602 µg Al/kg bw/week for worst case scenario (antiperspirant, lipstick/lip gloss, toothpaste).

AFSSAPS (2011) estimated the systemic exposure after daily exposure to an antiperspirant containing 5% aluminium on intact and stripped skin to be 2.1 µg/kg bw/day and 75 µg/kg bw/day, respectively. Compared to this, VKM has estimated higher systemic exposures after daily use of antiperspirants containing 4.1% aluminium (4.4 and 85 µg/kg bw/day for intact and impaired skin, respectively). However, AFFSAPS (2011) used a different version of SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (SCCS, 2010) with another default value (0.5 g) for antiperspirants and different dermal absorptions factors (0.5% and 18% for intact and impaired skin, respectively) than VKM. In addition, AFSSSAPS used a standard body weight of 60 kg, whereas in the present opinion, study specific weights were applied (9-year-old children: 32 kg; 13-year-old adolescents: 49.5 kg; adults: 77.5 kg).

4.3 Estimated total aluminium exposure through food and the use of cosmetic products

The aluminium exposures from food and from the use of cosmetic products are estimated using two different approaches. The estimated dietary exposure to aluminium was based on national food consumption surveys for various age groups and the aluminium concentration in food on the Norwegian market. The exposure from the use of cosmetics was estimated as the systemic exposure dose (SED) from topical application of cosmetic products (lipstick/lip gloss and antiperspirants) in different age groups according to the SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (SCCS, 2010). Two different exposure scenarios, based on different absorption values for normal (standard scenario) and stripped skin (worst case, representing shaved or impaired skin) and the measured concentrations of aluminium in cosmetic products on the Norwegian market, were applied. Stripping of the skin biopsies mimics shaving or waxing of the underarm. A daily use of cosmetic products in assumed in the scenarios.

The aluminium exposures from food were estimated as weekly intake of aluminium whereas exposure from cosmetic products is estimated as a systemic exposure dose. Since these two estimates cannot be directly compared, the total dietary exposure was converted to a systemic exposure dose taking into account the low oral bioavailability of aluminium. In this

assessment, an oral absorption of 0.1% is used, which is considered relevant for absorption from food and beverages (EFSA, 2008). However, it should be noted that the oral absorption of aluminium from food may vary at least 10-fold depending on the chemical form of aluminium (EFSA, 2008). Total systemic exposure was estimated by adding the systemic exposure doses after oral and dermal absorption.

4.3.1 Infants and children

One-year-old infants and 2- and 4-year-old children are only exposed to aluminium through their diet, while some 9-year-old children may have an additional exposure through the use of lip gloss and lipstick. The mean dietary exposures to aluminium were 0.89, 0.88 and 0.53 mg/kg bw/week for the 1-, 2- and 4-year-olds, respectively (Table 12). The high exposures (95-percentile) to aluminium were 1.9, 1.7 and 0.90 mg/kg bw/week for the 1-, 2- and 4-year-olds, respectively. For 9-year-old children, the mean dietary exposure to aluminium was 0.35 and 0.66 mg Al/kg bw/week for mean and high exposure, respectively, corresponding to systemic exposures of 0.35 and 0.66 µg Al/kg bw/week, respectively. Some 9-year-olds may use lip gloss and/or lipstick. With the additional contribution from the use of lipstick/lip gloss, the total exposure for consumers with mean dietary exposure was 1.0 µg Al/kg bw/week in a standard scenario (0.6% skin absorption, normal skin) and 14 µg Al/kg bw/week worst case scenario (10.7% skin absorption, stripped skin). For consumers with high dietary exposure, the total exposure was 1.4 and 14 Al/kg bw/week for standard and worst case scenario, respectively (Table 12).

4.3.2 Adolescents

For 13-year-old adolescents, the dietary exposure to aluminium was 0.22 and 0.49 mg Al/kg bw/week for mean and high (95-percentile) exposure, respectively, corresponding to systemic exposures of 0.22 and 0.49 µg Al/kg bw/week, respectively (Table 12). The use of lipstick/lip gloss and antiperspirants are considered relevant for 13-year-old adolescents. With the additional contribution from the use of lipstick/lip gloss, the total exposure in a standard scenario was 0.56 and 0.83 µg Al/kg bw/week for mean and high exposures, respectively. In a worst case scenario, the mean and high exposures were 6.9 and 7.2 µg Al/kg bw/week, respectively. With the additional contribution from the use of antiperspirants, the total exposure in a standard scenario (0.6% skin absorption) was 50 µg Al/kg bw/week both for the mean and high exposures. In a worst case scenario (10.7% skin absorption, stripped skin), both the mean and high exposures were 940 µg Al/kg bw/week (Table 12).

4.3.3 Adults

The mean dietary exposure to aluminium was 0.29 and 0.67 mg Al/kg bw/week for mean and high (95-percentile) exposures, respectively, corresponding to systemic exposures of 0.29 and 0.67 µg Al/kg bw/week, respectively (Table 12). The use of lipstick and lip gloss, antiperspirants and whitening toothpaste are considered relevant for adults. With the additional contribution from the use of lipstick/lip gloss the total exposure, in a standard scenario, was 0.51 and 0.89 µg Al/kg bw/week for mean and high exposures, respectively. In a worst case the mean and high exposures were 4.5 and 4.9 µg Al/kg bw/week, respectively. With the additional contribution from the use of antiperspirants the total exposure, in a standard scenario, was 31 and 32 µg Al/kg bw/week for mean and high exposures, respectively. In a worst case scenario, both the mean and high exposures were 600 µg Al/kg bw/week. Adding the contribution from the use of toothpaste in a worst case scenario did not change the total exposure (Table 12).

5 Risk characterisation

Safe intake levels of aluminium in food have been established by EFSA (2008) and JECFA (2012) on the basis of toxicity studies in animals. Safe intake levels are expressed as a TWI or PTWI. A TWI is an estimate of the amount of a potential harmful substance that a person can be exposed to weekly over a lifetime without appreciable health risks.

TWIs are derived from the toxicological effects triggered at the lowest exposure dose in the most sensitive experimental species. Due to the integrated uncertainty factors and the conservative way in which the tolerable intake levels are derived, exceeding the TWI will initially only represent a reduced safety margin. Thus, the TWIs are not a threshold for toxicity with onset of adverse effects, and it is therefore difficult to quantify the risk caused by intakes above the TWI.

The TWI and the PTWI are set for aluminium intake from food. In this risk assessment, the total exposure to aluminium from food and the use of cosmetic products was estimated as a "systemic" exposure (see Chapter 4.3). Thus for comparison, the TWI set by EFSA (2008) was recalculated to 1 µg Al/kg bw/week, while the PTWI set by JECFA (2012) was converted to 2 µg Al/kg bw/week, taking into account an oral bioavailability of 0.1% (EFSA, 2008) and assuming similar toxicity following oral and dermal exposure to aluminium. These tolerable intakes are termed systemic TWI, and are estimates of the amount of aluminium that can be absorbed (oral and dermal absorption) weekly over a lifetime without appreciable health risks.

5.1 Infants and children

One-year-old infants and 2- and 4-year-old children are only exposed to aluminium through their diet. The mean dietary exposures to aluminium ranged from 0.53 to 0.89 mg/kg bw/week depending on age group (Table 12), whereas the high exposures (95-percentile) to aluminium ranged from 0.90 to 1.9 mg/kg bw/week. The mean exposure for all three age groups was below the TWI of 1 mg Al/kg bw/week set by EFSA (2008), but for 1-year-old infants and 2-year-old children the highly exposed children (95-percentile exposure) did exceed the TWI of 1 mg Al/kg bw/week. All estimates were below the PTWI of 2 mg/kg bw/week set by JECFA (2012).

Nine-year-old children are exposed to aluminium through food and may have an additional exposure through the use of lipstick/lip gloss. The mean dietary exposure to aluminium was 0.35 and 0.66 mg Al/kg bw/week for mean and high exposures, respectively (Table 12), which is below the TWI of 1 mg Al/kg bw/week set by EFSA (2008) and the PTWI of 2 mg/kg bw/week set by JECFA (2012).

For 9-year-olds, the total systemic exposure (exposure from food and the use of cosmetic products) in a standard scenario (0.6% skin absorption) were 1.0 and 1.4 µg Al/kg bw/week for mean and high exposures, respectively (Table 12). In a worst case scenario (10.7% skin absorption), both the mean and high total systemic exposures were 14 µg Al/kg bw/week. All the estimates exceed the systemic TWI of 1 µg Al/kg bw/week and in the worst case scenarios by a factor of 14. The worst case scenarios estimates also exceed the systemic PTWI of 2 µg Al/kg bw/week by a factor of 7.

5.2 Adolescents and adults

Adolescents and adults are exposed to aluminium through food and the use of cosmetic products.

For 13-year-old adolescents the mean dietary exposure to aluminium was 0.22 and 0.49 mg Al/kg bw/week for mean and high (95-percentile) exposures, respectively (Table 12), which is below the TWI of 1 mg Al/kg bw/week set by EFSA (2008) and the PTWI of 2 mg/kg bw/week set by JECFA (2012).

