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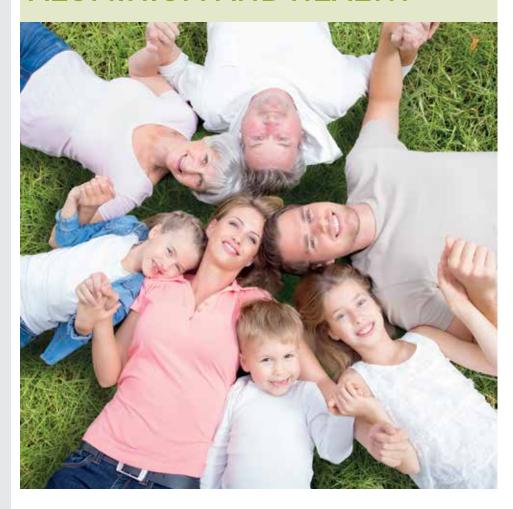
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SPECIAL ISSUE: **ALUMINIUM AND HEALTH**



Time and again critical questions are being asked as to whether aluminium is harmless to health. They include, for example, the question of whether aluminium contributes to the development of Alzheimer's disease or causes breast cancer. GDA's member companies are often asked about aluminium and health by the media, customers, employees, consumers and other stakeholders.

How much aluminium do we take in via unprocessed and processed food? How much aluminium can end up in the body via the skin if we use cosmetics? What effects can aluminium have on health? Questions that are asked again and again.

This special issue of GDA aktuell summarises the important aspects of this topic, offers member companies useful arguments and is intended to be a general contribution towards discussing this matter objectively.





Differentiation between **metallic aluminium** and aluminium compounds

Whenever this subject is discussed in public, people always refer simply to 'aluminium', just as above. Factually this is incorrect. Firstly it should be noted that one needs to differentiate between metallic aluminium and aluminium compounds (in other words compounds of other elements with aluminium in ionic form).

Metallic aluminium, mostly in the form of alloys with other elements, is used in the most diverse range of applications: in the automotive, building and construction, and electronics and electrical industries, and in materials and articles used for packaging, storing and processing food, cosmetics or pharmaceuticals, such as household equipment, cookware, cans, tubes, trays or foil.

Unlike gold or silver, **aluminium** does not occur naturally in metallic form; because of its strong tendency to react chemically it only ever occurs in **compounds**. Aluminium compounds, such as aluminium hydroxides, sulphates, chlorohydrates or fluorides, are also produced synthetically, in other words they are produced artificially in a chemical process. Some synthetic aluminium compounds are manufactured in large quantities. They find use in the most diverse industrial processes, such as water treatment, papermaking or the production of food additives, cosmetics and pharmaceutical products. Humans only take in aluminium in the form of compounds.

With **aluminium compounds** it should be noted that the fraction of aluminium in ionic form in a compound can vary depending on the type of compound. To evaluate the health risk to the consumer due to exposure to aluminium it is

not the aluminium compound as such that is important but merely the fraction of the aluminium in ionic form in the respective compound.

For simplicity, a differentiation will only be made here between metallic aluminium and aluminium compounds. And when one talks about limits for the intake of aluminium, one always means aluminium in ionic form.



Metallic aluminium



Aluminium compounds



Some 8% of the Earth's crust is aluminium

Aluminium is the third most abundant element after oxygen and silicon and the most common metal in the Earth's crust. However, because of its base nature it almost always only occurs in nature as a compound in combination with other elements, for example as a constituent of clay, gneiss or granite. Accordingly, aluminium compounds are also present as natural constituents in numerous unprocessed foodstuffs.

According to a scientific opinion on the safety of aluminium from dietary intake published by the European Food Safety Authority (EFSA) in May 2008, most unprocessed food contains less than 5 mg aluminium/kg.

Higher concentrations (average levels 5-10 mg/kg) are often found in bread, cakes and pastries (with the highest concentrations in biscuits), some vegetables (with the highest concentrations in mushrooms, spinach, radish, Swiss chard, lettuce and corn salad), glacé fruits, dairy products, sausages, offal, shellfish, sugar-rich foods, baking mixes, and the majority of flours and farinaceous products.

