# Aluminium-containing antiperspirants contribute to aluminium intake

BfR opinion No. 007/2014, 26 February 2014

Antiperspirants denote cosmetic products with an anti-perspiration effect which are available as roll-ons, sticks, creams or aerosols (sprays). The anti-perspiration effect is achieved by means of aluminium salts which block the ends of the sweat ducts for a certain amount of time. The safety of aluminium and antiperspirants continues to be critically examined. This is notably true with regard to possible development of Alzheimer's disease and the development of breast cancer. Scientific evidence shows that high doses of aluminium have neurotoxic effects on humans and embryotoxic effects in animal studies.

Not much is known, however, about the absorption of aluminium via the skin from cosmetic products, nor about the effects this may have. In this area, there is a lack of important studies involving human data. In contrast, the absorption rate and effect of aluminium via food is well researched. As an element found on earth, aluminium is naturally contained in numerous plant-based foods as well as drinking water. Additionally, some aluminium compounds are, in certain quantities, permitted in foods as food additives. Apart from antiperspirants, decorative cosmetics such as lipstick and eye shadow as well as toothpaste and sunscreen can contain aluminium.

For oral intake from food, the European Food Safety Authority (EFSA) has derived a tolerable weekly intake (TWI) of 1 milligram (mg) of aluminium per kilogram of bodyweight. In its health assessment, the EFSA states a medium bioavailability of 0.1 % for all aluminium compounds which are ingested with food. This corresponds to a systemically available tolerable daily dose of 0.143 microgrammes (µg) per kilogramme (kg) of body weight. This means that for an adult weighing 60 kg, a systemically available dose of 8.6 µg per day is considered safe.

The Federal Institute for Risk Assessment (BfR) has assessed the estimated aluminium absorption from antiperspirants. For this purpose, the data, derived from experimental studies, on dermal absorption of aluminium from antiperspirants for healthy and damaged skin was used as a basis. At about 10.5 µg, the calculated systemic intake values for healthy skin are above the 8.6 µg per day that are considered safe for an adult weighing 60 kg. If alumiunium-containing antiperspirants are used on a daily basis, the tolerable weekly intake determined by the EFSA is therefore exceeded. The values for damaged skin, for example injuries from shaving, are many times higher. This means that in case of daily use of an aluminium-containing antiperspirant alone, the TWI may be completely exhausted. In addition, further aluminium absorption sources such as food, cooking utensils and other cosmetic products must be taken into account.

Consumers already ingest large amounts of aluminium through food. This means that for a segment of the population, the tolerable weekly intake quantity is probably reached through food alone. In case of long-term use of aluminium-containing cosmetic products, the TWI could be permanently exceeded and aluminium could accumulate in the body. However, scientific uncertainties still exist, for example in relation to the effective penetration rate and the long-term effects of chronic aluminium exposure.

In principle, individual intake can be reduced. Aluminium-containing cosmetic products such as antiperspirants and creams contribute to a person's overall aluminium intake. Aluminium absorption via antiperspirants is notably lowered, if such products are not applied to the skin

immediately after shaving or to damaged armpit skin. Alternatively, a deodorant without any aluminium additives can be used.

Despite a series of relevant studies, it has not been possible so far to provide scientific evidence of a causal relationship between elevated aluminium intake from antiperspirants and Alzheimer's disease and / or breast cancer. This lack of evidence is due to the inconsistent data currently available.

In the opinion of the BfR, a need for research notably exists with regard to the effective absorption quantity of aluminium through the skin. In addition, the BfR does not have any data to conduct a risk assessment of aluminium following long-term dermal exposure. Only if such information is available can a final risk assessment of the health effects of aluminium-containing antiperspirants and other cosmetic products be conducted.

