German Federal Institute for Risk Assessment

Opinion 018/2024

doi https://doi.org/10.17590/20240524-132958-0

21 March 2024

Polycyclic aromatic hydrocarbons in smoked paprika powder

German Federal Institute for Risk Assessment assesses the concentration

High concentrations of polycyclic aromatic hydrocarbons (PAHs) were detected in three samples of smoked paprika powder as part of the official control of foodstuffs. The German Federal Institute for Risk Assessment (BfR) has carried out a toxicological assessment of these findings.

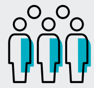
PAHs are a large group of organic compounds that can be formed, for example, during incomplete combustion processes of organic material. The four PAHs detected in the sample are classified as "*probably carcinogenic to humans*", i.e. they can be carcinogenic. The substances chrysene and benzo[*a*]pyrene are also classified as having the property of possibly causing mutations in the germ cells of humans.

The margin-of-exposure approach, or MOE approach for short, is used to characterise the potential risks of mutagenic and carcinogenic substances in food. The MOE is the quotient of a toxicological reference point and the level of human exposure to a substance. However, this value is not to be understood as a health-based guidance value, but rather serves to prioritise risk management measures.

Taking into account the existing uncertainties, it can be concluded from the MOE that the PAH concentrations in the samples analysed are of little concern with regard to public health. However, there is a lack of data on long-term consumption quantities and consumption frequencies for a reliable assessment of the situation.

In principle, exposure to mutagenic and carcinogenic substances in food should be minimised as far as possible in accordance with the ALARA (as low as reasonably achievable) principle.

PAH concentrations in smoked paprika powder

A Affected persons [1]	General population				
B Probability of adverse health effects, taking into account the existing uncertainties, in particular with regard to the consumption quantities of paprika powder containing PAHs	Very low	Low	Medium	High	Very high
C Severity of health impairment from the consumption of paprika powder containing PAHs	No impairment	Mild impairment [reversible/irreversible]	Moderate impairment [reversible/irreversible]	Severe impairment irreversible	
D Validity of available data	High: The most important data is available and there are no contradictions	Medium: Some important data is missing or contradictory	Low: Numerous important data are missing or contradictory		
E Controllability by the consumer	Control not necessary	Controllable by precautionary measures	Controllable through avoidance	Not controllable	

Fields with a dark grey background indicate the properties of the risk assessed in this opinion.

Explanations
The risk profiles are intended to visualise the risk outlined in the Opinion. The profile is not intended to be used to compare risks. The risk profiles should be read only in conjunction with the Opinion.

Row C - Severity of the health impairment:
The four PAHs (PAH4) quantitatively determined in the sample may be carcinogenic. The substances chrysene and benzo[a]pyrene (BaP) can also possibly trigger mutations in germ cells.
Row D - Validity of available data:
There is a lack of representative data on PAH concentrations in smoked paprika powder on the German market. There is also a lack of data on long-term consumption quantities and consumption frequencies of smoked paprika powder for a reliable assessment of the situation.
Row E - Controllability by the consumer
[1] - The information in the line "Controllability by the consumer" is not intended to be a recommendation by the BfR, but is descriptive in nature.

1 Subject of the assessment

The maximum levels for PAHs in dried spices set out in Regulation (EU) No. 2023/915 do not apply to paprika powder produced using the traditional smoking process. Due to the smoking process, paprika powder may be contaminated with polycyclic aromatic hydrocarbons (PAHs). The state laboratory for the official control of food and feed (Institute for Hygiene and Environment) of the Free and Hanseatic City of Hamburg found high levels of PAHs in three samples of Spanish smoked paprika powder. The BfR has carried out a toxicological assessment of these findings.

2 Result

From the BfR's point of view, the following aspects must be taken into account in the assessment of the findings reported by the Institute for Hygiene and Environment:

(1) The assessment of health risks due to exposure to PAHs is based in particular on the genotoxic and carcinogenic effects of some PAHs.

The four PAHs (PAH4) quantitatively determined in the sample are classified as "probably carcinogenic to humans" according to Annex VI of Regulation (EC) No. 1272/2008. Chrysene and benzo[a]pyrene (BaP) are also classified with regard to their property of possibly causing heritable mutations in the germ cells of humans (BaP: carc. 1b/muta. 1b, Chrysene: carc. 1b/muta. 2, benzo[b]fluoranthene: carc. 1b, benzo[a]anthracene: carc. 1b).

Exposure to PAH4 should therefore be minimised as far as possible in accordance with the ALARA (as low as reasonably achievable) principle .