Foodstuffs with very high mean concentrations include tea leaves, herbs, cocoa and cocoa products, and spices. Here the average aluminium

content can sometimes be well in excess of

100 mg/kg. ■



What are the sources of our aluminium intake?

The most important sources of the oral intake of aluminium compounds are

- non-processed foodstuffs with a high natural aluminium content (up to 60%)
- food additives (up to 40%).

Of secondary importance are

- food contact materials and articles made of aluminium, such as household utensils, packaging or household foil (1-4%)
- drinking water (1-2%).

According to a report by the European Food Safety Authority (EFSA), our daily aluminium intake via food is 1-15 mg aluminium depending on the country where we live and our dietary habits. This would represent up to 0.2 mg/kg body weight per day for adults and up to about 0,35 mg/kg body weight in the case of children and infants.

In the case of healthy people, more than 99% of the daily aluminium intake via food is discharged via excrement or the kidneys without being taken in by the body. However, for people with a damaged kidney function, especially chronic renal insufficiency (e.g. dialysis patients), the ability to secrete absorbed aluminium is limited; accumulations in the body and health damage (e.g. softening of the bones or damage to the central nervous system) can occur.

Packaging made from or with aluminium, for example (beverage) cans, bottles, tubes, drinks or food cartons, pouches or blisters, are mainly coated or lacquered to prevent a corrosive attack on the aluminium by the contents and a possible release of aluminium compounds into the products. The metallic aluminium is, as it were, being protected against the contents which it actually protects.







Uncoated aluminium materials and articles like cookware or aluminium foil carry advice for the consumer to ensure that they are properly used, pointing out that these items are unsuitable for contact with and/or for the storage of acidic or salty food. It should be noted here that the aluminium oxide that forms on the surface of metallic aluminium on exposure to air is stable over the pH range 4.5 to 8.5.

Intake via the skin

There is currently much discussion as to whether and to what extent the use of cosmetics leads to the intake of aluminium compounds via the skin (dermal ingestion).

Face creams, body lotions, haircare products or make-up can all contain aluminium compounds as additives, usually in small amounts. However, according to information from the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW), most of the aluminium-containing ingredients in cosmetics are practically insoluble so that the intake of aluminium via the skin is impossible. Antiperspirants do contain soluble aluminium salts but these form insoluble complexes on reaction with sweat on the surface of the skin.

Scientific evaluation of known data by IKW shows that the intake of aluminium as a result of the normal daily use of cosmetics like antiperspirants is within the weekly tolerable intake. This also applies when they are used with shaven skin. The German Federal Institute for Risk Assessment (BfR) has carried out its own investigation and points out that daily use may possibly result in the permitted limits being exceeded. However, the BfR says it will only be able to issue a final evaluation of the health risk due to aluminium-containing cosmetic products when the results of further studies are available. A relevant investigation is currently being carried out by an independent scientific institute. The study has been commissioned by an international consortium of companies from the cosmetics industry.





DIFFERENCE BETWEEN ANTIPERSPIRANTS AND DEODORANTS

Aluminium compounds like aluminium chlorohydrate are often used in **antiperspirants**. Aluminium chlorohydrate inhibits sweating as a result of its ability to tighten the skin and the fact that it forms a gel-like



protein complex that temporarily blocks the sweat ducts by acting like a plug. The plug is rejected after a certain time as a part of the skin's natural regeneration process.

Aluminium compounds are rarely used in **deodorants** for their antimicrobial properties. In contrast to antiperspirants, deodorants only tie up volatile, unpleasant smelling compounds and cover up the smell with perfume oils. They do so without blocking the sweat ducts. Deodorants therefore only act in an antibacterial and odour-inhibiting manner without reducing sweating. Underarm perspiration gradually reduces the antibacterial protection so that the effect is not as long lasting as it is with an antiperspirant.



SPECIAL CASE: PHARMACEUTICALS AND VACCINES

Aluminium compounds are used in medicines and vaccines.

