German Federal Institute for Risk Assessment

FAQ

31 January 2024

Smoke flavourings in food

Updated FAQ on smoke flavourings and their health risks

→ Changes compared to the version of 5 April 2017: Following a reassessment by the European Food Safety Authority (EFSA), the FAQs have been supplemented and fundamentally revised.

Smoke flavourings are used as an alternative to the flavouring effects of traditional smoking and are also used in foods that are not traditionally smoked. Unlike smoke, however, they do not serve to preserve foods but merely to give them a particular taste. As smoke flavourings are complex mixtures of many chemical substances, special provisions apply here which differ from those for chemically defined flavourings.

The German Federal Institute for Risk Assessment (BfR) has summarised the most important questions and answers on smoke flavourings.

What are smoke flavourings?

Smoke flavourings are produced from smoke that is also used in conventional food smoking. For this purpose, certain woods are smouldered under controlled conditions (temperature, air supply, etc.). The smoke is introduced into water or other liquids (e.g. containing ethanol), fractionated and purified. This results in the so-called primary products ("primary smoke condensates" and/or "primary tar fractions"), from which smoke flavourings are produced using carriers.

The main flavouring components of smoke flavourings are phenols and carbonyl compounds (aldehydes and ketones). The flavourings are incorporated directly into the food or applied to the surface by, e. g., dipping or spraying.

How is the use of smoke flavourings regulated by law?

Smoke flavourings can be added to fish and meat products, but also to some foods that are not traditionally smoked (e. g. soups, sauces and snacks) in certain maximum quantities. In the European Union (EU), the use of smoke flavourings is regulated by several regulations.

The aim of these regulations is to protect consumers. Regulation (EC) No. 2065/2003 primarily regulates the safety assessments of smoke flavourings and the authorisation procedure for primary products. Foods with smoke flavourings may only be placed on the market if no primary products other than the approved primary products have been used to produce the smoke flavourings. Other regulations include quality criteria for the analysis of primary products (Regulation (EC) No. 627/2006) and conditions of use for authorised primary products (Regulation (EU) No. 1321/2013).

How are smoke flavourings currently assessed in terms of health in the EU?

Primary products from which smoke flavourings are produced are complex mixtures of substances. They also contain polycyclic aromatic hydrocarbons (PAHs), such as benzo[a]pyrene, which are known to have genotoxic and carcinogenic properties.

In 2021, the European Food Safety Authority (EFSA) published a new guidance on the application for authorisation of primary products for the production of smoke flavourings. According to this, information on the chemical composition of the primary products is required, among other things. Available genotoxicity data must be evaluated for each identified substance. If no genotoxicity data are available, the genotoxic potential is predicted using "in silico" methods, i.e. computer simulations ((Quantitative) Structure-Activity Relationships ((Q)SAR), Read-Across). If such predictions indicate potential genotoxicity, experimental studies are required for further clarification.

Importantly, if an individual substance in a primary product is shown to be genotoxic in vivo or this is already known from the scientific literature, genotoxicity concerns also apply to the mixture as a whole.

What is known about the health risks of smoke flavourings?

The European Food Safety Authority (EFSA) first assessed the health risk of primary products for smoke flavourings between 2007 and 2012 in the context of an authorisation procedure. None of the primary products assessed exceeded the maximum levels for benzo[a]pyrene and benzo[a]anthracene of 10 and 20 micrograms (µg) per kilogramme (kg) of primary product. These substances belong to the group of polycyclic aromatic hydrocarbons (PAHs), several of which (e.g. benzo[a]pyrene) can damage the genome and cause cancer. The concentrations of twelve other PAHs measured were in most cases below - or only just above - the respective limits of detection. The ten currently authorised primary products proved to be genotoxic in bacterial gene mutation tests and/or in tests on mammalian cell cultures. However, this was not confirmed in animal studies. Therefore, there were no concerns regarding the genotoxic potential of the primary products at that time.

However, at that time, EFSA came to the conclusion that the intake levels for most primary products were too high under the conditions of use envisaged in the application documents. They should therefore be used in lower quantities or in fewer food groups than proposed by the applicants.

Ten primary products were subsequently authorised for ten years (until 1 January 2024), which has been extended for the time being by six months for formal reasons. The draft Implementing Regulation No. 1321/2013 on smoke flavourings was adopted by a qualified majority of the EU Member States on 21 October 2013. When using the ten primary products approved since the Implementing Regulation came into force on 1 January 2014 at

the maximum permitted levels, the margin of safety between the amount of primary products ingested with food and the highest dose at which no adverse effects occurred in the animal study on subchronic toxicity was lower than recommended by the EFSA and the BfR for seven of the ten approved primary products. The level of protection for these primary products was therefore lower than recommended. Germany therefore did not support the draft regulation at the time, taking into account an opinion from the BfR.