(2) The application of the MOE approach indicates a low priority for risk management measures from a public health perspective.

The Margin of Exposure (MOE) concept was used to prioritise the urgency of risk management measures with regard to long-term exposure to genotoxic carcinogens. The MOE is the quotient of a suitable reference point, i.e. a dose that is associated with a certain increase in the tumour rate (often $BMDL_{10}$), and the human exposure to this substance.

Due to a lack of data on the consumption of smoked paprika powder in Germany, it is not possible to make a valid estimate of the long-term exposure to PAHs through the consumption of smoked paprika powder. However, an internet search has shown that the quantities of non-smoked and smoked paprika powder in available recipes are similar. Therefore, the long-term intake of paprika powder in the German population based on the results of the National Nutrition Survey II was used to calculate the MOE. Based on the highest measured concentrations of BaP and PAH4 (70.4 and 311.7 µg/kg respectively) in sample 1, the MOE values for medium consumption levels are 994,318 for BaP and 1,090,792 for PAH4 and for high consumption levels the MOE values are 248,580 for BaP and 272,698 for PAH4.

For genotoxic-carcinogenic substances, an MOE of 10,000 or higher is generally considered a low priority for risk management measures, provided that a $BMDL_{10}$ from an animal study was used as a reference point. Taking into account the existing uncertainties, especially with regard to consumption levels, the concentrations of PAHs in the three samples of smoked paprika powder appear to be of low concern with regard to public health in relation to the chronic consumption of unsmoked paprika powder.

(3) There are data gaps with regard to long-term consumption levels and consumption frequencies of smoked paprika powder and with regard to representative data on PAH concentrations in smoked paprika powder.

In addition, the concentration data of the samples and the concentration data cited in the scientific literature suggest that the range of PAH contents in smoked paprika powder can be very wide. However, representative data on PAH concentrations in smoked paprika powder on the German market are lacking. It is therefore recommended that suitable data be collected, for example as part of project monitoring.

3 Rationale

3.1 Risk assessment

3.1.1 Hazard identification

If freshly developed smoke is used in the production of smoked paprika powder, polycyclic aromatic hydrocarbons (PAHs) may be formed as undesirable by-products from incomplete combustion processes of organic material (wood), which could potentially transfer to the paprika peppers. PAHs represent a large group of organic compounds that are formed during incomplete combustion processes of organic material (industrial processes, forest fires and also barbecues). These substances are made up of two to seven condensed aromatic hydrocarbon rings, whereby PAHs with different side chains can also be formed depending on the combustion temperature.

Elevated concentrations of PAHs were measured in three samples of smoked paprika powder. In detail, analysis of suspected samples as part of official controls using a GC-MS-MS method in accordance with DIN EN 16619 (06.2015) revealed in sample 1 70.4 µg BaP, 94.7 µg chrysene, 48.1 µg benzo[b]fluoranthene, 98.5 µg benzo[a]anthracene, in sample 2 43.8 µg BaP, 63.8 µg chrysene, 33,1 µg benzo[b]fluoranthene, 64.0 µg benzo[a]anthracene and in sample 3 40.1 µg BaP, 47.7 µg chrysene, 25.3 µg benzo[b]fluoranthene, 54.8 µg benzo[a]anthracene per kg of spice. The total PAH4 contents determined in samples 1 to 3 were thus 311.7 ± 62.3; 204.8 ± 41.0 and 167.9 ± 33.6 µg per kg of spice respectively. The measurements relate to three samples that were delivered on 2 June 2022 by a food business operator as suspected samples.

According to Article 1 of Regulation (EU) No. 2023/915, the foodstuffs listed in the Annex to this Regulation may not be placed on the market if they contain any of the contaminants listed in the Annex in a quantity exceeding the maximum level specified therein. According to section 5.1.10 in the Annex to Regulation (EU) No. 2023/915, BaP may not exceed a value of 10 µg per kg and the sum of PAH4 may not exceed a concentration of 50 µg per kg of dried spices and herbs. However, these maximum levels do not apply to cardamom and smoked *Capsicum* spp. (paprika).

3.1.2 Hazard characterisation

The publicly available literature contains a number of comprehensive toxicological assessments of PAHs, including those by the Agency for Toxic Substances and Disease Registry (ATSDR 1995), the World Health Organization (WHO 1998 and 2003) and the

European Food Safety Authority (EFSA 2008). The health risk assessments are based in particular on the carcinogenic effect of some PAHs, which is regarded as the most sensitive endpoint. The PAH4 quantitatively determined in the sample are classified as "probably carcinogenic to humans" according to Annex VI of Regulation (EC) No. 1272/2008, chrysene and BaP are also classified with regard to their property of possibly causing heritable mutations in the germ cells of humans (BaP: carc. 1b/muta. 1b, chrysene: carc. 1b/muta. 2, benzo[b]fluoranthene: carc. 1b, benzo[a]anthracene: carc. 1b).