These include, for example, popular medication for heartburn, some of which is available over the counter. Medicines that bind gastric acid (antacids) often contain aluminium trisilicate and aluminium hydroxide. They can contain more than 200 mg aluminium in the form of a single tablet.

Therefore to avoid an excessive intake of aluminium, especially in connection with renal insufficiency or long-term use, manufacturers advise users in the accompanying directions for use to regularly check the aluminium level in the body in order to avoid an excessive intake of aluminium.

Aluminium compounds are also present in some vaccines as so-called adjuvants, namely in the form of aluminium hydroxide, aluminium phosphate or aluminium hydroxyphosphate. The amount of aluminium contained in a vaccine is between 0.3 and 1.5 mg per dosage. If one takes the different vaccinations and the number of booster vaccinations required into account, a person would be subjected to a maximum dosage of 15 mg during his or her lifetime. This is approximately equivalent to the normal oral intake over two days.

Aluminium compounds injected subcutaneously (i.e. via the connective and adipose tissues) or intramuscularly dissolve slowly and enter the bloodstream. The aluminium is then discharged in the urine in the same way as the aluminium absorbed via the gastrointestinal tract. Replacing the currently used adjuvants would involve conducting an in-depth investigation of possible alternatives before they could receive approval. Any withdrawal on precautionary grounds would have grave consequences for the immunogenicity and protective effect of the vaccines currently used and would jeopardise vaccination programmes worldwide.







ALUMINIUM COMPOUNDS IN LYE ROLLS (E.G. PRETZELS)

The subject of aluminium compounds in lye rolls is particularly topical in southern Germany where these products are consumed in large quantities and where there is a correspondingly high level of exposure.

Checks carried out by Bavarian enforcement authorities repeatedly found levels of aluminium in lye rolls that exceeded the maximum permitted value in Bavaria of 10 mg/kg fresh weight (there is currently no legal limit that is valid for the whole of Germany or throughout Europe). Lye rolls with an aluminium content in excess of the maximum value of 10 mg/kg fresh weight are classified as being unsafe and thus not fit for consumption.

However, it was found it was possible to avoid the high aluminium values by introducing suitable technological measures. Already in November 2002 the Federal Institute for Risk Assessment (BfR) issued a statement on this subject in which it recommended avoiding using processes that cause a large amount of aluminium to be released into baked products (such as immersing the aluminium baking trays in caustic soda).

Via its member associations and the bakers' guild, the Central Association of German Bakers has called upon bakeries to avoid producing lye rolls with a high aluminium intake due to inappropriate production methods. In specially produced information sheets on the use of caustic soda with aluminium baking trays in the lye roll production it draws attention to the fact that the caustic soda becomes enriched with aluminium compounds if the aluminium trays are immersed repeatedly in the lye. If one avoids use of such lyes, the pieces of dough can be baked on aluminium trays without any reservations. Other alternatives for this special case are the additional use of baking paper or the use of stainless steel baking trays.

Limits and recommended labelling

The long-term intake of aluminium should not exceed the maximum level of 1 mg/kg body weight per week set by the European Food Safety Authority or the specific limiting value for the release of aluminium from food contact materials and articles of 5 mg/kg of food recommended by the Council of Europe.



The Council of Europe's guideline concerning metals and alloys intended to come into contact with foodstuffs specifies test methods to be used for determining the release of aluminium from utensils. Here one needs to know the natural aluminium content of the foodstuff before determining the relaease from the utensil. Only in this way can one properly judge whether the specific release limit specified by the Council of Europe is met.

The guideline also envisages suitable labelling for uncoated materials and articles made from metallic aluminium so that an improper use by the consumer can be avoided (e.g. packaging or storing salty or acidic foodstuffs in these utensils).

In 2011 and in the light of new scientific studies, the Joint FAO-WHO Expert Committee on Food Additives (JECFA) established a limit for the acceptable intake of aluminium of 2 mg/kg body weight per week (which is double the EFSA limit from 2008), so that there are currently two different scientifically derived limits here.

If the recommended limit is exceeded for a short while, and not permanently, one has to conduct a risk assessment in the specific case to ascertain whether the consumer's exposure poses a health risk. This need not necessarily be the case.