In 2023, eight of the authorised primary products were reassessed by the EFSA after their manufacturers submitted applications to the European Commission to extend the authorisation granted in 2013. In accordance with Regulation (EC) No. 2065/2003, new applications and new risk assessments by EFSA were required to extend the authorisation for a further ten years. The applicants submitted new data for this purpose.

Based on the available data, EFSA has now come to the conclusion that none of the eight smoke flavouring primary products assessed can be considered safe for human health.

EFSA's rationale is that six of the eight primary products assessed raise health concerns with regard to their genotoxic potential because they contain furan-2(5H)-on. The compound has been shown to be genotoxic in vivo. In addition, four of these primary products contain 1,2-dihydroxybenzene (synonym: catechol, pyrocatechol), which is also genotoxic in vivo. There are indications of genotoxic potential for the other two smoke flavouring primary products, which still need to be clarified experimentally. In addition, furan-2(5H)-on was not identified in one of these two primary products with the (inadequate) analytical methods used, but the absence of this substance was not convincingly demonstrated.

Are foods with smoke flavourings potentially more harmful to health than foods that have been traditionally smoked?

The genotoxic substances identified in smoke flavourings are also to be expected from traditional smoking. However, at least the concentrations of polycyclic aromatic hydrocarbons (PAHs) in foods containing smoke flavourings are generally lower than in foods that have been traditionally smoked.

Why was the result of the 2023 health risk assessment different from the first assessment around ten years earlier?

There are now EFSA recommendations on the assessment of genotoxicity. For example, a certain in vivo method that was still common at the time (in vivo UDS test) is no longer considered sufficiently meaningful. Instead, other methods are now used (e.g. the in vivo comet assay) that are more sensitive than the UDS test and for which there were no internationally harmonised recommendations for carrying out such tests (OECD test guidelines) at the time. In addition, there are now EFSA recommendations for genotoxicity assessment of mixtures and a new EFSA guideline for the assessment of smoke flavourings, according to which the composition of the primary products should first be examined as far as possible using chemical-analytical methods. The identified substances should then be assessed for their genotoxic potential. If any substance in the mixture is known to be genotoxic in vivo, genotoxicity concerns also apply to the mixture.

On the basis of new findings on the chemical composition of the primary products and after applying these EFSA guidelines, the result of the assessment is now different than it was about ten years ago.

What does the current assessment result from 2023 mean?

Substances that are DNA-reactive and damage the genome in vivo (i.e. in living organisms) can potentially lead to cancer and heritable diseases. The EFSA has emphasised that no safe concentrations can be defined for such substances. In principle, the health risk from exposure to such substances is increased. However, it is difficult to determine exactly how high it is or how high the probability of occurrence of such diseases is. This applies in particular to complex mixtures with a relevant proportion of unidentified components, such as the primary products for the production of smoke flavourings.

What follows the re-evaluation by EFSA?

EFSA is responsible for risk assessment and communication in the European Union. It cannot decide whether or not to renew the authorisation for the assessed smoke flavourings. Rather, its task is to communicate its scientific assessment of the substances to the bodies responsible for risk management and thus creating the basis for risk management decisions. It is now the responsibility of the risk management (representatives of the European Commission and the Member States) to decide, taking into account the current EFSA opinions, whether and, if so, under what conditions the authorisations for the eight primary products for the production of smoke flavourings can be renewed.

How is the amount of smoke flavouring primary products determined that consumers ingest via food on average?

Exposure to primary products for smoke flavourings, i.e. the quantity of primary products that consumers ingest through food, is estimated on the basis of food consumption quantities and data on the (intended or approved) levels of primary products in these foods. A distinction is made here between traditionally smoked foods, such as fish and meat products, and foods which were not smoked in the traditional way, such as soups, sauces and snacks.

What can consumers do?

As smoke flavourings have to be declared in the list of food ingredients, they can be identified as ingredients. In this way, consumers have the opportunity to align their consumption habits according to their individual safety requirements.

EFSA has published FAQs on smoke flavourings on the occasion of the re-evaluation in 2023. Further information is available both from EFSA and on the European Commission website.

Further information on food safety

Further Information on substance risks in foods:
https://www.bfr.bund.de/en/assessment_of_substance_risks_in_foods-738.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. The BfR advises the Federal Government and the States ('Laender') on questions of food, chemicals and product safety. The BfR conducts independent research on topics that are closely linked to its assessment tasks.

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Publisher:
German Federal Institute for Risk Assessment
Max-Dohrn-Straße 8-10
10589 Berlin, Germany
T +49 30 18412-0
F +49 30 18412-99099
bfr@bfr.bund.de
bfr.bund.de/en

Institution under public law
Represented by the president Professor Dr Dr Andreas Hensel
Supervisory Authority: Federal Ministry of Food and Agriculture
VAT ID No. DE 165 893 448
Responsible according to the German Press Law: Dr Suzan Fiack

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