Frequently asked questions regarding the BfR's reassessment of aluminium in antiperspirants from 20 July 2020

BfR FAQ of 14 August 2020

The BfR assesses aluminium because the metal can be detrimental to our health: having concentrations of aluminium in our body that are too high has negative effects on the nervous system and can damage the kidneys and bones. Aluminium occurs in food, drinking water, food additives, food contact materials, medicines and cosmetics, among other things.

The BfR assessed aluminium in antiperspirants in terms of health risks for the first time in 2014. In antiperspirants, the active ingredient most frequently used is aluminium chlorohydrate (ACH). Based on the data available at the time, the BfR came to the conclusion that for consumers, uptake of aluminium via antiperspirants is so high that the tolerable weekly intake (TWI) would possibly be exhausted just by using an antiperspirant alone. Since application on damaged skin could lead to an increased uptake of aluminium, the BfR had recommended not using antiperspirants immediately after shaving or if the underarm skin is damaged

The BfR pointed out that there was still uncertainty regarding the data and recommended carrying out new studies on the uptake of aluminium from antiperspirants. The BfR now has respective new data available. The BfR has examined these new data, carried out an updated risk assessment and published the reassessment on 20 July 2020.

https://www.bfr.bund.de/cm/349/new-studies-on-antiperspirants-containing-aluminium-impairments-to-health-unlikely-as-a-result-of-aluminium-uptake-via-the-skin.pdf

Result: According to the current state of scientific knowledge, adverse health effects resulting from daily use of antiperspirants containing ACH are unlikely.

In the following, the BfR answers questions on the different human studies on the dermal uptake of aluminium from antiperspirants.

The BfR already pointed out the scientific uncertainty in 2014, notably with regard to the uptake of aluminium through the skin. There are now new findings, which have led to a revised BfR assessment - what are the differences between the studies?

The data available in 2014 showed a wide variation in the amount of the possible dermal uptake of aluminium from antiperspirants. There are uncertainties especially in the extent to which the results obtained under experimental conditions reflected to the uptake that would be obtained under realistic conditions of use. A further uncertainty was the extent to which armpit shaving influences uptake through the skin.

A study was carried out in 2014/2015 on twelve test subjects (TNO 2016) to reduce these uncertainties[1]. To obtain as comprehensive as possible data, also e.g. for uptake via freshly shaved armpits, this study was performed in a crossover design. Each group ultimately consisted of four subjects because there were three different treatment regimens, which were

[1] TNO. Assessment of bioavailability of aluminium, as aluminium chlorohydrate, in humans after topical application of a representative antiperspirant formulation using a [26Al] microtracer approach. Study commissioned by the Cosmetics Industry via Cosmetics Europe. 2016

sequentially applied in a different order for each group. The extremely rare radionuclide aluminium-26 (^{26}Al) was used to unambiguously identify the amount of aluminium taken up through the skin and to distinguish it from background exposure from aluminium intake trough all other sources. The ^{26}Al was specifically produced and its annual production quantity is limited. For the dermal application, a ^{26}Al-labelled formulation containing aluminium chlorohydrate was used, which was thickened with hydroxyethylcellulose in the same way as in commercially available antiperspirants to achieve the viscosity typical for roll-on products. The intention was to measure the aluminium concentration in the blood as a correlate for uptake through the skin. In addition, urine samples were taken sporadically. The data were not available until 2016 because of the crossover design and the need to have the radionuclide ^{26}Al synthesised separately. After examination, the EU Commission's Scientific Committee on Consumer Safety (SCCS) decided that the data situation was not sufficient for an assessment; in the blood, ^{26}Al was only measurable in a few samples and an evaluation of the urine data was marked by uncertainty because these data had only been collected sporadically. However, the study provided important information for designing the new TNO study in 2019[2].

The new study, for which the rare ^{26}Al isotope was again synthesised, involved a group size of six subjects and a different design. Urine data was systematically collected. Furthermore, a higher amount of ^{26}Al was used to obtain a higher proportion of blood concentration values above the limit of quantification. These data were available to the SCCS in 2019. The SCCS' final opinion was published in 2020.