**BfR risk profile:**
**Aluminium-containing antipersprants (Opinon No. 007/2014)**

| | | | | | | |
|---|---|---|---|---|---|---|
| A | **Who is affected** | **General population** | | | | |
| B | **Probability of health impairment in case of using aluminim-containing antipersparants** | Practically non-existant | Unlikely | **Possible** | Probable | Certain |
| C | **Severity of health impairment in case of using aluminium-containing antipersparants[1]** | **No immediate impairment** | | | | |
| D | **Validity of available data [2]** | High: The most important data is available and there are no contradictions | | Medium: Some important data is missing | | **Low: much important data is missing or contradictory** |
| E | **Controllability by the consumer [3]** | Control not necessary | **Controllable through precautionary measures** | Controllable through avoidance | | Not controllable |

Text fields with dark blue background characterise the properties of the risk assessed in this opinion
(more detailed information on this can be found in the text of BfR opinion No 007/2014 of 26. Februar 2014)

**Notes**

The purpose of the risk profile is to visualise the risk described in the BfR opinion. It is not intended for risk comparisions. The risk profile should only be read in the context of the opinion.

**Line C – Severity of health impairement in case of using aluminium containing antipersparants**
[1] - Scientific evidence shows that high doses of aluminium have neurotoxic effects on humans and embryotoxic effects in animal studies. Despite a series of relevant studies, it has not been possible so far to provide scientific evidence of a causal relationship between elevated aluminium intake from antiperspirants and Alzheimer's disease and / or breast cancer. This lack of evidence is due to the inconsistent data currently available.

**Line D – Validity of available data**
[2] - There is a lack of human data. The BfR is of the opinion that research is needed on the actual quantities of aluminium absorbed through the skin and on long-term dermal exposure to aluminium.

**Line E – Controllability by the consumer**
[3] – The information given in the row „Controllability by consumers" is not intended as a BfR recommendations but is of a descriptive nature only. The BfR made recommendations for action in its opinion: It is possible to reduce individual aluminium intake. Cosmetic products such as aluminium-containing antiperspirants and creams contribute to the overall intake of aluminium. Aluminium absorption can notably be minimised by ensuring that aluminium-containing antiperspirants are not used immediately after shaving nor on damaged armpit skin. Instead, deodorants without aluminium salts can be used.
BUNDESINSTITUT FÜR RISIKOBEWERTUNG (BfR)

## 1 Subject of the Assessment

As the third-most abundant element found in the earth crust, aluminium is a natural component of drinking water as well as many untreated foods such as fruit and vegetables. Further sources of aluminium intake in humans are certain food additives and aluminium-containing consumer goods such as cooking utensils, cans, foils or tubes from which the light metal can be transferred to food. In 2008, the European Food Safety Authority (EFSA) defined a tolerable weekly intake (TWI) of 1 mg of aluminium / kg of bodyweight. A further source of aluminium exposure are cosmetic products. In antiperspirants, aluminium salts are used due to their anti-perspiration properties.

In recent years, the safety of aluminium intake from the mentioned sources including cosmetic products has repeatedly been critically examined. This notably applies to the possible development of breast cancer and Alzheimer's disease. According to some reports, Alzheimer's patients showed increased aluminium concentrations in the affected brain regions.

Based on more recent studies, for example on the penetration of aluminium salts from antiperspirants into human skin (Pineau et al., 2012) as well as risk assessments by the authorities in France and Norway (AFSSAPS, 2011; VKM, 2013), the Federal Institute for Risk Assessment (BfR) has assessed consumer exposure to aluminium from antiperspirants. The Scientific Committee Scientific Committee on Consumer Safety, SCCS of the European Commission is currently also conducting a risk assessment of aluminium in cosmetic products.

## 2 Result

The estimated aluminium intake from antiperspirants may be within the range which the EFSA has defined as the tolerable weekly intake (TWI). Exceeding this value leads to a decrease in the safety margin to the (maximum) dose which in animal experiments (only just) does not have any adverse health effects (NOAEL, no observed adverse effect level).

Due to the inconsistent data situation, no sound scientific evidence has, despite a series of relevant studies, emerged to date to prove a connection between, on the one hand, elevated aluminium intake from antiperspirants, food and drinking water or certain aluminium-containing drugs (so-called antacids) and, on the other hand, Alzheimer's disease and / or breast cancer.

Consumers already ingest large quantities of aluminium via food, and for a proportion of the population, the tolerable weekly intake is probably reached through food alone. In case of long-term use of aluminium-containing cosmetic products, the TWI could be permanently exceeded and aluminium could accumulate in the body. However, scientific uncertainties still exist, for example in relation to the effective penetration rate and the long-term effects of chronic aluminium exposure.