With the additional contribution from the use of lipstick/lip gloss, the total systemic exposures in 13-year old adolescents in a standard scenario were 0.56 and 0.83 µg Al/kg bw/week for mean and 95-percentile exposures, respectively. These estimates are below the systemic TWI of 1 µg Al/kg bw/week. In a worst case scenario, the mean and high systemic exposures were 6.9 and 7.2 µg Al/kg bw/week, respectively, and these estimates exceed the systemic TWI of 1 µg Al/kg bw by a factor of 7, and the systemic PTWI of 2 µg Al/kg bw/week by a factor of 3.5. With the additional contribution from the use of antiperspirants, the total systemic exposures in a standard scenario were 50 µg Al/kg bw/week for both mean and high exposures. Both estimates exceed the systemic TWI by a factor of 50, and the systemic PTWI by a factor of 25. In a worst case scenario both the mean and high systemic exposures were 940 µg Al/kg bw/week (Table 12). The worst case scenario estimates exceed the systemic TWI by a factor of 940, and the systemic PTWI by a factor of 470.

For adults the mean dietary exposure to aluminium was 0.29 and 0.67 mg Al/kg bw/week for mean and high exposures, respectively (Table 12), which is below the TWI of 1 mg Al/kg bw/week set by EFSA (2008) and the PTWI of 2 mg/kg bw/week set by JECFA (2012).

With the additional contribution from the use of lipstick/lip gloss, the total systemic exposures in adults in a standard scenario were 0.51 and 0.89 µg Al/kg bw/week for mean and 95-percentile exposures, respectively. These estimates are below the systemic TWI of 1 µg Al/kg bw/week. In a worst case scenario, the mean and high systemic exposures were 4.5 and 4.9 µg Al/kg bw/week, respectively, and thus, these estimates exceed the systemic TWI of 1 µg Al/kg bw/week by a factor of 4.5-4.9, and the systemic PTWI of 2 µg Al/kg bw by a factor of 2.2-2.5. With the additional contribution from the use of antiperspirants, the total systemic exposure in a standard scenario was 30 µg Al/kg bw/week for both mean and high exposures. Both estimates exceed the systemic TWI by a factor of 30, and the systemic PTWI by a factor of 15. In a worst case scenario, both the mean and high systemic exposures were 600 µg Al/kg bw/week. The worst case scenario estimates exceed the systemic TWI by a factor of 600, and the systemic PTWI by a factor of 300. Adding the contribution from the use of toothpaste in a worst case scenario did not change the total systemic exposure (Table 12).

Table 12: **Overview of mean and high (95-percentile) aluminium exposure through food and the use of cosmetics for different age groups (µg/kg bw/week). In order to sum up the two sources of exposures, the dietary exposure (mg/kg bw/week) was converted to a systemic exposure taking into account the low oral bioavailability (0.1%) of aluminium (EFSA, 2008). The TWI set by EFSA (2008) was recalculated to a systemic TWI of 1 µg Al/kg bw/week taking into account an oral bioavailability of 0.1%. Correspondingly, the PTWI set by JECFA (2012) was converted to a systemic PTWI of 2 µg Al/kg bw/week. Values in italic indicate exposure above the systemic TWI of 1 µg/kg bw/week. Values in bold indicate exposure above the systemic PTWI of 2 µg Al/kg bw/week.**

Age groups	Exposure categories	Exposure from food	Systemic exposure food (0.1% oral absorption)	Systemic exposure through food and the use of lipstick/lip gloss		Systemic exposure through food and the use of lipstick/lip gloss and antiperspirants		Systemic exposure though food and the use of lipstick/lip gloss, antiperspirants and toothpaste
		mg/kg bw/week	µg/kg bw/week	Standard scenario* µg/kg bw/week	Worst case scenario** µg/kg bw/week	Standard scenario* µg/kg bw/week	Worst case scenario** µg/kg bw/week	Worst case scenario*** µg/kg bw/week
1-year-old infants	**Mean**	0.89	0.89					
	High	*1.9*	*1.9*					
2-year-old children	**Mean**	0.88	0.88					
	High	*1.7*	*1.7*					
4-year-old children	**Mean**	0.53	0.53					
	High	0.90	0.90					
9-year-old children	**Mean**	0.35	0.35	1.0	***14***			
	High	0.66	0.66	*1.4*	***14***			
13-year-olds	**Mean**	0.22	0.22	0.56	***6.9***	***50***	***940***	
	High	0.49	0.49	0.83	***7.2***	***50***	***940***	
Adults	**Mean**	0.29	0.29	0.51	***4.5***	***30***	***600***	***600***
	High	0.67	0.67	0.89	***4.9***	***30***	***600***	***600***

*Standard scenario: 0.6% skin absorption, **Worst case scenario 10.7% skin absorption, ***Worst case scenario: 0.1% oral absorption.

6 Uncertainties

6.1 Uncertainties concerning dietary exposure

Every dietary assessment is connected with uncertainty. A description of the most important uncertainties and assumptions in the dietary exposure calculations is described below.

Three concepts are fundamental to understanding the limitations of dietary assessment: habitual consumption, validity and precision (Livingstone and Black, 2003).

The habitual consumption of an individual is the person's consumption averaged over a prolonged period of time, such as weeks and months rather than days. However, this is a largely hypothetical concept; the consumption period covered in a dietary assessment is a compromise between desired goal and feasibility. In the Norwegian dietary surveys the time period covered are 14-days among the 1- and 2-year-olds (Sped- and Småbarnskost 2006/2007), four consecutive days among the 4-, 9- and 13-year-olds (UNGKOST 2000) and two none-consecutive days among the adults (Norkost 3).

Aluminium has been analysed and found in a relatively limited number of foods, and it is only the reported aluminium contents in the limited number of food groups/food items analysed (NILU, 2011) that are included in the exposure calculations.

The analysed foods (NILU, 2011) were not directly comparable with consumption data. Some food groups have a low number of analysed samples, while some foods analysed are not much consumed according to the consumption data. Also the variation in aluminium concentration in single foods in some of the food groups was large. The food category with the highest aluminium concentration was seeds, and the consumption data for seeds in the Norwegian dietary studies are limited. In the EFSA risk assessment (EFSA, 2008) soya milk came out as a main source of exposure. Soya is neither analysed in the NILU report (2011), nor do the consumption surveys have extensive information of use of soya products.

The analysed aluminium values did not show a consistent higher aluminium concentration when food were cooked in aluminium containers such as pots, pans, cookers and aluminium foil. Cooking utensils have not been considered as sources for aluminium other than in the few samples where fish has been prepared in aluminium foil, or water heated in an aluminium pan (NILU, 2011). However, due to few analysed values this could contribute to an underestimation of aluminium in prepared food.

Both large within-person and between-person variations in consumption of aluminium-containing foods were seen in the consumption surveys. In this risk assessment we report aluminium exposure in all participants within an age group because all the participants have eaten aluminium-containing food. A large number of repeated days of dietary measurements and a comprehensive database on aluminium contents in different foods would be required to obtain an accurate estimate of individual aluminium exposure (Willett, 1998).

The validity of a dietary assessment method refers to the degree to which the method actually measures the aspect of diet that it was designed to measure (Nelson and Margetts, 1997). Lack of validity is strongly associated with systematic errors (Burema et al., 1988). With systematic errors all respondents in a dietary study or each subgroup in a population produce the same type of error, like systematic underestimation or overestimation of intake. All the three different dietary assessment methods used in this risk assessment have limitations when it comes to validity. Results from validation studies among 9- and 13-year-olds indicate an underestimation of energy intake around 20% when the precoded food diary, used in UNGKOST 2000, is compared with energy expenditure (Andersen et al., 2005; Lillegaard and Andersen, 2005). The validation studies among 1- and 2-year-olds were performed on a

previously established questionnaire, but the results showed a significantly higher energy intake with the FFQ than with the weighed record reference method (Andersen et al., 2003; Andersen et al., 2004; Andersen et al., 2009). The Norwegian 24-hour recall method used among adults in Norkost 3 has not been validated. However, other similar 24-hour recall methods have been validated and show an underestimation in energy intake of around 15% (Subar et al., 2003; Poslusna et al., 2009). Underestimation of energy intake indicates that not all foods eaten are reported, but not which foods are underreported. It has been shown that foods perceived as unhealthy such as fats, sweets, desserts and snacks tend to be underreported to a larger degree than foods perceived as healthy (Olafsdottir et al., 2006). However, among children and adolescents there have been studies were this selective underreporting was not shown (Sjøberg et al., 2003; Lillegaard and Andersen, 2005). As aluminium is found in foods perceived both as unhealthy and healthy, it is not likely that the misreporting would strongly bias the estimated aluminium exposure. However, if underreporting of aluminium-containing foods is of the same magnitude as for total energy, the estimates for aluminium exposure are more likely to be underreported than over reported.

The precision of a technique is one that gives the same answer on repeated administrations (Livingstone and Black, 2003). Poor precision derives from large random errors in the techniques of dietary assessment. The effect of random errors can be reduced by increasing the number of observations, but cannot be entirely eliminated (Rothman, 2002).