What makes the 2019 study so superior that BfR has now revised its statement?
The 2019 study involved the use of a larger quantity of the extremely rare radionuclide aluminium-26 (^{26}Al). Moreover, in contrast to the 2016 study, urine data were systematically collected to enable determination of the cumulative urinary excretion of ^{26}Al. The mass balance (the question of whether the aluminium applied to the skin with the antiperspirant can also be recovered later from e.g. the dermal layers or the clothing) is sufficiently acceptable for this type of study. Also see answer to the question above.

The first assessment was based on a study on two subjects; now, two additional studies with 12 and 6 subjects are available. How reliable are the new data?
Group sizes of 4-6 individuals are common in toxicology for studies on bioavailability and toxicokinetics (uptake, distribution, metabolism and excretion) of a substance. These are controlled studies in which the experimental conditions, including the administered dose, are kept constant so that the variation in the target parameter largely reflects the interindividual variability. Interfering variables, such as background exposure to a substance, can be minimised by using a rare nuclide of the substance. Special experimental designs, such as a crossover study, in which the substance is administered to the same individuals in a sequential manner in different ways (e.g. intravenously and dermally) or after various pre-treatments (e.g. with and without shaving the skin), can be used to optimise group sizes.

There are a number of human studies on toxicokinetics and oral bioavailability for aluminium that have been carried out with the extremely rare radionuclide ^{26}Al. Group sizes ranged from 1-6 subjects. ^{26}Al was also used in the two new human studies on dermal bioavailability. The

[2] TNO. Assessment of bioavailability of aluminium in humans after topical application of a representative antiperspirant formulation using a [26Al] microtracer approach. Study commissioned by the Cosmetics Industry via Cosmetics Europe. 2019

2016 TNO study used a crossover design with 12 subjects divided into three groups of four. The 2019 TNO study was carried out on 6 subjects. The group sizes are therefore within the typical range for these kinds of studies.

The criteria for evaluating a study's reliability or robustness include the variability in the target parameter (variation around the mean value) and comparability with the results of previous studies. In the case of the 2019 TNO study, the proportion of the dose excreted via the urine showed a relatively low variation. Furthermore, the results from intravenous administration agreed very well with those from the 2016 TNO study. The reasons for the differences between the two studies regarding the results of dermal administration are discussed in opinion 030/2020:

https://www.bfr.bund.de/cm/349/new-studies-on-antiperspirants-containing-aluminium-impairments-to-health-unlikely-as-a-result-of-aluminium-uptake-via-the-skin.pdf

In the BfR's first risk assessment, the tolerable weekly intake (TWI) was used as the level of safety, now, a Margin of Safety (MoS). What was the rationale for this different approach?

TWI and MoS are two different assessment concepts that come from different regulatory areas. The BfR pointed out in 2014 that uptake via the skin must be better investigated because the tolerable weekly intake (TWI), as defined by the European Food Safety Authority (EFSA) for food, was exceeded in connection with aluminium intake from other sources such as food or drinking water.

Consumers cannot generally avoid aluminium intake from food or drinking water, however, they can avoid uptake from antiperspirants by not using them. In its 2014 opinion, the BfR pointed out that antiperspirants may contribute to the total intake permanently exceeding the TWI.

Reliable data are now available on the uptake of aluminium from antiperspirants through the skin. In its revised opinion, the BfR has, therefore, applied the relevant guideline, i.e. the SCCS Notes of Guidance (10th revision), for the assessment of cosmetics, which foresees an assessment in terms of the Margin of Safety (MoS).

What should consumers be aware of?
According to the current state of scientific knowledge, adverse health effects resulting from the daily use of antiperspirants containing ACH are unlikely.

Further information on the subject from the BfR website:

Publications about aluminium on the BfR website:

https://www.bfr.bund.de/en/a-z_index/aluminium-129853.html

About the BfR
The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the German federal government and German federal states (“Laender”) on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.