Frequently asked questions regarding the contamination of foods with 3-MCPD, 2-MCPD and glycidyl fatty acid esters

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3-monochloropropanediol (3-MCPD), 2-monochloropropanediol (2-MCPD) and their fatty acid esters as well as glycidyl fatty acid esters are process contaminants in foods that have the potential to be harmful to health and are therefore undesirable in foods.

Since 3-MCPD fatty acid esters were detected in refined vegetable fats for the first time in 2007, the Federal Institute for Risk Assessment (BfR) has assessed the health risks of these process contaminants in foods multiple times, most recently in 2012. The European Food Safety Authority (EFSA) has now assessed possible risks to human health of 2-MCPD, 3-MCPD and their fatty acid esters, as well as of glycidyl fatty acid esters, in foods. During this process, EFSA documented analytical data on the occurrence of these process contaminants in foods from a total of 23 EU member states (collected between 2009 and 2015) and performed an exposure assessment for different groups of the population. In its expert report, EFSA identified potential health risks from fatty esters of 3-MCPD, 2-MCPD and glycidol in foods in particular for younger age groups of the population.

What are 3-MCPD, 2-MCPD and glycidol or their fatty acid esters?

3-monochloropropanediol (3-MCPD) und 2-monochloropropanediol (2-MCPD) belong to the chemical group of chloropropanols. What is characteristic for this group of substances is that they possess the basic structure of glycerol in which a hydroxyl group is replaced by a chlorine atom. In 3-MCPD, the chlorine atom is in position 3, in 2-MCPD in position 2. The fatty acid esters consist of the chloropropanol esterified with one or two fatty acid esters (monoesters and diesters).

Glycidol has the same basic glycerol structure as the chloropropanols but possesses an epoxide structure. Accordingly glycidyl fatty acid esters are compounds consisting of glycidol esterified with a fatty acid.

How are these compounds formed?

Chloropropanols have been detected in numerous heated foods, such as dark brown toast, in the crust of bread and in soy sauces. Free 3-monochloropropanediol (3-MCPD) or free 2-monochloropropanediol (2-MCPD) can be formed when foods that contain both fat and salt are exposed to high temperatures during production. Based on current knowledge, the ester-bound forms, in other words fatty acid esters of 2-MCPD, 3-MCPD and glycidol, are formed above all during the refining of vegetable fats and oils, i.e. during heat treatment for the purpose of purification and processing. Crude oils usually contain various accompanying substances which are removed, for among other reasons, to improve odour and taste. Refined oils, in other words not "native" edible oils and fats, therefore contain fatty acid esters of 2-MCPD, 3-MCPD and glycidol in sometimes high amounts.

What harmful effects of 2-MCPD, 3-MCPD and their fatty acid esters have been observed in toxicological studies?

The effects of 2-MCPD and its fatty acid esters on the organism have not yet been investigated, and as a result no toxicological studies are currently available that are suitable for the derivation of a health based reference value within the context of risk assessment. What are above all necessary, therefore, are long-term studies and studies on possible mechanisms of the toxicity of 2-MCPD and its fatty acid esters.

The situation is different in the case of 3-MCPD and its fatty acid esters. A study on bioavailability in rats showed that 3-MCPD fatty acid esters are almost completely hydrolysed during digestion in the intestine with the release of 3-MCPD. In long-term toxicological studies, administration of 3-MCPD to laboratory animals led to an increase in the cell count (hyperplasia) in the renal tubules as the most sensitive endpoint. Higher doses triggered benign tumours in the treated animals. No genotoxic effect was observed. It can therefore be assumed that the tumours observed in the animal study only occur above a certain threshold value.

Is there a tolerable daily intake for 3-MCPD and its fatty acid esters?
Based on the available toxicological data, EFSA calculated a BMDL10 reference value of 0.077 mg/kg body weight and day. From this, EFSA derived a value for the tolerable daily intake (TDI) of 3-MCPD of 0.8 µg/kg body weight using an uncertainty factor of 100. In 2012, the BfR calculated a BMDL10 value of 0.27 mg/kg body weight using benchmark modelling and the criteria published by EFSA in 2009, and used this value to derive a TDI of 2 µg/kg body weight and day. The BfR can comprehend the more conservative derivation of a TDI value by EFSA, as it ensures a higher level of protection for consumers. Based on the TDI concept, occasional exceeding of the TDI value can be tolerated if the adverse effect concerned is only observed in animal experiments after long-term intake of the substance. Therefore, short-term exceeding of the TDI is not expected to result in any adverse health effects in consumers. Continuous intake levels above this value would, however, be of health concern.