The data collection in UNGKOST 2000 was performed in year 2000-2001, and dietary patterns are constantly changing. It is difficult to know if the dietary pattern has changed toward more aluminium-containing foods or not.

It is unclear to which extent a low participation rate will influence the assessment of aluminium exposure. It has been shown that health-conscious people are more likely to participate in a dietary survey. This can indicate a somewhat different dietary pattern among the participants than among the whole population. Norkost 3 among adults had a participation rate of only 37%. However, the direction of the uncertainty regarding aluminium exposure is difficult to estimate.

Individual consumption data reported in the dietary surveys have been paired with person-specific self-reported body weights for the same individuals. Furthermore, where no body weight was given the mean body weight from the study was imputed. Person-specific weights give a higher certainty than use of default values. Although, self-reported weights have shown a tendency to underestimate the accurate body weight of individuals (Nyholm et al., 2007; Niedhammer et al., 2000), this was not shown in the UNGKOST 2000 validation study (Andersen et al., 2005).

In this opinion the dietary exposure to aluminium is compared with dermal exposure to estimate a total exposure to aluminium from food and the use of cosmetic products. As the aluminium exposures from food and from the use of cosmetic products were estimated using different approaches the two estimates cannot be directly compared. To sum up the two exposures as total exposure, the total dietary exposure was converted to a systemic exposure taking into account the low oral bioavailability of aluminium. In this assessment, an oral absorption of 0.1% is used, which is considered relevant for absorption from food and beverages (EFSA, 2008). However, it should be noted that the oral absorption of aluminium from food may vary at least 10-fold depending on the chemical form of aluminium (EFSA, 2008).

6.2 Uncertainties concerning dermal exposure

There are few studies on dermal absorption of aluminium. Although the study VKM has used in this risk assessment, Pineau et al. (2012), was performed according to the SCCS's basic criteria for *in vitro* studies of dermal absorption, there may be uncertainties in whether these absorption data correctly represent the *in vivo* human dermal absorption. Uncertainties regarding the true absorption values may lead to either an underestimation or overestimation of the systemic exposure doses.

Furthermore, in the worst case scenarios, the absorption rate was estimated using stripped skin. In contrast to the normal skin samples that were not occluded after application of the test substances, stripped skin were occluded with Parafilm®. Occlusion may increase the skin absorption, thus the systemic exposure dose in worst case scenarios may overestimated.

The default values of daily applied dose for the different product types in SCCS' Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (SCCS, 2010) correspond to the 90th percentile of consumer use. Thus, for a large group of consumers, smaller amounts of the cosmetic products may be applied on a daily basis. This may lead to an overestimation of the systemic exposure doses.

In the worst case scenarios, systemic exposures were assessed based on absorption values derived from stripped skin. This treatment may mimic newly shaved/waxed skin. VKM assumes that these procedures are most likely not performed on a daily basis; however, no information regarding frequency of shaving/waxing is available. The systemic exposure doses in the worst case scenarios may, thus, be overestimated.

In the exposure scenarios presented in this opinion, VKM has assumed daily applications of lipstick/lip gloss in 9-year-old children. However, children may not use such products daily. In addition, it can be assumed that 9-year old children would use lip gloss instead of lip stick. Lipsticks were found to contain on average higher levels of aluminium than lip glosses. Thus, the systemic exposure dose from the use of lipstick/lip gloss may be overestimated.

The use of antiperspirants in 9-year-old children was not included in the exposure scenarios. Some children may start using antiperspirants at this age. For these consumers, there may be an underestimation of the systemic exposure dose.

For 13-year-old adolescents and adults, VKM assumed daily use of aluminium-containing antiperspirants. However, deodorants that do not contain aluminium are available on the Norwegian market. Thus, for consumers using deodorants without aluminium, the systemic exposure dose will be overestimated.

There are several cosmetic products on the Norwegian market that contain aluminium compounds. In the present opinion, however, only antiperspirants, lipstick/lip gloss and whitening toothpaste were included in the different exposure scenarios. The systemic exposure dose for consumers (of all age groups) using other aluminium-containing cosmetic products may therefore be underestimated.

6.3 Summary table of uncertainties

Evaluations of the overall effect of identified uncertainties are presented in Table 13, highlighting the main sources of uncertainty and indicating whether the respective source of uncertainty might have led to an overestimation or underestimation of the exposure and/or the resulting risk (EFSA, 2006).

Table 13: Qualitative evaluation of influences of uncertainties on the assessment of aluminium exposure.

Source of uncertainty	Direction
Dietary exposure assessment	
Different dietary assessment methods	+/-
Measurement uncertainty in the aluminium concentrations analysed	+/-
Limited number of food groups are included in the survey of aluminium in food on the Norwegian market	-
Selected food groups not representative for food actually consumed	+/-
Food with an assumed high level of aluminium were selected	+
Limited number of analysed samples per food group	+/-
Limited data on food prepared in aluminium cooking utensils	-
Middle bound, median aluminium values were used for the food groups	+/-
Sped- and småbarnskost 2006/2007	
FFQ time span is 14 days	+/-
Ungkost 2000	
Study conducted in 2000-2001 - Possible changes in the food patterns can have occurred	+/-
Use of 95-percentile - The number of participants among 4-year-olds is only 391	+/-
Low participation rate among 4-year-olds	+/-
Four registration days	+/-
Norkost 3, Adults	
Low participation rate	+/-
Two registration days	+/-
Oral absorption Oral absorption of aluminium varies depending on type of food and beverages and chemical form of aluminium	+/-
Dermal absorption	
Uncertainty regarding the amount of aluminium absorbed in human skin	+/-
Occlusion of stripped skin biopsies used for measuring dermal absorption	+
SCCS's default value for amount of product daily applied corresponding to the 90th percentile of consumer use	+
Assumed daily application on impaired skin in worst case scenario	+
Assumed daily application of lipstick/lip gloss in 9-year-old children	+
Daily use of antiperspirants in 9-year-old children not included in the exposure scenarios	-
Assumed daily application of aluminium-containing antiperspirants for 13-year-old adolescents and adults	+
Limited selection of cosmetic products were included in the survey of aluminium in cosmetics on the Norwegian market	+/-
Qualitative evaluation of overall effect of identified uncertainties: +: uncertainty likely to cause over-estimation of exposure -: uncertainty likely to cause under-estimation of exposure	+/-

The dietary exposures of aluminium can be considered realistic for each age groups, despite of the limitations in assessing the food consumptions and the uncertainties related to estimating the aluminium exposures outlined above. Taking all sources of uncertainty regarding dermal exposure into consideration, an over-estimation is most likely for cosmetics because of the default values and assumptions used, especially in the worst case scenarios.

Data gaps

- A small number of samples and food types has been analysed for aluminium concentrations. Analyses of more food samples are warranted.
- A comprehensive and continually updated national aluminium database is necessary for estimating more accurately the overall exposure of aluminium through diet.
- More data is needed to understand under-/over-reporting of food consumption in dietary surveys.
- Further research is needed to get more accurate portion size estimations in the dietary surveys.
- Further research is needed to evaluate the impact of variations in number of registration days in the dietary surveys.
- There are few good studies on absorption of aluminium in human skin. Additional studies on dermal absorption are needed.
- There is lack of surveys regarding the use of cosmetic products in the Norwegian population.
- There is limited information on the concentration of aluminium in cosmetic products.

Conclusions

The aluminium concentration in food and cosmetic products on the Norwegian market was analysed in 2010/2011. VKM has chosen to use these national occurrence data and hence no additional international occurrence data of aluminium has been included in the estimations of human exposure.

The human exposure to aluminium from food and the use of cosmetic products were estimated using two different approaches. The estimated dietary exposure to aluminium was based on national food consumption surveys for various ages, while the exposure from the use of cosmetics was estimated as a systemic exposure dose (SED) from topical application of cosmetic products (lipstick/lip gloss and antiperspirants). The SED from whitening toothpaste was estimated based on oral absorption. Hence the two exposure estimates from dietary intake and use of cosmetic products cannot be directly compared. To sum up the two exposures, the dietary exposure was converted to a systemic exposure taking into account the low oral bioavailability (0.1%) of aluminium.

The tolerable weekly intake (TWI) (EFSA, 2008) and the provisional tolerable weekly intake (PTWI) (JECFA, 2012) are set for aluminium intake from food. The TWI and PTWI are estimates of the amount of a potential harmful substance that a person can be exposed to weekly over a lifetime without appreciable health risks. As the total exposure to aluminium from food and the use of cosmetic products was estimated as a systemic exposure, the TWI set by EFSA (2008) was recalculated to a systemic TWI of 1 µg Al/kg bw/week, while the PTWI set by JECFA (2012) was converted to a systemic PTWI of 2 µg Al/kg bw/week, taking into account the low oral bioavailability and assuming similar toxicity following oral and dermal exposure to aluminium.

- The mean dietary exposure to aluminium in the Norwegian population did not exceed the TWI of 1 mg Al/kg bw/week or the PTWI of 2 mg Al/kg bw/week.