It is possible to reduce individual aluminium intake. Cosmetic products such as aluminium-containing antiperspirants and creams can contribute to a person's overall aluminium intake. Aluminium absorption via antiperspirants is notably lowered, if such products are not applied to the skin immediately after shaving or to damaged armpit skin. Alternatively, deodorants without any aluminium additives can be used.

## 3 Statement of Reasons

The BfR has assessed the presence of aluminium in certain foods and consumer goods on more than one occasion in the past (BfR 2012, 2008, 2007, 2002). Since aluminium salts are frequently used in antiperspirants, the intake of aluminium from such cosmetic substances has been estimated and assessed in addition to the already mentioned sources.

### 3.1 Risk Assessment

A search of the current literature was conducted in the following databases: DIMDIs databases, ISI/Web of Science, Pubmed, Scopus, ScienceDirect, NTP, Litdoc, Chemici (last updated: September 2013).

#### 3.1.1 Agents

One of the main sources of exposure to aluminium for humans is food. Being the third-most abundant element found in the earth crust, aluminium is a natural component of human nutrition, especially of plant-based foods (EFSA, 2008). Many compounds of the metal are water-insoluble when pH-neutral; however solubility increases if the pH becomes acidic or alkaline. The existence of aluminium in food can be traced back to different sources. Apart from the natural presence mentioned, certain aluminium-containing additives can be added to particular foods. In addition, aluminium can migrate to food from aluminium-containing food contact materials such as cooking utensils, kitchen equipment and packaging materials. Aluminium is also contained in drinking water, certain drugs and consumer products. In the cosmetic industry, aluminium compounds have been used, especially aluminium chlorohydrate (aluminium hydroxychloride, CAS-No. 1327-41-9), since the beginning of the 1960s. They are predominantly used as active ingredients in antiperspirants. Whereas the use of substances belonging to the group of aluminium zirconium chloride hydroxides or its complexes with glycine is restricted to a maximum of 20 % (as water-free aluminium zirconium chloride hydroxide) by the European Cosmetics Regulation (Regulation (EC) No. 1223/2009), aluminium chlorohydrate is currently not regulated. According to information obtained by the BfR, concentrations of approximately 20 % are common in antiperspirants. This is the equivalent of an aluminium proportion of approximately 5 %. In contrast, the group fact sheets of the Industrial Association for Body Care and Cleaning Products (Industrieverband Körperpflege- und Waschmittel e.V.) state, for example for antiperspirant creams, concentrations of up to 30 % aluminium chlorohydrate (Association for Body Care and Cleaning Products, 2012). In addition, aluminium compounds are found, for example, as coating of titanium dioxide in sunscreens, as a colour pigment in decorative cosmetic products and, in the form of aluminium fluoride, in some toothpastes.

Aluminium has a double anti-perspiration effect. On the one hand, it causes the pores of the skin to close (adstringent effect). On the other hand, it forms a jellylike protein complex which acts as a kind of plug temporarily blocking the ends of the sweat ducts.

3.1.2 Hazard Potential

Aluminium compounds can irritate the skin. No irreversible toxic effects following dermal application are described in the literature, however. The BfR at this point only has limited data on the absorption of aluminium through the skin, e.g. from cosmetic products (see Item 3.1.3 Exposure). An *in-vivo* study showed a penetration rate of approximately 0.014 % (Flarend et al., 2001).

Following oral ingestion, resorption of aluminium from the gastronitestinal tract is usually low in humans: it amounts to a maximum of 1 % and, in case of high intake (>1 g aluminium) drops as low as 0.01 %. In the presence of certain anions such as citrate or ascorbate (e.g. from fruit juices) oral resorption can increase. The concentration in blood serum is given as 1-3 µg/L (Liao et al., 2004).

Aluminium intake from food varies greatly between individuals. For adults it is in the range between 1.6 mg and 13 mg per day (EFSA, 2008). When aluminium is ingested with food, its acute toxicity is low. There is evidence of interaction with phosphate and calcium metabolism in humans and in animal experiments. For high doses of aluminium chloride (355 mg/kg) mice showed a reduction in phosphate retention. At levels of 0.1 % and 0.2 % aluminium chloride in feed, functional or neurochemical changes were observed. However, no evidence of the neurofibrillary degeneration typical of Alzheimer's disease was found in studies involving administration of aluminium to animals.

