

Levels of pharmacologically active opium alkaloids in poppy seeds should be lowered to the minimum technologically achievable level

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The ripe seeds of opium poppy are highly regarded for their level of oil and protein, and are used in the manufacture of bakery produce and vegetable oil. The milky sap (latex) of unripe capsules in particular is also used to obtain opium alkaloids for pharmacological purposes. Opium alkaloids include morphine and codeine. The poppy seeds themselves contain only very small quantities of opium alkaloids. However, poppy seeds may be contaminated with alkaloid-containing latex, e.g. during mechanical harvesting processes.

The European Food Safety Authority (EFSA) updated its opinion on opium alkaloids in poppy seeds on 16 May 2018 (<https://www.efsa.europa.eu/en/efsajournal/pub/5243>). The assessment is based on data on morphine and other alkaloids in poppy seed samples. An acute reference dose (ARfD) of 10 µg morphine equivalents per kg body weight (bw) was derived as a group ARfD for morphine and codeine. The ARfD is defined as quantity of a substance which consumers can ingest with food in the course of one day without any recognisable health risk. The BfR agrees with the statements made in the latest EFSA opinion. In compliance with the assessment approach taken by the BfR in 2005, EFSA derived an ARfD starting from the lowest oral single dose which still shows a pharmacological effect.

The data upon which the assessment is based show that the morphine content of food poppies varies greatly. For example, the poppy plant variety, time of harvest and the geographical origin may influence the morphine content. With poppy seeds containing high levels of opium alkaloids, people of all age groups can exceed the derived health-based guidance value. High levels are usually found in varieties bred primarily for pharmaceutical purposes. With poppy seeds containing relatively low amounts of opium alkaloids, an exceedance is possible only for high consumers. Low levels commonly originate from varieties cultivated for food use.

The BfR still recommends that all efforts should be made to lower levels of pharmacologically active opium alkaloids in poppy seeds to the technologically feasible minimum. Since, latest EFSA exposure estimates also showed that people of all age groups can exceed the health-based guidance level, especially when poppy seeds with high opium alkaloid levels are consumed, the BfR still advises against excessive consumption of foods containing high amounts of poppy seeds, especially during pregnancy.

The European Food Safety Authority (EFSA) updated its opinion on opium alkaloids in poppy seeds on 16 May 2018. EFSA confirms the acute reference dose (ARfD) of 10 µg morphine/kg body weight (bw) it derived in 2011 and recommends that the concentration of codeine in the poppy seed samples should also be taken into account. The ARfD is therefore a group ARfD for morphine and codeine expressed in morphine equivalents. In compliance with the assessment approach taken by the BfR in 2005, EFSA derived an ARfD in 2011 starting from the lowest oral single dose which still shows a pharmacological effect. When selecting an uncertainty factor, EFSA included extrapolation of the "lowest observed effect level" (LOEL) to the "no observed effect level" (NOEL) and individual differences in sensitivity, but disregarded uncertainties relating to intensification of undesired effects due to parallel consumption of alcohol or intake of medication. Therefore, the derived ARfD is 10 µg mor-

phine equivalents/kg bw. The ARfD represents the dose at which no undesired effects are to be expected, if it is ingested in the course of a meal or spread over a whole day.

Morphine is mostly used for treatment of severe pain. Its undesired effects include nausea, vomiting, dizziness, respiratory depression and cardiovascular effects. Long-term use can lead to the development of tolerance as well as psychological and physical dependence. Individual sensitivity fluctuates considerably. This applies both to its pharmaceutically desired as well as undesired effects. In animal studies, morphine mediated negative effects on development and reproduction. Mutagenic effects were also observed.

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Therefore, the BfR still recommends that all efforts should be made to lower the levels of pharmacologically active opium alkaloids in poppy seeds to the technologically feasible minimum. The opium alkaloid content in poppy seeds can also be further reduced through washing, as well as baking and milling. Since, latest EFSA exposure estimates also showed that people of all age groups can exceed the guideline health values, especially when poppy seeds with high opium alkaloid levels are consumed, the BfR still advises against excessive consumption of foods containing high levels of poppy seeds, especially during pregnancy. Larger quantities of poppy seeds can occur above all in poppy cake, desserts containing poppy seeds, such as poppy dumplings, and dishes sprinkled with poppy seeds, such as *Dampfnudel* dough balls.

More information on the subject of poppies at the BfR website (German only)

http://www.bfr.bund.de/de/a-z_index/mohnsamensamen-7392.html



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