- The estimated mean dietary exposures to aluminium are comparable to estimated dietary exposure for populations in other European countries.

- The high (95-percentile) dietary exposure to aluminium for 1-year-old infants and 2-year-old children exceeded the TWI, but were below the PTWI.

- Nine-year-old children, 13-year-old adolescents and adults may have an additional exposure to aluminium though the use of cosmetic products (lipstick/lip gloss, antiperspirants and/or whitening toothpaste).

- Cosmetic products, in particular antiperspirants, contributed substantially to the total systemic aluminium exposure in the Norwegian population in age groups that use cosmetic products (assumed for 9-year-olds to adults). High systemic exposures were estimated in the worst case scenarios. These estimations are based on skin absorption values derived from skin biopsies after tape-stripping that mimics shaving or waxing of the armpit, or impaired skin caused by skin conditions such as eczema.

- For persons using lipstick/lip gloss daily, only the total systemic exposure in 9-year-old children equalled (mean) or exceeded (95-percentile) the systemic TWI of 1 µg Al/kg bw/week in the standard scenario (0.6% skin absorption, normal skin). None of the estimated total systemic exposures exceeded the systemic PTWI of 2 µg Al/kg bw/week. In a worst case scenario (10.7% skin absorption, stripped skin), the mean and high total

systemic exposures exceeded both the systemic TWI and PTWI for all age groups by factors of 5-14 and 2.5-7, respectively.

- VKM assumed that adolescents and adults use lipstick/lip gloss and/or antiperspirants on a daily basis. With the additional contribution from the use of lipstick/lip gloss and antiperspirants:
    - For adolescents, the mean and high (95-percentile) total systemic exposures in a standard scenario (0.6% skin absorption, normal skin) exceeded the systemic TWI and systemic PTWI by a factor of 50 and 25, respectively. In a worst case scenario (10.7% skin absorption, stripped skin) the mean and high total systemic exposures exceeded the systemic TWI and systemic PTWI by a factor of 940 and 470, respectively.
    - For adults, the mean and high total systemic exposures in a standard scenario exceeded the systemic TWI and systemic PTWI by a factor of 30 and 15, respectively. In a worst case scenario the mean and high total systemic exposures exceeded the TWI and PTWI by a factor of 600 and 300, respectively.

- The additional use of whitening toothpaste containing aluminium did not contribute much to the total systemic exposure to aluminium in adults.

- Exposure levels above the TWI and PTWI values are not desirable. A small exceedance of these values represents a reduced safety margin. However, the large exceedance (15-50 folds) of the systemic TWI and systemic PTWI, which was seen for persons using several cosmetic products in addition to the dietary exposure, will reduce the safety margin further and may increase the risk of adverse effects. The situation is even more of concern for persons shaving/waxing their armpits often or having impaired skin caused by skin conditions such as eczema, where the exceedance of TWI/PTWI was 300-940 folds.

References

2003/15/EC – Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. Official Journal L66, 11/03/2003 p.26.

Agence française de sécurité sanitaire des produits de santé (AFSSAPS). Évaluation du risqué lié à l'utilisation de l'aluminium dans les produits cosmétiques, 2011. (*Available at: http://www.afssaps.fr/var/afssaps_site/storage/original/application/ad548a50ee74cc320c788ce8d11ba373.pdfhttp://www.afssaps.fr/var/afssaps_site/storage/original/application/ad548a50ee74cc320c788ce8d11ba373.pdf*)

Anane R, Bonini M, Grafeille JM, Creppy EE. Bioaccumulation of water soluble aluminium chloride in the hippocampus after transdermal uptake in mice. Arch Toxicol 1995;69:568-571.

Andersen LF, Lande B, Arsky GH, Trygg K. Validation of a semi-quantitative food-frequency questionnaire used among 12-month-old Norwegian infants. Eur J Clin Nutr 2003;57:881-888.

Andersen LF, Lande B, Trygg K and Hay G. Validation of a semi-qualitative food-frequency questionnaire used among 2-year-old Norwegian children. Public Health Nutr. 2004;7:757-764.

Andersen LF, Pollestad ML, Jacobs DR Jr, Lovo A and Hustvedt BE. Validation of a pre-coded food diary used among 13-year-olds: comparison of energy intake with energy expenditure. Public Health Nutr. 2005;8:1315-1321.

Andersen LF, Lande B, Trygg K, Hay G. Validation of a semi-quantitative food-frequency questionnaire used among 2-year-old Norwegian children – Corrigendum. Pub Health Nutr. 2009;12:1026-1027.

Andersen LF, Lillegaard ITL, Øverby N, Lytle L, Klepp K-I & Johansson L 2005: Overweight and obesity among Norwegian schoolchildren: Changes from 1993 to 2000. Scan J Public Health, 2005; 33: 99–106.

ATSDR, Agency for Toxic Substances and Disease Control. Toxicological profile for aluminium. Atlanta, GA.: US Department of Health and Human Services, Public Health Service. *Available at:* http://www.atsdr.cdc.gov/toxprofiles/tp22.pdf [Accessed 20. April 2012].

Burema J, van Staveren WA, van den Brandt P. Validity and reproducibility. In: Cameron ME, van Staveren WA (eds.). Manual on Methodology for Food Consumption Studies, pp. 171-182. Oxford: Oxford University Press; 1988.

Caroli S, Alimonti A, Coni E, Petrucci F, Senofonte O, Violante N. The assessment of reference values for elements in huan biological tissues and fluids: a systematic review. Crit Rev Anal Chem 1994;24:363-398.

DG SANCO. Sanco/222/2000: Guidance document on dermal absorption,. European Commission, Health and Consumer Protection Directorate-General, Doc. Sanco/222/2000 revision 7 of 19 March 2004.

EC B.44 – Skin absorption: *In vitro* method. Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Official Journal L142, 31/05/2008, p. 432.

EC B.45 – Skin absorption: *In vitro* method. Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Official Journal L142, 31/05/2008, p. 438.

ECETOC. Percutanous absorption. European centre for ecotoxicology and toxicology of chemicals, Monograph No 20, Brussels, 1993.

EFSA (European Food Safety Authority). Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials on a request from European Commission on Safety of aluminium from dietary intake. The EFSA Journal 2008, 754; 1-34 *(Available at http://www.efsa.europa.eu/en/efsajournal/pub/754.htm)*

EFSA (European Food Safety Authority). Guidance of the Scientific Committee on a request from EFSA related to Uncertainties in Dietary Exposure Assessment. The EFSA Journal. 2006;438:1-54. *Available at http://www.efsa.europa.eu/en/efsajournal/doc/438.pdf)*

Flarend R, Bin T, Elmore D, Hem SL. A preliminary study of the dermal absorption of aluminium from antiperspirants using aluminium-26. Food Chem Toxicol 2001;39:163-168.

Gramiccioni L, Ingrao G, Milana MR et al. Aluminium levels in Italian diets and in selected foods from aluminium utensils. Food Addit Contam 1996; 13(7): 767-74 *(Available at http://www.ncbi.nlm.nih.gov/pubmed/8885317).*

Howes D, Guy R, Hadgraft J, Heylings J, Hoeck U, Kemper F, Maibach H, Marty J-P, Merk H, Perra J, REkkas D, Rondelli I, Schaefer H, Täuber U, Verbiese N. Methods for assessing percutaneous absorption, ECVAM Workshop Report n. 13. Alternatives to laboratory animals 1996; 24: 81-106.

IAI. Human health risk assessment for aluminium, aluminium oxide, and aluminium hydroxide. Expert Panel: Krewski D, Yokel RA, Nieboer E, Borchelt D, Joshua Cohen J, Harry J, Kacew S, Lindsay J, Mahfouz AM, Rondeau V. International Aluminium Institute, February 13, 2007.

JECFA. Safety evaluation of certain food additives / prepared by the Sixty-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives (JEFCA). WHO food additives series; 58, 2007. ISBN 978 92 4 166065 5 (*Available at http://whqlibdoc.who.int/publications/2007/9789241660587_eng.pdf*)

JECFA. Safety evaluation of certain food additives / prepared by the Seventy-fourth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JEFCA). WHO food additives series; 65, 2012. ISBN 978 92 4 166058 7 (*Available at: http://whqlibdoc.who.int/publications/2012/9789241660655_eng.pdf)*

Kristiansen AL, Andersen LF, Lande B (2009). Småbarnskost 2 år. Landsomfattende kostholdsundersøkelse blant 2 år gamle barn. Helsedirektoratet, Oslo. *Available in Norwegian at http://www.helsedirektoratet.no/publikasjoner/rapport-smabarnskost-2-aringer-2009/Publikasjoner/rapport-smabarnskost-2-aringer-2009.pdf*

Lillegaard IT, Andersen LF. Validation of a pre-coded food diary with energy expenditure, comparison of under-reporters v. acceptable reporters. Br J Nutr. 2005;94:998-1003.

Livingstone MB, Black AE. Markers of the validity of reported energy intake. J Nutr. 2003;133 Suppl 3:895S-920S.