PAHs are a group of organic compounds comprising several hundred compounds that are made up of two to seven condensed aromatic hydrocarbon rings. The molecules can also carry various side chains. BaP, which has long been used as a lead substance for the assessment of the carcinogenicity of PAHs after oral intake, is converted into highly reactive genotoxic metabolites. An initial step in the metabolisation of BaP is, for example, the formation of dihydrodiole epoxides catalysed by cytochrome P450 monoxygenases, which can undergo further metabolisation by phase II enzymes of xenobiotic metabolism. The ability of the electrophilic products formed in this process to bind covalently to DNA, forming DNA adducts, is considered to be particularly responsible for the genotoxic effect (EFSA 2008).

In its opinion, however, the EFSA came to the conclusion that BaP alone is not a suitable indicator for the presence of PAHs in food. Following an evaluation of the occurrence of PAHs in food, a group consisting of chrysene, benzo[a]anthracene, benzo[b]fluoranthene and BaP was identified instead ("PAH4"), which proved to be suitable indicators for the occurrence of PAHs in food (EFSA 2008). They belong to a group of 16 potentially genotoxic and carcinogenic PAHs, although data on carcinogenicity after oral intake are only available for 8 of these PAHs. From a study on the carcinogenicity of PAHs after oral intake in mice, EFSA derived a dose associated with the lower confidence limit of the BMD ($BMDL_{10}$) of 0.07 mg/kg body weight (bw) for BaP and 0.34 mg/kg bw per day for the group of PAH4 as reference points (EFSA 2008).

For genotoxic carcinogens, based on current knowledge, it is not possible to derive a safe intake level and therefore it is not considered appropriate to derive a health-based guidance value. EFSA recommends the margin of exposure (MOE) concept for the assessment of substances which are both genotoxic and carcinogenic in order to provide a basis for the prioritization of risk management measures (EFSA, 2005). According to EFSA, an MOE of 10,000 or higher, if derived on the basis of a $BMDL_{10}$ from an animal carcinogenicity study, is considered to be of low concern from a public health perspective, but not harmless, and is therefore regarded as a criterion for a low priority for risk management measures.

3.1.3 Exposure estimation and exposure assessment

In order to assess the use of smoked paprika powder, particularly in comparison to standard paprika powder in the German population, an online search was carried out for recipes that contain smoked paprika powder as an ingredient. This showed that between one teaspoon and two tablespoons of smoked paprika powder were listed as an ingredient in dishes with or without meat for four people. Smoked paprika powder was also frequently listed as half a teaspoon to two teaspoons per 4 portions when preparing sauces. In home-made spreads, half a teaspoon to a whole teaspoon of smoked paprika powder was used per 2 portions. This corresponds to the information for comparable dishes prepared with non-smoked paprika powder. Based on this research, consumption data of non-smoked paprika powder were used for the assessment of the chronic exposure. The research also showed that smoked paprika powder is used particularly in the production of chorizo sausage.

Consumption data on paprika powder in adolescents and adults were taken from the National Nutrition Survey II (NVS II) of the Max Rubner Institute (MRI). The NVS II is the current representative study on the food consumption of the German population. The study, in which around 20,000 people between the ages of 14 and 80 were surveyed on their dietary behaviour using three different survey methods (dietary history, 24-hour recall and weighing protocol), took place throughout Germany between 2005 and 2006 (Krems et al. 2006; MRI 2008). The consumption analyses are based on the data from the "Dietary History" interviews of the NVS II, which were collected using the "DISHES 05" programme. Using the "Dietary History" method, 15,371 people were surveyed and their usual consumption of foods over the last four weeks was recorded retrospectively. As part of the LExUKon research project (Foodborne intake of environmental contaminants - data preparation to support and standardise exposure assessments based on the National Nutrition Survey II) (BfR 2010), which ran from autumn 2008 to the end of 2010, the consumption levels of various food groups of adolescents and adults were determined on the basis of the DISHES data from the National Nutrition Survey II, including paprika powder. The determination of the consumption quantities of paprika powder includes dried paprika, sweet paprika and rose paprika and is based on the data status in which almost all compound foods were broken down into the respective individual components based on the maximum content groups for environmental contaminants. The evaluations were carried out using SPSS version 21.