Whereas studies on the reproductive toxicity did show embryotoxic effects, if high doses of aluminium were used, no teratogenic effects (deformities) were observed (Schmidt and Grunow, 1991). The oral feeding studies on different species (mice, rats, dogs) assessed by the AFC-Panel (Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food) of the EFSA showed values between 50 and 75 mg/kg of bodyweight per day for the lowest observed effect level (LOEL). For the lowest LOEL value derived from these studies, an additional uncertainty factor of 3 was, in addition to the usual uncertainty factor of 100, taken into account for uncertainties resulting from the data basis used (no defined value for no observed adverse effect level (NOAEL, no chronic studies). This resulted in a TWI of 1.2 mg/kg of body weight. Similarly, the lowest NOAEL of 10 mg/kg of bodyweight per day of a study to determine the developmental and neurotoxic effects of aluminium on mice resulted in a TWI of 0.7 mg/kg of bodyweight. From both values, the AFC Panel of the EFSA derived a value of 1 mg/kg of bodyweight in 2008 (JECFA, 2012; EFSA, 2008).

For all aluminium compounds from food, the EFSA states a median oral bioavailability of 0.1 %. This means that the TWI for an adult weighing 60 kg converts to a systemically available dose of 8.6 µg/day (0.0086 mg/day).

In contrast, a more recent study on the developmental neurotoxicity conducted with rats by Poirier et al. (2011) calculated a NOAEL of 30 mg/kg bodyweight per day. Factoring in an uncertainty factor of 100, the Joint FAO/WHO Expert Committee on Food Additives, JECFA) determined a provisional tolerable weekly intake, PTWI) of 2 mg/kg of bodyweight / week (JECFA, 2012).

Neurotoxic effects in humans were observed, for example, in patients parenterally exposed to high doses of aluminium. The effects took the form of a so-called dialysis encephalopathy. (Candy et al, 1992). If aluminium is administered parenterally, i.e. not via food but, bypassing

the gastrointestinal tract, directly to the body (for example as a drug), it is distributed in all tissues and then predominantly excreted via the kidneys. Since the elimination process is slow and incomplete, the light metal gradually accumulates in the body with increasing age, mainly in the skeletal system and the lungs.

Aluminium can pass the blood brain barrier and enter the brain via two different mechanisms which probably occur in parallel: on the one hand, via a transport system which is coupled to citrate, i.e. the salt of citric acid (Yokel et al., 2002); on the other hand, attached to transferrin, a transport protein for iron, via its receptor (Yokel et al., 2002a).

The neurotoxic effect of aluminium has been linked to Alzheimer's disease. Different epidemiological studies attempting to prove a connection between aluminium intake from drinking water and Alzheimer's disease do not provide sound scientific evidence due to the inconsistent data situation. The World Health Organisation (WHO) reached the conclusion that increased aluminium intake is very unlikely to be a causal factor for Alzheimer's disease (IPCS, 1997).

Equally, no causal relation has so far been scientifically established between the intake of aluminium from cosmetic products and the development of cancer, especially breast cancer. Indications for such a connection arose from studies on breast cancer patients who showed significantly higher aluminium contents in the tissue of the typically affected outer breast region (axillary quadrant) compared to the inner (medial) area (Exley et al., 2007). Whereas some researchers made a link between this observation and the use of aluminium-containing antiperspirants (Darbre, 2001), others advanced the explanation that the increased presence of tumours is due the fact that the outer areas of the breast contain more tissue (Lee, 2004). Two studies published in 2011 in which mammary gland tissue and secretion of both cancer patients and healthy women were tested for aluminium contents again suggested a possible link (Mannello et al., 2011, Romanowicz-Makowska et al., 2011). In contrast, another group detected no differences in the aluminium contents of healthy versus tumour tissue of cancer patients (Rodrigues-Peres et al., 2013). However, there was no control group consisting of healthy women in this study.

Nor do these studies explain whether aluminium is the trigger of cancer or simply constitutes a concomitant of it. Indications that aluminium is more likely to accumulate in tumour tissue as a consequence of cancer than being its cause is suggested by a study involving animal experiments conducted in 1994 (Ogoshi et al., 1994). By administering a carcinogenic substance (2.7-Dimethylbenz[*a*]anthracene) with the feed, tumours were triggered in the mammary gland of rats. Higher levels of aluminium were discovered in the breast tissue of animals with tumours compared to the healthy control animals.