Nelson M, Margetts BM. Overview of the principles of nutritional epidemiology. In: Margetts BM, Nelson M (eds.). Design concepts in nutritional epidemiology, 2nd ed., pp. 123-169. New York: Oxford University Press; 1997.

Niedhammer I, Bugel I, Bonenfant S, Goldberg M, Leclerc A. Validity of self-reported weight and height in the French GAZEL cohort. Int J Obes Relat Metab Disord. 2000;24: 1111–18

NILU; Norwegian Institute for Air Research. Metaller i næringsmidler, kroppspleieprodukter og kosmetikk. Bestemmelse av aluminium, kadmium og barium. Oppdragsrapport. Kjeller, NILU (NILU OR 16/2011). ISBN: 978-82-425-2377-8

Nyholm M, Gullberg B, Merlo J, Lundqvist-Persson C, Rastam L, Lindblad U. The validity of obesity based on self-reported weight and height: Implications for population studies. Obesity. 2007;15:197–208.

Olafsdottir AS, Thorsdottir I, Gunnarsdottir I, Thorgeirsdottir H, Steingrimsdottir L. Comparison of women's diet assessed by FFQs and 24-hour recalls with and without underreporters: association with biomarkers. Ann Nutr Metab. 2006;50:450-460.

OECD 427 – OECD Guideline for testing of chemicals – Guideline 427: Skin absorption: *In vivo* method, Organization for Economic Cooperation and Development, Paris, adopted 13 April 2004.

OECD 428 – OECD Guideline for testing of chemicals – Guideline 428: Skin absorption: *In vitro* method, Organization for Economic Cooperation and Development, Paris, adopted 13 April 2004.

OECD. Guidance Document for the conduct of skin absorption studies. Document number ENV/JM/MONO(2004)2. Organization for Economic Cooperation and Development (OECD), Environment Directorate, OECD Environmental Health and Safety Publications, Series on testing and assessment No. 28, Paris, 5 March 2004.

Pineau A, Guillard O, Fauconneau B, Favreau F, Marty MH, Gaudin A, Vincent CM, Marrauld A, Marty JP. In vitro study of percutaneous absorption of aluminum from antiperspirants through human skin in the Franz™ diffusion cell. J Inorg Biochem 2012; 110:21-26.

Pollestad ML, Øverby NC, Andersen LF (2002). Kosthold blant 4-åringer. Landsomfattende kostholdsundersøkelse. UNGKOST-2000. Sosial- og helsedirektoratet, Oslo. *Available in Norwegian at: http://www.helsedirektoratet.no/publikasjoner/ungkost-2000-kosthold-blant-4-aringer/Publikasjoner/ungkost-2000-kosthold-blant-4-aringer.pdf*

Poslusna K, Ruprich J, de Vries JHM, Jakubikova M, van't Veer P. Misreporting of energy and micronutrient intake estimated by food records and 24 hour recalls, control and adjustment methods in practice. Br J Nutr. 2009;101:S73-S85.

Priest ND. The biological behaviour and bioavailability of aluminium in man, with special reference to studies employing aluminium-26 as a tracer: review and study update. J Environ Monitor 2004;6:375-403.

Priest ND, Newton D, Day JP, Talbot RJ, Warner AJ. Human metabolism of aluminium-26 and gallium-67 injected as citrates. Hum Exp Toxicol 1995;14:287-293.

Rimestad AH, Løken EB, Nordbotten A. The Norwegian food composition table and calculation system used at the Institute for Nutrition Research. Norwegian Journal of Epidemiology. 2000;10:107-10.

Rothman KJ. Random error and the role of statistics. In: Epidemiology: An introduction, pp. 94-112. New York: Oxford University Press; 2002.

SCCNFP/0167/99: Basic criteria for the *in vitro* assessment of percutaneous absorption of cosmetic ingredients, adopted by the SCCNFP during the 8th plenary meeting of 23 June 1999.

SCCS/1358/10: Basic criteria for the *in vitro* assessment of dermal absorption of cosmetic ingredients, adopted by the Scientific Committee on Consumer Safety (SCCS) during the 7th plenary meeting on 22 June 2010.

SCCS/1313/11: Opinion on triclosan, adopted by the SCCS during the 10th plenary meeting on 22 March 2011.

SCCS (Scientific Committee on Consumer Safety) notes of guidance for the testing of cosmetic ingredients and their safety evaluation (7th revision) *Available at* *http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_004.pdf*

Schaefer H, Redelmeier TE. Skin barrier, principles of percutaneous absorption, Karger, Basel, 1996.

Sjøberg A, Slinde F, Arvidsson D, Ellegård L, Gramatkovski E, Hallberg L, Hulthén L. Energy intake in Swedish adolescents: validation of diet history with doubly labelled water. Eur J Clin Nutr. 2003;57:1643-1652.

Storehagen S, Ose N, Midha S. Dentifrices and mouthwashes Ingredients and their use. [Term essay] Oslo: Institute of Clinical Dentistry, Faculty of Dentistry, University of Oslo. 2003.

Talbot RJ, Newton D, Priest ND, Austin JG, Day JP. Inter-subject variability in the metabolism of aluminium following intravenous injection as citrate. Hum Exp Toxicol 1995;14:595-599.

The Norwegian Food Composition Table (i.e. Matvaretabellen) 1995, 2006. *Available in Norwegian at*: http://www.matportalen.no/verktoy/Matvaretabellen/gamle_tabeller

Totland TH, Melnæs BK, Lundberg-Hallèn N, Helland-Kigen KM, Lund-Blix NA, Myhre JB, Johansen AMW, Løken EB & Andersen LF (2012): Norkost 3 - En landsomfattende kostholdsundersøkelse blant menn og kvinner i Norge i alderen 18-70 år, 2010-11. Helsedirektoratet. Oslo. *Available in Norwegian at:* *http://www.helsedirektoratet.no/publikasjoner/norkost-3-en-landsomfattende-kostholdsundersokelse-blant-menn-og-kvinner-i-norge-i-alderen-18-70-ar/Publikasjoner/norkost-3-is-2000.pdf*

Turner GA, Moore AE, Marti VP, Paterson SE, James AG (2007). Impact of shaving and anti-perspirant use on the axillary vault Int J Cosmet 29:31-38.

US EPA. Health effect test guidelines. Dermal penetration. US Environmental Protection Agency (EPA). Doc EPA 712-C-96-350, Washington DC, 1996.

WHO (1997). Aluminium (Environmental Health Criteria 194). Geneva: International Program on Chemical Safety (IPCS). *Available at: http://www.inchem.org/documents/ehc/ehc/ehc194.htm#SectionNumber:1.1*

Øverby NC, Andersen LF (2002). Ungkost 2000. Landsomfattende kostholdsundersøkelse blant elever i 4.- og 8. klasse i Norge. Sosial- og helsedirektoratet, Oslo.
Available in Norwegian at: *http://www.helsedirektoratet.no/publikasjoner/ungkost-2000-landsomfattende-kostholdsundersokelse-blant-elever-i-4-og-8klasse-i-norge/Publikasjoner/ungkost-2000-landsomfattende-kostholdsundersokelse-blant-elever-i-4-og-8klasse-i-norge.pdf*

Øverby NC, Kristiansen AL, Andersen LF, Lande B (2009). Spedkost 12 måneder. Landsomfattende kostholdsundersøkelse blant 12 måneder gamle barn (Spedkost 2006 - 2007). Helsedirektoratet, Oslo. *Available in Norwegian at* *http://www.helsedirektoratet.no/publikasjoner/rapport-spedkost-12-maneder-2009/Publikasjoner/rapport-spedkost-12-maneder-2009.pdf*

Appendices

Appendix 1. Text from SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (SCCS, 2010) relevant for this assessment.

Dermal/percutaneous absorption

a. Major guidelines for dermal / percutaneous absorption

Human exposure to cosmetic ingredients occurs mainly via the skin. In order to reach the circulation (blood and lymph vessels) cosmetic ingredients must cross a number of cell layers of the skin, where the rate-determining layer is considered to be the stratum corneum (SC). A number of factors play a key role in this process, including the lipophilicity of the compounds, the thickness and composition of the SC (body site), the duration of exposure, the amount of topically applied product, the concentration of target compounds, occlusion, etc. (for review see Schaefer et al., 1996; ECETOC 1993; Howes et al., 1996). The dermal/percutaneous absorption has been described by several international bodies (ECETOC 1993, US EPA 1996a, OECD 2004) using a wide variety of terms and it is recognised that confusion is possible. Therefore it seems appropriate to define some important terms in this particular field (SCCS/1358/10).

The dermal/percutaneous absorption process is a global term which describes the passage of compounds across the skin. This process can be divided into three steps:

- *penetration* is the entry of a substance into a particular layer or structure such as the entrance of a compound into the stratum corneum;
- *permeation* is the penetration through one layer into another, which is both functionally and structurally different from the first layer;
- *resorption* is the uptake of a substance into the vascular system (lymph and/or blood vessel), which acts as the central compartment.