What is known about the potential harmful effects of glycidol and its fatty acid esters?
Glycidol possesses genotoxic and carcinogenic properties and has been classified as probably carcinogenic to humans by various scientific bodies (IARC, MAK Commission). Studies on bioavailability have shown that glycidyl fatty acid esters are hydrolysed (de-esterified) during digestion, and the free glycidol is almost completely released. The glycidyl fatty acid esters are therefore treated like glycidol from a toxicological point of view. Due to the genotoxic potential of glycidol, it is not possible to derive any safe intake quantities for glycidyl fatty acid esters.

What concentrations of glycidyl fatty acid esters should be targeted in foods?
The concentrations of genotoxic carcinogenic substances like glycidyl fatty acid esters in foods should always be minimised to the lowest achievable level. Like the BfR in its 2009 assessment, EFSA also chose the MoE approach (margin of exposure) for its risk assessment of glycidyl fatty acid esters. In order to describe the risk resulting from exposure to carcinogenic and genotoxic substances in foods, this approach creates the MoE value as the ratio of the smallest dose with which a measurable adverse effect is observed and estimates of the level of exposure to the substance in question, taking account of different intake patterns. The required reference point is usually derived on the basis of chronic animal studies. In concurrence with the opinion of the BfR, EFSA has derived a T25 value of 10.2 mg glycidol/kg body weight and day from animal studies as a reference point for the determination of a MoE value for glycidyl fatty acid esters. MoE values based on the T25 value should be higher than 25,000 to be of low health concern only.

In what kind of foods have 3-MCPD, 2-MCPD and glycidyl fatty acid esters been detected?
The compounds have been detected in refined edible oils and edible fats as well as in foods manufactured from these oils and fats, such as margarine, bakery and pastry products, deep-fried products and various snack products as well as infant formula and follow-up formula.

The most recent collection of concentration data in foods can be found in the 2016 report of EFSA. This report documents a total of 7,175 analycal data sets on the occurrence of these process contaminants in foods from a total of 23 EU member states (collected between 2009 and 2015). In order to improve the data basis for exposure estimates for Germany, the BfR has initiated a project for the measurement of concentrations of fatty acid esters of 3-MCPD, 2-MCPD and glycidol in foods.

Do the detected concentrations of 3-MCPD fatty acid esters pose an increased health risk for consumers and in particular for infants?
The mean exposure estimate to 3-MCPD and its fatty acid esters drawn up by EFSA on the basis of the analytical data was above the TDI of 0.8 µg/kg body weight and day among the younger groups of the population (children above one year old and below the age of ten). Particularly high exposure values were calculated for infants who were exclusively given industrially produced infant formula. These values averaged 2.4 µg/kg body weight and day. This is more than three times the TDI and presents a health risk in the view of EFSA. There is therefore a continuing need to take steps to minimise the concentrations in these products.

What health risk is associated with the detected concentrations of glycidyl fatty acid esters?
EFSA comes to the conclusion that above all younger population groups, in particular infants who are not breastfed but exclusively given industrially produced infant formula, can ingest glycidol in amounts that are harmful to health. There is therefore a need for action with regard to the minimisation of concentrations in accordance with the ALARA principle (as low as reasonably achievable).

What should mothers do who do not breastfeed and who give their babies industrially produced infant formula?
The composition of infant formula is tailored to the specific needs of children in the first months of life. These formula products are made using individual components in line with the latest scientific knowledge on nutrient requirements. Refined vegetable fats have long been used to provide the fat content for these products. The fact that 3-monochloropropanediol (3-MCPD), 2-monochloropropanediol (2-MCPD) and glycidyl fatty acid esters have been detected in these fats means that these substances are also present in infant formula.

The higher exposure of formula-fed infants to fatty acid esters of 3-MCPD, 2-MCPD and glycidol only became known a few years ago, but has probably existed for decades. To date, there are no indications that children fed with industrially produced baby milk might have suffered damage to their health due to the intake of the aforementioned fatty acid esters. In the opinion of the BfR, therefore, the probability that the current exposure levels of formula-fed infants will result in health impairments is low, particularly as the activities of authorities and industry are currently showing the first signs of success in the endeavour to reduce the concentrations of these fatty acid esters.

When infants are not breastfed, there is basically no alternative to industrially produced infant formula. It is the only way to ensure optimum nutrition if mothers do not breastfeed. The BfR therefore emphatically advises parents to continue to feed their babies with the products made specifically for this purpose where necessary, as these products contain the right mix of nutrients that are essential for babies.

This text version is a translation of the original German text which is the only legally binding version.