German Federal Institute for Risk Assessment

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# New EFSA assessment: no evidence of genomic damage from styrene in food packaging

The substance styrene is used as a raw material in the manufacture of many plastics. These plastics are also used for products that may come into contact with food, such as yoghurt pots, lids for takeaway cups, and takeaway tableware. Small amounts of styrene can migrate from such food contact materials into food. Whether this poses a health risk to consumers has been the subject of intense debate in recent years.

The European Food Safety Authority (EFSA) has now updated its previous risk assessment on the use of styrene in food packaging. EFSA's results show no evidence of a mutagenic effect of styrene when ingested orally through food.

The EU Commission has tasked EFSA with reviewing a planned limit value for styrene. According to the proposed limit value, a maximum amount of 40 micrograms of styrene from food contact materials may be transferred to one kilogram of food. According to EFSA, no health risk to consumers is to be expected when this limit value is adhered to.

The vast majority of the concentrations of styrene actually detected in food in the past were below 10 micrograms per kilogram of food. However, in isolated cases, concentrations of up to 230 micrograms of styrene per kilogram have been measured. In accordance with its mandate from the EU Commission and in line with the respective guideline for the safety assessment of substances in plastic food contact materials (“Note for guidance”), EFSA has not carried out a risk assessment for styrene levels above 50 micrograms per kilogram of food.

In a preliminary assessment in 2020, EFSA had noted uncertainties regarding possible genetic damage caused by styrene. Among other things, there were still gaps in data and knowledge about the metabolism of styrene in the body. These gaps have been closed in the new assessment.

The BfR shares EFSA's assessment and considers health impairments due to the intake of styrene in the amounts typically found in food to be unlikely.

One of the reasons for the EFSA risk assessment was a publication by the International Agency for Research on Cancer (IARC). In 2018, the IARC classified styrene as "probably carcinogenic to humans". The EU Commission then asked EFSA to check if using styrene in food contact materials poses a health risk to consumers.

In an initial, preliminary opinion, EFSA had stated that the IARC's assessment did not refer to the intake of styrene via food. Furthermore, in its classification, the IARC only considered the theoretical carcinogenic potential of styrene without taking into account the actual amounts ingested via different routes of exposure (e.g. inhalation, oral intake via food or through the skin).

However, the studies evaluated by the IARC had primarily considered very high intake of styrene via the respiratory tract. Such data may be relevant, for example, for occupational safety in the production of materials made from styrene. However, these findings cannot be applied to the intake of far smaller amounts of styrene via food. Accordingly, in 2020, EFSA concluded that there is no evidence that styrene from food contact materials increases the risk of cancer. However, in its opinion at that time, EFSA noted that there were still uncertainties and gaps in data regarding the potential for styrene to cause genetic damage.

For its assessment, EFSA evaluated new animal studies on the possible mutagenic effects of styrene in the body. These studies examined the stomach, intestine, liver, kidney and lung tissue as well as blood cells of mice and rats fed styrene. In addition, data on the concentrations of styrene actually detected in food and the amounts typically ingested by humans were taken into account. All studies were reviewed and evaluated for their relevance, reliability and the transferability of their results to humans.

**Links:**

EFSA 2008: Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials
https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2008.21r

EFSA Opinion 2020: Assessment of the impact of the IARC Monograph Vol. 121 on the safety of the substance styrene (FCM No 193) for its use in plastic food contact materials
https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.6247

EFSA Opinion 2025: Re-assessment of the risks to public health related to the genotoxicity of styrene present in plastic food contact materials
https://www.efsa.europa.eu/en/efsajournal/pub/9473

**Further information on the BfR website on food contact materials**

Frequently Asked Questions and Answers concerning the BfR recommendations on Food Contact Materials
https://www.bfr.bund.de/en/service/frequently-asked-questions/topic/frequently-asked-questions-and-answers-concerning-the-bfr-recommendations-on-food-contact-materials/

**About the BfR**

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent public health institute within the portfolio of the German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH). The BfR advises the Federal Government and the States ('Laender') on questions related to food, feed, chemical and product safety. The BfR conducts independent research on topics that are closely linked to its assessment tasks.

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