Dermal/percutaneous absorption studies can be performed *in vivo* or *in vitro*. Today, however, *in vivo* dermal/percutaneous absorption testing is not an option any more for cosmetic ingredients in the European context, as the animal testing deadline of 11 March 2009 has passed (2003/15/EC).

Both *in vivo* and *in vitro* testing protocols form part of the lists of official EU and OECD test methods (EC B.44, 45; OECD 427, 428), accompanied by more detailed guidance on their performance (DG SANCO 2004, OECD 2004). Whereas the first version of above-mentioned OECD Guideline 428 was issued in 2000, the SCCNFP already adopted its first set of basic criteria for the *in vitro* assessment of dermal absorption of cosmetic ingredients in 1999 (SCCNFP/0167/99). This opinion, most recently updated in 2010 (SCCS/1358/10), focuses on the *in vitro* testing of cosmetic ingredients, whereas the general EU and OECD Guidance (DG SANCO 2004, OECD 2004) addresses percutaneous absorption from a much broader point of view by mentioning *in vivo* methods besides *in vitro* testing and by providing specifications for agricultural products and industrial chemicals besides cosmetics.

As a result, the SCC(NF)P/SCCS has always considered *a combination of the EU/OECD Guidelines* and its own *"Basic criteria" as essential for dermal / percutaneous absorption studies*.

b. The SCCS "Basic criteria"

The purpose of *in vitro* dermal absorption studies of cosmetic ingredients is to obtain qualitative and/or quantitative information on the substances that may enter, under in-use conditions, into the systemic compartment of the human body. The quantities can then be taken into consideration to calculate the margin of safety using the NOAEL of an appropriate repeated dose toxicity study with the respective substance.

In these relatively complex *in vitro* studies, there are a number of points that require special attention:

1) The design of the diffusion cell (technicalities and choice between static and flow through system).
2) The choice of the receptor fluid (physiological pH, solubility and stability of chemical in receptor fluid should be demonstrated, no interference with skin/membrane integrity, analytical method, etc.).
3) The skin preparations should be chosen and treated with care (human skin from an appropriate site remains the gold standard).
4) Skin integrity is of key importance and should be verified.
5) Skin temperature has to be ascertained at normal human skin temperature.
6) The test substance has to be rigorously characterised and should correspond to the substance that is intended to be used in the finished cosmetic products.
7) Dose and vehicle/formulation should be representative for the in-use conditions of the intended cosmetic product. Several concentrations, including the highest concentration of the test substance in a typical formulation, should be included.
8) Dose, volume and contact time with the skin have to mimic in-use conditions.
9) Regular sampling is required over the whole exposure period.
10) Appropriate analytical techniques should be used. Their validity, sensitivity and detection limits should be documented in the report.
11) The test compound is to be determined in all relevant compartments:
    - product excess on the skin surface (dislodgeable dose),
    - stratum corneum (e.g. adhesive tape strips),
    - living epidermis (without stratum corneum),
    - dermis,
    - receptor fluid.
12) Mass balance analysis and recovery data are to be provided. The overall recovery of test substance (including metabolites) should be within the range of 85-115%.
13) Variability/validity/reproducibility of the method should be discussed. The SCCS considers that for a reliable dermal absorption study, 8 skin samples from at least 4 donors should be used.

The amounts measured in the dermis, epidermis (without stratum corneum) and the receptor fluid will be considered as dermally absorbed and taken into account for further calculations.

When studies correspond to all of the basic requirements of the SCCS, the mean + 1SD will be used for the calculation of the margin of safety (MoS). The reason for not using the mean per se is the frequently observed high variability in the *in vitro* dermal absorption assays. In case of significant deviations from the protocol and/or very high variability, the mean + 2SD will be used as dermal absorption for the MoS calculation1. In case the results are derived from an inadequate *in vitro* study, 100% dermal absorption is used. However, in case MW > 500 Da and log Pow is smaller than -1 or higher than 4, the value of 10% dermal absorption is considered.

Appendix 2. Aluminium concentrations in foods.

Aluminium concentrations in food were analysed by the Norwegian Institute for Air Research (NILU, 2011) on commission from the Norwegian Food Safety Authority. VKM has modified the tables from the NILU report (2011) with regard to groups of food items and used the middle bound approach for samples below the limit of detection (LOD) and the limit of quantification (LOQ), respectively. Thereafter, the median values for each food group were calculated.

The middle bound approach has been used in the following manner: In cases where the analysed aluminium value in food was below the limit of detection (LOD), half of the LOD value was used. Correspondingly, when the analysed aluminium value was below the limit of quantification (LOQ), but above LOD, half of the LOQ value was used. The LOD and LOQ for solid food and liquid were different (NILU, 2011).

	Limit of detection (LOD)	**Limit of quantification (LOQ)**
Solid food	0.35 mg Al/kg	1.2 mg Al/kg
Liquid	0.001 mg Al/L	0.004 mg Al/L

Due to few analysed foods for each food group, the median values have been calculated for all food groupings (termed *middle bound, median* in the tables below).

The minimum and maximum values given in the tables below reflect the actual analysed aluminium values from the NILU report (2011), including values below LOQ but above LOD.

Table 1: Concentration in crisp bread

Product name in Norwegian	**Aluminium (mg/kg)**		
Wasa Husmann	0.6**		
Wasa Havre	0.5**		
Wasa Frukost	< LOD*		
Finn Crisp	1.7		
	Minimum	**Middle bound, median**	**Maximum**
Crisp bread (N=4)	< LOD*	0.6***	1.7

* Below the limit of detection (LOD) of 0.35 mg Al/kg.
** Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 2: Concentration in bread

Product name in Norwegian	Aluminium (mg/kg)		
Ingers Fibermat/Ingers rugbrød	1.2		
Familiebrød med spelt	1.2		
Grovbrød	1.4		
Kneipp	1.2		
Coop Idrettsbrød	1.7		
Istid matpakkebrød	2.0		
Loff	1.1**		
Finbrød	1.4		
Pågen Jättefranska	2.4		
Regal Solsikkebrød	1.5		
Grove rundstykker	1.7		
Spesialrundstykker	2.4		
Fine rundstykker	7.3		
Lyse rundstykker	1.5		
	Minimum	**Middle bound, median**	**Maximum**
Bread (N=14)	1.1**	1.5***	7.3

** Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above the limit of detection (LOD) of 0.35 mg Al/kg. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 3: Concentration in flatbread and potato cake (lompe)

Product name in Norwegian	Aluminium (mg/kg)		
Kavli Korni flatbrød	1.7		
Ideal Flatbrød	1.8		
Frostalompa	1.8		
Lompebakeriet	6.2		
	Minimum	**Middle bound, median**	**Maximum**
Flatbread and potato cake (N=4)	1.7	1.8	6.2

Table 4: Concentration in flour

Product name in Norwegian	Aluminium (mg/kg)		
Regal Sammalt rug grov	1.1**		
Møllerens sammalt rug grov	1.2		
Møllerens siktet hvetemel	0.9**		
	Minimum	**Middle bound, median**	**Maximum**
Flour (N=3)	0.9**	0.6***	1.2

** Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above limit of detection (LOD) of 0.35 mg Al/kg. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 5: Concentration in dry rice

Product name in Norwegian	Aluminium (mg/kg)		
Harlem food Grøtris	< LOD*		
Toro Jasminris	< LOD*		
	Minimum	**Middle bound, median**	**Maximum**
Rice (N=2)	< LOD*	0.18***	<LOD*

* Below the limit of detection (LOD) 0.35 mg Al/kg.
*** The middle bound approach has been used in calculation of the median.

Table 6: Concentration in breakfast cereals

Product name in Norwegian	Aluminium (mg/kg)		
Axa Go'dag fruktmüsli	2.2		
Landlord fruktmüsli	3.2		
Euro Shopper Corn Flakes	< LOD*		
Kellogg's Special K	2.7		
First Price Honey puffs	0.7**		
Landlord kakaokuler	26		
Bjørn Lettkokte havregryn	< LOD*		
	Minimum	**Middle bound, median**	**Maximum**
Breakfast cereals (N=7)	< LOD*	2.2***	26

* Below the limit of detection (LOD) of 0.35 mg Al/kg.
** Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 7: Concentration in biscuits

Product name in Norwegian	Aluminium (mg/kg)		
Kraft Foods Ritz	16		
Sætre Salinas	0.8**		
Pauly snack mix	0.9**		
Sætre Mariekjeks	1.4		
Sætre Gjende	< LOD*		
Royal Vanilla	4.8		
Mc Vities milk chokolate	3.5		
Sætre Tom &Jerry	0.6**		
Kavli Lazy Town	3.4		
Sunny Spelt cookies	1.6		
	Minimum	**Middle bound, median**	**Maximum**
Biscuits (N=10)	< LOD*	1.5***	16

* Below the limit of detection (LOD) of 0.35 mg Al/kg.
** Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 8: Concentrations in cakes

Product name in Norwegian	Aluminium (mg/kg)		
Scones Blåbær/Vaniljeform	1.0**		
Calas Vaniljemazarin	< LOD*		
Dancake Hindebærroulade	0.4**		
Calas Sitronkake	0.5**		
Bjørken kakebunn	1.8		
Bakers ferske hveteboller	0.9**		
Mesterbakers Gode Boller	2.2		
	Minimum	**Middle bound, median**	**Maximum**
Cakes (N=7)	< LOD*	0.6***	2.2

* Below the limit of detection (LOD) of 0.35 mg Al/kg.
** Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 9: Concentration in pasta (unprepared)

Product name in Norwegian	Aluminium (mg/kg)		
Eldorado Tagliatelle	5.0		
X-tra U-makaroni	5.6		
Barilla Spaghetti n,5	2.1		
Giovanni Rana Tortellini	1.1**		
Fjordland Tagliatelle	3.7		
	Minimum	**Middle bound, median**	**Maximum**
Pasta (N=5)	1.1**	3.7***	5.6

** Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above the limit of detection (LOD) of 0.35 mg Al/kg. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 10: Concentration in milk

Product name in Norwegian	Aluminium (mg/kg)		
Tine Helmelk	< LOD*		
Tine Lettmelk	< LOD*		
	Minimum	**Middle bound, median**	**Maximum**
Milk (N=2)	< LOD*	0.18***	<LOD*

* Below the limit of detection (LOD) of 0.35 mg Al/kg.
*** The middle bound approach has been used in calculation of the median.