An epidemiological case study found a correlation between the use of aluminium-containing antiperspirants and the incidence of breast cancer (McGrath, 2003). However, two further studies did not (Mirick et al., 2002; Fakri et al., 2006). In addition, even high dosages of up to 850 mg/kg of bodyweight / day did not produce any carcinogenic effects in animal experiments.

Having critically evaluated all published studies on the subject, a French panel of experts concluded in 2008 that the use of aluminium-containing antiperspirants probably does not constitute a risk factor for the development of breast cancer (Namer et al., 2008). The EFSA too holds the view that aluminium is unlikely to have carcinogenic potential for humans in nutritionally relevant doses (EFSA, 2008).

Apart from its neurotoxic effects and its impact on bone development, its toxic effect on reproduction and embryo development are major manifestations of the hazard potential of aluminium (Krewski, 2007). Thus various animal studies describe the embryotoxic potential of aluminium. The toxicity largely depended on the exposure route and / or the solubility of the aluminium compound used (Domingo, 2000). The concentrations used were much higher, however, than those which are reached when antiperspirants are used. For this reason, it is unlikely that the use of aluminium-containing antiperspirants leads to concentrations in the embryo or foetus which would do harm to the unborn child.

Aluminium is found in low concentrations in breast milk. In a study by Hawkins, aluminium concentrations were measured in the blood plasma of infants who had been fed either breast milk or various preparations of infant and follow-on formula (Hawkins, 1994). It was found that for infants who were fed breast milk containing 9.2 µg aluminium/L, the concentration in blood plasma was, at 8.6 µg/L roughly the same as in babies fed formula for premature babies (300 µg Aluminium/L) whose blood plasma on average showed 9.7 µg/L. While it is true that the use of an aluminium-containing antiperspirant would lead to some increase in the aluminium concentration of breast milk, it is nevertheless unlikely that this would lead to an increase in the concentration in the blood plasma of infants.

### 3.1.3 Exposure

Based on the information available to the BfR, the main active ingredient used in antiperspirants is aluminium chlorohydrate in a concentration of about 20 %. This corresponds to an aluminium content of approximately 5 %.

An *in-vitro* study published in 2012 on the penetration of aluminium through human skin calculated penetration rates for the formulations “Deospray”, “Roll-On” and “Stick” of 0.65 %, 0.18 % and 0.96 % respectively (Pineau et al., 2012). At the same time as determining the penetration rate for intact skin, Pineau and colleagues also tested the penetration rate of “Stick” formulation on skin damaged by “Tape stripping”. The penetration rate found here was 5.9 % (Pineau et al., 2012). The BfR is currently aware of only one *in-vivo* study on the skin penetration of aluminium chlorohydrate in human subjects (Flarend et al., 2001). On the basis of the excreted quantity of isotope-marked aluminium over 14 days in the urine, which was the equivalent of 0.012 % of the applied quantity, the authors calculated a penetration rate of approximately 0.014 %. This value deviates by at least factor 12 from the penetration rates, which were determined in the *in-vitro* experiment. Possible explanations for this discrepancy are explained in Chapter 3.1.4.

On the basis of the Notes of Guidance of the SCCS (SCCS, 2012) with the penetration rates, determined through the *in-vitro* experiment, for two applications on an area of 200 cm² systemic exposure rates (SED) of 0.0107 (spray), 0.002 (roll-on) and 0.0105 (stick) mg/kg of bodyweight/day were calculated. For skin damaged by “tape stripping”, the SED was 0.0745 mg/kg of bodyweight/day. For an adult weighing 60 kg, this would result in possible systemic absorption of 0.64 mg (spray), 0.12 mg (roll-on), 0.63 mg (stick) and 4.5 mg (stick, damaged skin) of aluminium per day.

By comparison, if the penetration rate from the *in-vivo* experiment (Flarend et al., 2001) is used as a basis, this results in an SED of 0.175 µg/kg of bodyweight/day or, for an adult of 60 kg, a daily absorption of 0.0105 mg of aluminium.

### 3.1.4 Risk Characterisation

As can be gleaned from Chapter 3.1.3, the possible systemic exposure doses vary to a great extent. This is due to a number of factors which are explained in detail below.