Table 1 Long-term consumption of paprika powder compared to total spices, based on body weight (Basis: NVSII, only consumers).

		Average amount consumed**	
	Consumers*	**Median**	**Percentile 95**
Paprika powder	14.537 (94,6 %)	0,001	0,004
Total spices	15.335 (99,8 %)	0,009	0,030

* absolute number (in %);
** Monthly average in g/kg bw and day.

Table 1 shows the daily intake of paprika powder by consumers in grams per kg body weight. The median is the value that 50 percent of the population under consideration falls below or exceeds.. The 95th percentile represents the consumption behaviour of high consumers. The median intake of unsmoked paprika powder is 0.001 g/kg body weight (bw); high consumers consume 0.004 g/kg bw per day.

As part of a Spanish study to determine the average total consumption of smoked paprika over a year, an average intake of 139 g per person per year was determined for the Spanish population. This corresponds to an average intake of 0.005 g/kg bw per day (Coleto et al., 2021). As smoked paprika powder is a traditional Spanish spice, it seems plausible that the chronic daily intake determined for the Spanish population is higher than the intake of paprika powder in Germany.

3.1.4 Risk characterisation

There is a broad consensus in scientific risk assessment that, according to current knowledge, no threshold can be derived for DNA-reactive carcinogens below which it can be assumed with sufficient certainty that there is no risk to health. The risk assessment is then based on the assumption that it is not possible to determine an exposure level that is entirely without additional risk. In the European Union, the margin of exposure (MOE) approach is usually used to characterise the potential risk of genotoxic and carcinogenic substances in food. The MOE is the quotient of a suitable reference point, i.e. a dose that is associated with a certain increase in the tumour rate (often $BMDL_{10}$), and the human exposure to this substance. The MOE is not a health-based guidance value, but serves to prioritise risk management measures. For genotoxic-carcinogenic substances, an MOE of 10,000 or higher is generally considered a low priority for risk management measures, provided that a $BMDL_{10}$ from an animal study was used as a reference point (EFSA 2005).

In relation to the $BMDL_{10}$ values for BaP and the group of PAH4 (0.07 and 0.34 mg/kg bw and day), EFSA (2008) determined MOE values for the total intake across all foods of 17,900 for BaP and 17,500 for PAH4 at average consumption levels. At high consumption levels (high consumers: percentile 97.5 for cereals and seafood, average intake levels for all other food groups), the MOE values are 10,800 for BaP and 9,900 for PAH4. From these MOE values, the EFSA concluded that at medium intake levels, exposure to PAHs can be considered to be of little concern with regard to public health, but at higher intake levels there is a possible risk to public health and risk management measures are required to reduce exposure to PAHs (EFSA 2005).

The determination of the long-term consumption of spices is subject to some uncertainty (see Chapter 3.2). In the case to be assessed here, the MOE was determined based on the BaP/PAK4 concentrations of sample 1 of the smoked paprika powder under the assumption of the same consumption frequency and quantities of non-smoked paprika powder (70.4 µg BaP/kg; 311.7 µg PAH4/kg). In addition, the MOE for the daily intake in Spain was calculated based on the data from Coleto et al. (2021). For all exposure scenarios, an MOE value greater than 10,000 was calculated (Table 2). Under the assumption of an average consumption, an MOE value of 994,318 for BaP and 1,090,792 for PAH4 is calculated, for a high consumption 248,580 for BaP and 272,698 for PAH4. Based on the consumption data for medium consumption from the study by Coleto et al. and the content data reported from Hamburg, MOE values of 182,779 for BaP and 200,513 for PAH4 were calculated. From these MOE values, it can be concluded that exposure to PAHs from smoked paprika powder can be considered of low public health concern.

Table 2: Calculation of the MOE based on the determined maximum concentrationsof PAH in smoked paprika and the long-term consumption of paprika powder (see Table 1).

Source		Paprika powder[a]	BaP[b]	PAH4[b]	MOE*	
					BaP	PAH4
NSVII	Mean consumption	1	0.07	0.31	994,318	1,090,792
	High consumer	4	0.28	1.25	248,580	272,698
Coleto et al. (2021) Mean consumption		5.44	0.35	1.57	182,779	200,513

[a] Specified in mg/kg bw and day;
[b] Intake of PAH in ng/kg bw and day based on the concentrations in sample 1 (70.4 µg BaP/kg smoked paprika powder, 311.7 µg PAH4/kg smoked paprika powder);
* Reference point BaP (BMDL10): 0.07 mg/kg body weight (bw);
Reference point PAH4 (BMDL10): 0.34 mg/kg bw and day (EFSA 2008).