No causal relationship between the intake of aluminium and Alzheimer's disease, breast cancer and allergies

Time and again there is debate both in public and within the scientific community as to whether there is a causal relationship between the intake of aluminium and Alzheimer's disease, breast cancer and allergies.

At the international BfR Consumer Protection Forum entitled 'Aluminium in Everyday Life: A Health Risk?' held at the Federal Institute for Risk Assessment (BfR) in Berlin on 26 and 27 November 2014, the BfR declared that

- no clear link between increased aluminium intake and Alzheimer's disease or breast cancer has yet been proven scientifically because of the contradictory data available
- · aluminium is not suspected of causing allergies.

The conclusions of the BfR are also backed by the respective positions of the Alzheimer Association and the World Health Organisation (WHO).

What can the consumer do?

For many years, aluminium compounds have been included in the list of ingredients shown on food packaging (E numbers) and cosmetics. Consumers can reduce their intake of aluminium compounds from foodstuffs, food additives and uncoated materials and articles via their eating habits and the proper use of aluminium materials and articles in accordance with attached instructions for use. In addition, some cosmetics manufacturers voluntarily provide additional product labelling which is intended, for example, to make it easier for consumers to choose whether they use antiperspirants or deodorants with or without aluminium salts.



The industry has been demonstrating a sense of responsibility for years!

Manufacturers of aluminium packaging or composite packaging containing aluminium foil as well as food producers ensure that packaging is suitable for the products



to be packed and conforms to food legislative requirements by means of suitable packaging specifications (choice of material, composite structure, lacquering) and the associated compliance and storage tests.

As part of their due diligence, all participants in the supply chain work together to avoid exceeding the release limits and reducing consumers' exposure to aluminium compounds from various sources of intake.

Currently the enforcement authorities and the legislator do not see any risk to the consumer's health and consequently any need for legislative action.



Aluminium products contribute to safeguarding public health

Despite all the discussion about the above-mentioned aspects one should not forget that numerous products made from metallic aluminium make a significant contribution to safeguarding or improving public health.

Whether it be asthma sprays in aluminium cans, medicinal creams in aluminium tubes, tablets in blister packs, healthy meals on wheels in aluminium trays, stretchers or patient lifts for nursing staff, equipment for physical training such as bicycles or football goal posts, noise barriers, heat-resistant protective suits for rescue workers or first-aid blankets, metallic aluminium helps improve public health in many ways thanks amongst others to its excellent barrier properties and its lightness.



Further sources of information on the subject of aluminium and health



The European Aluminium Association (EAA) has published a series of useful fact sheets on the subject of aluminium and health which can be downloaded via the following link:

http://www.alueurope.eu/health-fact-sheets/



The Federal Institute for Risk Assessment (BfR) published a paper entitled 'FAQs about aluminium in food and products intended for consumers' on 26 February 2014, which is available via the following link:

http://www.bfr.bund.de/cm/349/faqs-about-aluminium-infood-and-products-intended-for-consumers.pdf

The Federal Institute for Risk Assessment (BfR) published



an opinion entitled 'Aluminium-containing antiperspirants contribute to the intake of aluminium' on 26 February 2014, which is available via the following link:

http://www.bfr.bund.de/cm/349/alumini-

um-containing-antiperspirants-contribute-to-aluminium-intake.pdf



The Federal Institute for Risk Assessment (BfR) published an updated health risk assessment entitled 'No risk of Alzheimer's disease from aluminium in consumer products' on 22 July 2007, which is avail-

able via the following link:

http://www.bfr.bund.de/cm/349/no_risk_of_alzheimers_disease_from_aluminium_in_consumer_products.pdf



The Federal Institute for Risk Assessment (BfR) published an opinion on the subject of enhanced aluminium levels in lye rolls on 25 November 2002, which is available only in German via the following link:

http://www.bfr.bund.de/cm/343/erhoehte_gehalte_von_aluminium_in_laugengebaeck.pdf



The Alzheimer Association's position on the subject of aluminium and Alzheimer is available via the following link:

http://www.alz.org/alzheimers_disease_ myths_about_alzheimers.asp

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