On the one hand, the determination of the penetration rate of aluminium from aluminium compounds through *in-vitro* experiments, calculated from the sum of the penetration of aluminium into the epidermis (exclusive *stratum corneum*), dermis and the receptor fluid may be subject to artefacts (adulteration). This adulteration might be due to the way the agent works (e.g. by blocking the ends of the sweat ducts, see, among others, Yanagishita et al., 2012). This means that the effective systemic absorption is probably lower than calculated in this study. The *in-vitro* experiment conducted by Pineau did not find any higher aluminium levels in the receptor fluid than the blank value. Since, however, an astringent (contracting) effect of the aluminium salt is postulated which would in term mean binding to cellular proteins, at least low systemic availability of the applied aluminium seems possible. This was indeed confirmed by the *in-vivo* experiment conducted by Flarend. However, the *in-vitro* experiment unequivocally shows the already known influence of the formulation on the penetration rate (Samaras et al., 2012).

“Tape stripping” before application of the agent to be tested done in *in-vitro* experiments strive to simulate the scenario of skin with impaired barrier function. Various studies have shown that the penetration rate for substances is generally higher for damaged than for undamaged skin (see Gattu & Maibach, 2009). It is unknown, however, to what extent the data calculated by Pineau and colleagues can be transferred to shaved skin. Up to 36 % of the biological material removed through shaving of the armpits consists of keratinised cells (*stratum corneum*) and leads to short-term functional impairment of the barrier against exogenous substances (Marti et al., 2003; Turner et al., 2007; Evans et al., 2012). An increase in penetration, especially in case of small injuries from shaving, therefore seems likely. The penetration through damaged skin was measured by Pineau under occlusion, i.e. by covering the treated skin area with an (airtight) plaster. This results in a higher moisture content of the skin and usually results in an increase in penetration.

The only *in-vivo* study on the skin penetration of aluminium from aluminium chlorohydrate-containing antiperspirants only involved two subjects, a man and a woman (Flarend et al., 2001). The data showed major differences between the two test persons. On the basis of the excreted quantity of isotope-marked aluminium over 14 days via the urine, the authors calculated a penetration rate of approximately 0.014 %. Since aluminium chlorohydrate, for example, was not used in any cosmetic formulation, but in a solution and the experiment was conducted under occlusion, it is conceivable that the calculated penetration rate does not correspond to what would have been found under realistic conditions. The quantity applied (per area) also has an influence on the level of penetration. This is usually inversely correlated to penetration, i.e. for large quantities the penetration rate is lower than for small quantities. In case of an applied quantity of 75 mg of aluminium, the effective penetration rate could therefore be lower than the 0.014 % that Flarend and colleagues determined for approximately 13 mg of applied aluminium.

In case an aluminium-containing antiperspirant in the form of a spray is used, the possibility of inhaling must be taken into account in addition to dermal absorption. Studies showed that the inhalation absorption of aluminium is greater than the absorption via drinking water for which an oral bioavailability of 0.3 % is assumed. It must be taken into account, however, that only particles with a size <10 µm are considered to be respirable (Rothe et al., 2011; Heyder et al., 1986). A study on the inhalation of aluminium chlorohydrate-containing sprays on monkeys showed that following a five-second jet straight in the face of the monkeys, only

a small proportion of the spray remained in the lungs. The majority of the substance was excreted again through breathing over the following 14 days (Finkelstein & Wulf, 1974).

In addition, the exposed skin surface is possibly greater for the use of an aerosol than if a stick or roll-on is used, whereas the applied quantity is typically lower, according to the Notes of Guidance of the SCCS.

Based on the the current TWI amounting to 1 mg/kg of bodyweight for the total intake of aluminium via food (EFSA 2008), this results in a tolerable intake of 0.14 mg/kg of bodyweight per day. For an oral bioavailability of 0.1 % for all aluminium compounds ingested with food, this corresponds to a systemic absorption of 0.14 µg per kg of bodyweight / day (equivalent to 0.00014 mg/kg of bodyweight/day ). Daily use of an aluminium-containing antiperspirant alone with a possible absorption of 0.175 µg/kg of bodyweight/day (corresponds to 0.000175 mg/kg of bodyweight/day) would therefore completely exhaust the TWI or even exceed it. Exceeding the TWI does not directly lead to health problems but means a reduction in the safety margin. Exceeding this value on a permanent basis would not be tolerable from a toxicological viewpoint.