Table 11: Concentration in cheese

Product name in Norwegian	Aluminium (mg/kg)		
Fløtemysost	< LOD*		
Vita hjertego ost	< LOD*		
Synnøve Finden Revet	< LOD*		
Arla Finello Mozerella	< LOD*		
Tine Jarlsberg	< LOD*		
Kavli Skinkeost	0.7 **		
	Minimum	**Middle bound, median**	**Maximum**
Cheese (N=6)	< LOD*	0.18***	0.7**

* Below the limit of detection (LOD) of 0.35 mg Al/kg.
** Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 12: Concentration in potatoes

Product name in Norwegian	Aluminium (mg/kg)		
Poteter Juno	1.1**		
Poteter Ostara	3.1		
	Minimum	**Middle bound, median**	**Maximum**
Potatoes (N=2)	1.1**	1.9***	3.1

** Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above the limit of detection (LOD) of 0.35 mg Al/kg. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 13: Concentration in fresh and canned vegetables

Product name in Norwegian	Aluminium (mg/kg)
Gulrøtter	1.3
Gulrøtter, knaskerøtter	< LOD*
Hodekål	< LOD*
Broccoli	17
Tomater	16
Tomater Cherry	< LOD*
Sopp Sjampinjong (canned)	1.3
Sopp Chestnut (canned)	0.8**

Reddiker	< LOD*		
Salat Hjertesalat	0.7**		
Salat Isbergsalat	< LOD*		
Elfsøen Spinat	17		
Coop mais (canned)	< LOD*		
Exotic mais (canned)	< LOD*		
Coop tomater økologiske (canned)	23		
X-tra Tomater flodde (canned)	2.2		
	Minimum	**Middle bound, median**	**Maximum**
Vegetables (N=16)	< LOD*	0.6***	23

* Below the limit of detection (LOD) of 0.35 mg Al/kg.
** Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 14: Concentration in fresh and canned fruit

Product name in Norwegian	**Aluminium (mg/kg)**		
Dole Ananas (canned)	8.3		
Coop Ananas (canned)	< LOD*		
Cavedish Bananer	< LOD*		
Golden Delicios Epler	7.9		
Cripps Pink Epler	13		
	Minimum	**Middle bound, median**	**Maximum**
Fresh and canned fruit (N=5)	< LOD*	7.9***	13

* Below the limit of detection (LOD) of 0.35 mg Al/kg.
*** The middle bound approach has been used in calculation of the median.

Table 15: Concentration in seeds

Product name in Norwegian	**Aluminium (mg/kg)**		
Solsikkekjerner	5.1		
Sesamfrø	1224		
Gresskarkjerner	35		
Linfrø	17		
	Minimum	**Middle bound, median**	**Maximum**
Seeds (N=4)	5.1	26	1224

Table 16: Concentration in meat and meat products

Product name in Norwegian	**Aluminium (mg/kg)**		
Gilde kjøttdeig	1.3		
Gilde grillpølser	0.8**		
Finnsbråten Wienerpølser	2.5		
Gilde leverpostei	0.9**		
Mills leverpostei	3.6		
Gilde kokt skinke	< LOD*		
Grillstad Jubelsalami	0.8**		
Coop servelat	1.4		
Gilde storfelever	< LOD*		
Gilde lungemos	1.6		
	Minimum	**Middle bound, median**	**Maximum**
Meat and meat products (N=10)	< LOD*	1.0***	3.6

*Below the limit of detection (LOD) of 0.35 mg Al/kg.
**Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 17: Concentration in fish and fish products

Product name in Norwegian	Aluminium (mg/kg)		
Salma laks (prepared without Al-foil)	< LOD*		
Salma laks (prepared in Al-foil, type 1)[a]	0.5**		
Salma laks (prepared in Al-foil, type 2)[a]	0.8**		
Meny laks hel filet med salt og sitron (prepared in Al-foil, type 1)[a]	12		
Meny laks hel filet med salt og sitron (prepared in Al-foil, type 2)[a]	4		
Spar Laks hel filet uten salt og sitron (prepared in Al-foil, type 1)[a]	< LOD*		
Spar Laks hel filet uten salt og sitron (prepared in Al-foil, type 2)[a]	< LOD*		
Findus frossen laks med urter og chilli (prepared without Al-foil)	1.3		
Findus frossen laks med urter og chilli (prepared in Al-foil, type 1)[a]	2.8		
Findus frossen laks med urter og chilli (prepared in Al-foil, type 2)[a]	1.8		
Coop lettsaltet torsk	< LOD*		
Mills kaviar (tube)	< LOD*		
X-tra kaviar (tube)	< LOD*		
Engelsviken pillede reker	1.8		
Godehav pillede reker	0.6**		
Stabburet Makrell i tomat, (canned)	0.5**		
Stabburet Makrell i tomat (tube)	1.0**		
Landlord Makrell i tomat (canned)	0.8**		
	Minimum	**Middle bound, median**	**Maximum**
Fish and fish products (N=18)	< LOD*	0.6***	12

*Below the limit of detection (LOD) of 0.35 mg Al/kg.
**Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.
[a] Salmon was wrapped in aluminium foil and prepared in oven at 190°C for 30 minutes. Type 1 aluminium foil: ICA AB Ovn og grillfolie, Type 2 aluminium foil: EuroShopper aluminium foil.

Table 18: Concentration in powder-based porridges

Product name in Norwegian	Aluminium (mg/kg)		
Nestlè Fruktgrøt, cornflakes og eple	0.6**		
Nestlè Risgrøt 4mnd	0.6**		
Småfolk Havregrøt	2.0		
Hipp Mild grøt med frukt og hvete	< LOD*		
	Minimum	**Middle bound, median**	**Maximum**
Powder-based porridges (N=4)	< LOD*	0.6***	2

*Below the limit of detection (LOD) of 0.35 mg Al/kg.
**Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given
*** The middle bound approach has been used in calculation of the median.

Table 19: Concentration in canned baby food

Product name in Norwegian	Aluminium (mg/kg)		
Småfolk kjøttkaker i brun saus 6 mnd	< LOD*		
Småfolk Fiskegrateng 1 år	0.4**		
Småfolk Mango og banan 6 mnd	< LOD*		
Hipp Mild grøt med grønnsaker 6 mnd	< LOD*		
	Minimum	**Middle bound, median**	**Maximum**
Canned baby food (N=4)	< LOD*	0.18***	0.4**

*Below the limit of detection (LOD) of 0.35 mg Al/kg.
**Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 20: Concentration in infant formula

Product name in Norwegian	Aluminium (mg/kg)		
NAN morsmelkerstatning 4 mnd	0.5**		
Hipp morsmelkerstatning	1.4		
Småfolk morsmelkerstatning 4-12mnd	0.9**		
	Minimum	**Middle bound, median**	**Maximum**
Infant formula (N=3)	0.5**	0.6***	1.4

**Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above the limit of detection (LOD) of 0.35 mg Al/kg. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 21: Concentration in cake mixes

Product name in Norwegian	Aluminium (mg/kg)		
Regal Langpanne sjokoladekake	8.2		
Regal Brownies	4.6		
Regal Gulrotkake	3.5		
Toro Pannekaker	1.3		
Toro Glutenfrie vaffler	2.5		
Toro Langpanne sjokoladekake	13		
Toro Lyse muffins	3.2		
	Minimum	**Middle bound, median**	**Maximum**
Cake mixes (N=7)	1.3	3.5	13

Table 22: Concentration in sweets

Product name in Norwegian	Aluminium (mg/kg)		
Freia Gelepynt	1.0**		
Freia Sølvkuler	< LOD*		
Brynhild Orginal Supermix	1.8		
Brynhild Sur Supermix	1.1**		
Fazer Tutti Frutti smoothiemix	0.5**		
Ahlgrens Biler	0.8**		
First Price Seigmenn	1.9		
	Minimum	**Middle bound, median**	**Maximum**
Sweets (N=7)	< LOD*	0.6***	1.9

