

## Frequently asked questions about smoke flavourings

BfR FAQ of 5 April 2017

Smoke flavourings are used as an alternative to traditional smoking. 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 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 the conventional smoking of foods. To do so, certain wood varieties are smouldered under controlled conditions (temperature, air supply etc.). The smoke is fed into water or other liquids (containing ethanol, for example), fractionated and purified. The so-called primary products are produced here ("primary smoke condensates" and/or "primary tar fractions") from which smoke flavourings are produced using carriers. The flavourings are incorporated into the foods directly or applied to the surface using immersion or spray methods. Smoke flavourings can be added in specified maximum quantities to fish and meat products, as well several other foods which are not traditionally smoked (e.g. soups, sauces and snacks). The flavour of smoke flavourings is primarily determined by phenols and carbonyl compounds (aldehydes and ketones).

### To what extent do smoke flavourings have the potential to impair health and what were the results of the risk assessment of smoke flavourings?

Several of the polycyclic aromatic hydrocarbons (PAH) contained in the smoke, such as benzo[a]pyrene, can damage the genetic material and cause cancer. The level of such substances in the primary products from which smoke flavourings are produced is limited by law, however, and can be kept low through controlled manufacturing conditions. There are also maximum levels for PAHs in foods, including smoked fish and meat products. The ten primary products currently approved were shown to be genotoxic in bacterial gene mutation tests and/or tests on mammalian cell cultures, but this was not confirmed in animal studies.

The European Food Safety Authority (EFSA) assessed the health risk of eleven primary products for smoke flavourings within the scope of the approval system. One application for approval was withdrawn upon completion of the assessment.

Overall, there was no concern regarding the genotoxic potential of the primary products used for smoke flavourings. In none of the assessed primary products were the maximum levels for benzo[a]pyrene and benz[a]anthracene of 10 and 20 micrograms (µg) respectively per kilogram (kg) of primary product exceeded. The levels measured in twelve other PAHs lay mostly below or only slightly above each respective detection limit.

EFSA concludes, however, that the intake quantities of most primary products under the conditions of use suggested in the application documents are too high. Accordingly, they should be used in smaller quantities and/or in fewer food groups than intended by the applicants.

### Are foods with smoke flavourings potentially more damaging to health than foods smoked the traditional way?

No, the levels of polycyclic aromatic hydrocarbons (PAH) are usually lower in foods containing smoke flavourings than in foods smoked the traditional way.

### **How is the use of smoke flavourings regulated from a legal point of view?**

The essential aspects are covered in the following regulations:

- Regulation (EC) No. 2065/2003: The regulation on smoke flavourings used or intended for use in or on foods regulates the health assessment and authorisation of smoke flavourings.
- Regulation (EC) No. 627/2006: Quality criteria for validated analytical methods for the sampling, identification and characterisation of primary smoke products are determined in this regulation implementing Regulation (EC) No. 2065/2003.
- Regulation (EU) No. 1321/2013: Conditions of use for ten authorised primary products were stipulated in the implementing regulation establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings.

### **How are smoke flavourings assessed from a health point of view?**

Two aspects are of particular importance in the risk assessment:

- Primary products from which smoke flavourings are produced are complex substance mixtures containing among others polycyclic aromatic hydrocarbons (PAH), such as benzo[a]pyrene which are known to have genotoxic and carcinogenic properties. Therefore, the assessment of the genotoxic potential is important as an indicator of carcinogenic potential in addition to the information on PAH levels in primary products.
- If there are no concerns regarding the genotoxic potential and thereby a possible carcinogenic effect too, the safety margin between the quantity of primary products ingested with foods and the highest dose at which no undesired effects occurred in animal studies on sub-chronic or chronic toxicity is of importance for risk assessment.

In addition to data on the production method and the chemical characterisation of these complex substance mixtures, the basis for the assessment of primary products from which smoke flavourings are produced, which was conducted and completed by EFSA, was formed by data on genotoxicity and sub-chronic toxicity (animal study over 90 days). As no data on reproductive and developmental toxicity, chronic toxicity and carcinogenicity was available for primary products, however, no acceptable daily intake (ADI) values could be derived here. Instead values for the margin of safety (MOS) were calculated as parameters for risk characterisation. This MOS indicates the ratio of the highest doses established in animal studies at which no undesired effects are observed to the quantity of the substance that consumers ingest through food on average in relation to their body weight (exposure).

In order to take the scientific uncertainty that exists due to the limited data situation into account, EFSA has recommended that a further uncertainty factor of times 3 be used in addition to the otherwise customary uncertainty factor of 100 for the primary products. This means that EFSA regards an MOS of at least 300 as appropriate. Put another way, this means that the intake quantity of primary products which consumers can ingest through food (in relation to their body weight) should not exceed three hundredths (0.33%) of the highest dose at which no undesired effects occurred in the animal study on sub-chronic toxicity. The BfR concurs with this recommendation.

### **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.

### **Why did the German federal government not consent to the latest EU regulation on smoke flavourings?**

Ten primary products have been approved since the implementation regulation came into effect on 1 January 2014.

If each of the primary products is used at the maximum level permitted, the safety margin between the quantity of primary products ingested with the food and the highest dose at which no undesired effects occurred in the animal study on sub-chronic toxicity is lower than recommended by EFSA and the BfR in seven of the ten approved primary products. The protection level is therefore lower than recommended for these primary products.

The draft of Implementing Regulation No. 1321/2013 was adopted by the EU member states with a qualified majority on 21.10.2013. Germany did not support the draft regulation under consideration of an opinion put forward by the BfR.

### **What can consumers do?**

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

### **EFSA information on smoke flavourings**

<http://www.efsa.europa.eu/de/topics/topic/smokeflavourings.htm>

### **EU Commission information on smoke flavourings**

[http://ec.europa.eu/food/food/fAEF/flavouring/smokeflavouring\\_en.htm](http://ec.europa.eu/food/food/fAEF/flavouring/smokeflavouring_en.htm)

### **About the BfR**

The 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 Federal Government and Federal 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.

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