Since antiperspirants are not the only aluminium source for consumers, calculating the safety margin for a single product cannot be the goal of risk assessment. Rather, it is important to take into account the cumulative aluminium intake from all sources such as food, cooking utensils and other cosmetic products as well as the possibility that an aluminium-containing product is applied several times a day and / or on shaved or damaged skin.

Regular use of an aluminium-containing antiperspirant over decades could potentially lead to increased aluminium levels in the body which at a later stage might lead to health impairments. The BfR does not have scientific data enabling estimation of long-term effects of chronic aluminium exposure. For this reason, the BfR cannot conduct a conclusive risk assessment.

### 3.2 Other Aspects

Apart from aluminium-containing antiperspirants there is a host of other cosmetic products containing aluminium compounds such as lipsticks, toothpastes, creams and sun lotions. Due to their application to large areas, sun lotions in particular can significantly increase the intake of aluminium from cosmetic products. This is justified by the assumption that under certain conditions, detachment of aluminium coating of titanium oxide nanoparticles used in some sunscreens could occur (Virkutyte et al., 2012). A study by Nicholson and Exley (2007) calculated that if such products are applied five times a day, up to 1000 mg of aluminium are applied per day. At a penetration rate of 0.014 % this would mean additional absorption of approximately 140 µg (0.14 mg). However, the BfR has not seen any data on the penetration of aluminium from coatings of titanium oxide in sunscreens through human skin.

Furthermore, aluminium chlorohydrate-containing (5 %) skin creams, recommended also for use on damaged skin, is available on the market. The manufacturer recommends that the cream is applied several times a day (before start of work and after breaks). In case of occupational use, e.g. as a medicinal product, a separate benefit / risk analysis would have to be conducted.

## 4 Measures / Framework of Action

The wide range of exposure doses ascertained clearly shows the urgent need for research in order to establish the actual penetration rate under realistic conditions. This is essential for a risk assessment of the health implications of aluminium-containing antiperspirants.

Even if it has not been possible so far to provide scientific evidence of a causal relationship between increased aluminium intake and incidence of breast cancer and / or Alzheimer's disease, the overall exposure of consumers should, given the proven developmental and neurotoxicity of aluminium, not lead to a situation where the TWI is exceeded on a permanent basis. Although aluminium intake through the skin is probably very low, even such low penetration of approximately 0.014 % (Flarend et al., 2001) could lead to physiologically relevant systemic absorption, if a high external dose is applied. It is possible that this absorption is within the range which the EFSA has defined as the tolerable weekly intake (TWI). Together with other sources of intake such as food this would then make it likely that consumers exceed the TWI. Exceeding this value on a permanent basis would not be tolerable from a toxicological viewpoint.

Consumers already ingest high quantities of aluminium via food, and for a proportion of the population, the weekly tolerable intake is probably exhausted through food alone (Arnich et al., 2013; Fekete et al., 2013; Food Standards Australia New Zealand (FSANZ), 2011). In case of long-term use of aluminium-containing cosmetic products, the TWI could therefore be permanently exceeded and aluminium could accumulate in the body. However, scientific uncertainties still exist, for example in relation to the effective penetration rate and the long-term effects of chronic aluminium exposure.

It is possible to reduce individual aluminium intake. Aluminium-containing cosmetic products such as antiperspirants and creams contribute to overall aluminium intake. Aluminium intake via antiperspirants is notably lowered, if such products are not applied to the skin immediately after shaving, nor to damaged armpit skin. In addition, deodorants are available on the market which do not contain any aluminium salts.

A voluntary note ("Do not apply to damaged skin") already exists in some EU countries and is currently being discussed in others, for example in Austria. For aluminium zirconium chloride hydroxides such a note is, in accordance with Regulation (EC) No. 1223/2009 already compulsory for cosmetic products in Germany. In order to ensure a reduction in aluminium exposure from cosmetic products in the long run, the BfR recommends that the contents of aluminium salts is limited generally, as opposed to only regulating individual aluminium salts such as aluminium zirconium chloride hydroxides.

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