*Below the limit of detection (LOD) of 0.35 mg Al/kg.
**Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 23: Concentration in chocolate and chocolate products

Product name in Norwegian	Aluminium (mg/kg)		
Ferrero Kinder Bueno	4.7		
Eldorado Lys kokesjokolade	22		
Freia Selskapssjokolade	32		
Freia Melkesjokolade	4.3		
Freia Kvikkluch	3.6		
Stabburet Nugatti	8.9		
	Minimum	**Middle bound, median**	**Maximum**
Chocolate/chocolate products (N=6)	3.6	6.8	32

Table 24: Concentration in desserts

Product name in Norwegian	Aluminium (mg/kg)		
Freia Karamellpudding	1.0**		
Freia sjokoladepudding	4.3		
Tine Piano jordbærgele	< LOD*		
Tine Piano sjokoladepudding	4.6		
Tine Piano Riskrem	< LOD*		
	Minimum	**Middle bound, median**	**Maximum**
Dessert (N=5)	< LOD*	0.6***	4.6

*Below the limit of detection (LOD) of 0.35 mg Al/kg.
**Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 25: Concentration in ready-to-cook food (prepared according to packaging instruction)

Product name in Norwegian	Aluminium (mg/kg)		
Findus Fransk fiskegrateng (tray[a])	0.7**		
First Price Fiskegrateng (tray[a])	0.5**		
Familien D Lasagne (tray[a])	5.5		
Gilde Kjøttpudding (tray[a])	1.0**		
Kyllingvinger (tray[a])	3.7		
Spaghetti (canned[a])	3.3		
Ternia Brun lapskaus (canned[a])	0.5**		
Fjordland ferske tortellini (plastic bag)	11		
	Minimum	**Middle bound, median**	**Maximum**
Ready-to-cook food (N=8)	0.5**	2.0***	11

**Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above the limit of detection (LOD) of 0.35 mg Al/kg. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.
[a] Aluminium packaging

Table 26: Concentration in ready-to-cook potato products (prepared according to packaging instruction)

Product name in Norwegian	Aluminium (mg/kg)		
EuroShopper Pommes frites	< LOD*		
Eldorado Pommes Noisettes	0.7**		
Hoff Potetbåter med skall	1.6		
Hoff Røsti	0.6**		
	Minimum	**Middle bound, median**	**Maximum**
Ready-to-cook potato products (N=4)	< LOD*	0.6***	1.6

*Below the limit of detection (LOD) of 0.35 mg Al/kg.
**Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above LOD. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 27: Aluminium Concentration in coffee white (powder for milk substitution)

Product name in Norwegian	Aluminium (mg/kg)		
Nestlè Coffee-Mate	< LOD*		
Cafe Crown Milky Coffee creamer	2.3		
Frieschevlag Completa	5.4		
	Minimum	**Middle bound, median**	**Maximum**
Coffee white (N=3)	< LOD*	2.3	5.4

* Below the limit of detection (LOD) of 0.35 mg Al/kg.

Table 28: Concentration in snacks wrapped in aluminium bags

Product name in Norwegian	Aluminium (mg/kg)		
Kims Potetgull salt	1.2		
Maarud Sourcream&Onion	6.1		
Coop Potetgull salt	0.6**		
Polly Peanøtter Salt	0.6**		
Kims Elias salt	1.2		
Stark Smoki	2.9		
	Minimum	**Middle bound, median**	**Maximum**
Snacks in aluminium bags (N=6)	0.6**	1.2***	6.1

**Below the limit of quantification (LOQ) of 1.2 mg Al/kg, but above the limit of detection (LOD) of 0.35 mg Al/kg. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 29: Concentration in spices

Product name in Norwegian	Aluminium (mg/kg)		
Rajan Chilli Powder (in box)	416		
Hindu Biffkrydder (in glass)	125		
Hindu Oregano (in bag)	926		
Hindu Timian (in bag)	1005		
	Minimum	**Middle bound, median**	**Maximum**
Spices (N=4)	125	671	1005

Table 30: Concentration in tapped and bottled water

Product name in Norwegian	Aluminium (mg/L)		
Eden Isklar	0.003**		
Ringnes Imsdal	< LOD*		
Tap water	0.004		
Maximum Concentration of aluminium given in Drikke-vannsforskriften (National Regulation of drinking water)	0.2		
	Minimum	**Middle bound, median**	**Maximum**
Water (N=4)	< LOD*	0.002***	0.2

*Below the limit of detection (LOD) of 0.001 mg Al/L.
**Below the limit of quantification (LOQ) of 0.004 mg Al/L, but above LOD.
*** The middle bound approach has been used in calculation of the median.

Table 31: Concentration in tea (prepared[a])

Product name in Norwegian	Aluminium (mg/L)		
Lipton Yellow label	4		
Landlord Earl Gray	5		
Twinigs Classic	4		
Ricola Urtete	0.02		
Lipton Rosehip	0.11		
	Minimum	**Middle bound, median**	**Maximum**
Tea (N=5)	0.02	4	5

[a] The tea was prepared as 5 g leaves in 2 dl hot water.

Table 32: Concentration in coffee (prepared)

Product name in Norwegian	Aluminium (mg/L)		
Kjeldsberg kaffe	0.02		
Friele frokostkaffe	0.013		
Nescafe Gull	0.013		
Friele Instant	0.035		
Musetti espressokaffe[a]	0.14		
Illy espressokaffe[a]	0.06		
	Minimum	**Middle bound, median**	**Maximum**
Coffee (N=6)	0.013	0.03	0.14

[a] Espresso coffee (16 g and 2 dl water) was prepared in an aluminium pot.

Table 33: Concentration in 'saft' concentrate[a]

Product name in Norwegian	Aluminium (mg/L)		
Nora Bringebærsaft	2		
Lerum Eple og pæresaft	0.5		
	Minimum	**Middle bound, median**	**Maximum**
"Saft" (N=2)	0.5	1.3	2

[a]'Saft' is a traditional Norwegian product subjected to national legislation, and cannot be translated directly into English. 'Saft' is a fruit concentrate which is to be mixed with water before drinking.

Table 34: Concentration in cocoa (prepared according to packaging instruction)

Product name in Norwegian	Aluminium (mg/L)		
Freia Regia kakaopulver	0.002**		
Options kakaodrikk	0.26		
	Minimum	**Middle bound, median**	**Maximum**
Cocoa (N=2)	0.002**	0.13***	0.26

* Below the limit of quantification (LOQ) of 0.004 mg Al/Litre, but above the limit of detection of 0.001 mg Al/L. The actual analysed value is given.
*** The middle bound approach has been used in calculation of the median.

Table 35: Concentration in soft drinks

Product name in Norwegian	Aluminium (mg/L)		
CocaCola (can)	0.19		
CocaCola (glass bottle)	0.018		
Ringnes Solo (plastic bottle)	0.031		
Urge Intense (can)	0.040		
	Minimum	**Middle bound, median**	**Maximum**
Soft drinks (N=4)	0.018	0.036	0.19

Appendix 3. Aluminium concentrations in cosmetics.

Aluminium concentrations in cosmetics were analysed by the Norwegian Institute for Air Research (NILU, 2011) on commission from the Norwegian Food Safety Authority. Total aluminium concentration was analysed by high resolution inductively coupled plasma mass spectrometry (HR-ICPMS) following microwave assisted acid decomposition.

VKM has modified the tables from the NILU report (2011) with regard to the given minimum and maximum values and calculated the median value.

Table 1: Concentration in lipstick/lip gloss.

Product name in Norwegian[a]	**Aluminium (g/kg)**		
Estee Lauder IEO	6.0		
Dior Rouge 966	11		
Clarins Joli Rouge 704	11		
L'Oreal 502	7.0		
Max Factor 820	13		
Boots No 7	8.6		
Lipgloss H&M	0.79		
Maybeline 530	28		
Isadora 47	0.52		
Lypsyl Kiss in a Tube	< LOD*		
Maybeline Super Stay Gloss	0.74		
	Minimum	**Median**	**Maximum**
Lipstick/lip gloss (N=11)	< LOD	7.7	28

* Below the limit of detection (LOD) of 0.35 mg Al/kg.
[a] From three parallels of each products, 0.3 g sample was collected.

Table 2: Concentration in antiperspirants.

Product name in Norwegian[a]	**Aluminium (g/kg)**		
Cosmica Body Roll on ACO	71		
Special Care ekstra effektiv antiperspirant ACO	42		
Lilleborg Sterilan Men Power	41		
Colgate-Palmolive Palmolive Naturals Invisible	39		
Lilleborg Vaseline Intensive Care Cooling m/Aloe Vera	46		
Lilleborg Dove	28		
Colgate-Palmolive Palmolive Naturals Delicate Fresh	39		
LdB Puls Sport	58		
	Minimum	**Median**	**Maximum**
Antiperspirants (N=8)	28	41	71

[a] Liquid deodorants were shaken prior to sample collection of 0.3 g. From deodorant sticks small pieces were collected, in total 0.3 g sample.