Due to their genotoxic and carcinogenic properties, exposure to PAH4 should be minimised as far as possible in accordance with the ALARA (as low as reasonably achievable) principle.

3.2 Uncertainties

Information on the consumption of spices is generally subject to uncertainty, as their consumption is often not documented and it can therefore be assumed that the amount consumed is underestimated. Furthermore, it is very difficult to estimate portion sizes in dietary surveys due to the very low weight of spices and the fact that they are added during preparation or seasoned from a shaker can. In addition, most of the information on spices comes from standard recipes in the German Nutrient Database and therefore does not necessarily reflect the amount consumed individually. The values shown in Table 1 are in some cases significantly lower than the average amount consumed by an individual person when eating dishes with smoked paprika powder (up to 2 tablespoons per 4 portions, internet research). This may be due to the fact that paprika powder is not consumed daily, as well as to the above-mentioned uncertainties in the recording of spices. In addition, there is currently no information available on the frequency of consumption of dishes containing smoked paprika powder. If corresponding dishes containing one teaspoon of paprika powder (1.5 g according to the EAT recording software of the University of Paderborn) or more were consumed daily, the amount consumed would therefore be many times higher than the values given in Table 1. Similarly, higher intakes can be assumed if smoked paprika powder is also used in chorizo sausage, which is available on the German market. As a rule, the use of paprika powder is stated in the list of ingredients without further specification of the exact variety. If the proportion of a foodstuff, such as smoked paprika powder, does not exceed two per cent by weight of the foodstuff, the general term "spices" may be used in accordance with Regulation (EU) No. 1169/2011.

The NVS II data are currently the most up-to-date, representative consumption data of the German population. However, they were already collected in 2005/2006. Any changes in consumption habits were not taken into account in this analysis. Rarely consumed foods, such as smoked paprika powder, are also difficult to capture in general nutritional surveys (niche products). The extent to which this affects not only food prepared in the household but also vegan food available in shops is not known at this time. Furthermore, no statement can be made on the consumption of paprika powder by children. The KiESEL study (Nowak et al. 2022) does not specify consumption levels of smoked paprika powder for children aged 6 months to 5 years.

In addition to the quantities and frequencies of consumption, further uncertainties concern the concentrations of PAHs in smoked paprika powder on the German market. At present, the BfR only has a few measured values. In the samples taken by the Institute for Hygiene and Environment of the Free and Hanseatic City of Hamburg, only three samples from one food business operator were measured. In the study by Coleto et al. (2021), 144 Spanish smoked paprika powders were measured and average BaP and PAH4 concentrations of 49 and 780 µg per kg of spice were measured. The range of concentrations within the 144 samples analysed in this study could not be confirmed in an internet search. However, the data from the study by Coleto et al. (2021) show that significantly higher concentrations of PAHs can occur in smoked paprika powder than was assumed for the calculation of the MOE here. This could lead to correspondingly higher intake levels.

3.3 Risk management options, Recommended measures

The assessment of health risks due to exposure to polycyclic aromatic hydrocarbons is based in particular on the genotoxic-carcinogenic effect of some PAHs. In the European Union, the general recommendation is to minimise exposure to genotoxic and carcinogenic substances as far as reasonably achievable (ALARA principle: as low as reasonably achievable), as even low intake levels, especially with regular consumption, can be associated with an increase in health risks. The available concentration data of the three samples of smoked paprika indicate in their range that the contents can be influenced by the manufacturing process and that a minimisation of the PAH contents is possible by optimising the manufacturing process.

On the basis of the calculations made here and taking into account the existing uncertainties, the PAH concentrations in the three smoked paprika powders appear to be of low concern with regard to chronic consumption. However, a more robust risk assessment would require a reduction of the uncertainties regarding chronic consumption levels of smoked paprika powder in Germany, taking into account the potential change in dietary habits towards vegetarian and vegan nutrition. Representative PAH content data in smoked paprika powder could, for example, be collected as part of specific monitoring projects (project monitoring).

Further information on the BfR website on polycyclic aromatic hydrocarbons (PAHs)

Questions and answers about smoke flavours
https://www.bfr.bund.de/en/smoke_flavourings_in_food-201317.html

A-Z Index Polycyclic Aromatic Hydrocarbons (PAH),
https://www.bfr.bund.de/en/a-z_index/polycyclic_aromatic_hydrocarbons__pah_-130109.html

4 References

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Responsible according to the German Press Law: Dr Suzan Fiack

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