

## FAQ

27 July 2024

### Questions and answers on ergot alkaloids in cereal products

→ This version updates the version dated 12 November 2013 and has been revised throughout.

Ergot alkaloids are metabolites of certain fungi, e.g. *Claviceps purpurea*. Depending on the dose, these alkaloids can cause mild to severe health impairments. Investigations in Germany and the European Union have shown that rye products in particular, but also cereal products derived from other cereals, can contain high levels of ergot alkaloids: Depending on the cultivation and weather conditions in the respective harvest year, cereals can be increasingly infested with the permanent form of the fungus, the dark-coloured solid-walled sclerotia (ergot), which can then lead to increased ergot alkaloid levels in cereal products under unfavourable conditions. The BfR has compiled questions and answers on the health risk of ergot alkaloids in cereal products.

#### What are ergot alkaloids?

Ergot alkaloids are mainly found in the ergot. The term ergot refers to structures formed by phytopathogenic fungi such as the ergot fungus (*Claviceps purpurea*). These permanent forms of the fungus, scientifically known as sclerotia, protrude from the husks of the ears of infected wild grasses and cereals as "ergot", usually clearly visible due to their dark colour. Among the agriculturally cultivated cereals, rye is particularly affected, but other cereals such as wheat can also be infected by the fungus.

#### What health risks can ergot alkaloids pose to humans?

After oral intake of small amounts of ergot alkaloids, acute symptoms such as nausea, abdominal pain, muscle contractions, headaches, cardiovascular problems (e.g. high blood pressure) and disorders of the central nervous system (CNS) may occur. Human data show that uterine contractions can occur even at low intake levels, possibly leading to uterine haemorrhage and abortion. After ingestion of large amounts of ergot alkaloids, acute toxic effects described include circulatory disorders due to the vasoconstrictive effect on the blood vessels, particularly in the heart muscle, but also in the kidneys and limbs. The

symptoms can be accompanied by hallucinations, convulsions, sensory disturbances and paralyses and can lead to death after respiratory or cardiac arrest.

After chronic intake of moderate amounts of ergot alkaloids, reproductive effects may also occur (e.g. triggering of miscarriages, lower birth weights, lack of milk production). Chronic oral intake of high levels of ergot alkaloids causes symptoms similar to those of acute intake of high levels of ergot alkaloids. Knowledge of this is based on observations of adverse effects when certain ergot alkaloids were used as active pharmaceutical ingredients or when disease outbreaks occurred after the consumption of cereal products containing high levels of ergot alkaloids.

### **Are there health-based guideline values that can be used for the health risk assessment of ergot alkaloids in food?**

In 2012, the European Food Safety Authority (EFSA) derived health-based guidance values (HBGVs) for tolerable intake levels of ergot alkaloids for the first time: an acute reference dose (ARfD) of 1 microgram ( $\mu\text{g}$ ) per kilogram (kg) body weight (bw) for short-term intake and a tolerable daily intake (TDI) of 0.6  $\mu\text{g}$  per kg bw per day for long-term intake. The HBGVs were derived from an animal study in rats and compared with pharmacological findings from drug use. Vaso- and uterine contractions were used as the most sensitive toxicological endpoints.

### **Through which foods can consumers ingest ergot alkaloids?**

The main source for the intake of ergot alkaloids are cereal products such as flour, bread and bakery wares. Depending on the harvest conditions, in particular products made from rye (rye flour, wholemeal rye bread, rye bread and rolls), which are consumed comparatively frequently in Germany, but also other types of grain, such as wheat or spelt, can have increased levels of ergot alkaloids.

### **How do ergot alkaloids end up in cereal products?**

In addition to climatic conditions, agricultural engineering measures in particular influence the concentration of ergot alkaloids along the entire value chain: from the selection of seeds and cultivation to the selection of raw materials and the technological processing of the grain. For example, inadequate removal of ergot before processing of the grain can result in ergot alkaloids ending up in the grain products when the grain is milled. However, contamination with ergot alkaloids can also occur after the grain has been cleaned, e.g. through fragments or dust from the ergot containing ergot alkaloids.

### **Can consumers recognise whether cereal products contain ergot alkaloids?**

Consumers cannot recognise the presence of ergot alkaloids in cereal products. Ergot alkaloids can only be detected in cereal products using chemical analytical methods. For this reason, cereal products are analysed for ergot alkaloids both as part of the official food control and the food monitoring as well as the self-controls of food business operators.

### **Which consumer groups are particularly at risk from ergot alkaloids in food?**

Children are considered as a vulnerable consumer group due to their lower body weight compared to the amount consumed. In addition, pregnant women, unborn children and newborns are also considered particularly vulnerable consumer groups.

### **How does the BfR assess the health risks of ergot alkaloids in cereal products?**

In 2023, the BfR carried out an assessment of the health risks from ergot alkaloids in selected cereal products. Children aged between six months and six years were considered, who represent a vulnerable consumer group due to their lower body weight compared to the amount consumed. Based on data from official food monitoring in Germany from 2013 to 2021, the BfR concludes that acute health impairments can occur with a medium likelihood, in particular through the consumption of rye products. From a toxicological point of view, further efforts should therefore be made to further reduce the concentration of ergot alkaloids in food.

### **Are there legal regulations for the levels of ergot sclerotia and ergot alkaloids in cereals and cereal products?**

Since 2015, a maximum level of 0.5 g ergot sclerotia per kilogramme (kg) of unprocessed cereals (except maize and rice) has applied in accordance with Regulation (EU) 2015/1940. This was lowered to 0.2 g/kg on 1 January 2022 (Regulation (EU) 2021/1399). A maximum level of 0.5 g/kg still applies to unprocessed rye. From 1 July 2025, a lowering to 0.2 g/kg is also planned here (Regulation (EU) 2024/1808).

As previously explained (question: How do ergot alkaloids get into cereal products?), ergot alkaloids can enter the food chain not only via intact ergot sclerotia, but also via fragments or dust from ergot sclerotia formed during transport, storage and processing of the cereals. Therefore, in addition to the legally binding regulation for the levels of ergot sclerotia in cereals, Regulation (EU) 2021/1399 also sets maximum levels for the sum of the twelve toxicologically most relevant ergot alkaloids (ergotamine, ergocristine, ergocryptine, ergosine, ergometrine, ergocornine and their epimers). These came into force on 1 January 2022.

In order to further reduce the intake of ergot alkaloids via the consumption of food, a lowering of individual maximum levels has been implemented or is planned in accordance with Regulation (EU) 2024/1808:

For milling products of barley, wheat, spelt and oats (with an ash content of less than 900 mg/100 g) from previously 100 µg/kg

- to 50 µg/kg from 01/07/2024 for barley, spelt and oats
- to 50 µg/kg from 01/07/2028 for wheat.

For milling products of rye and rye that is placed on the market for the final consumer, from previously 500 µg/kg

- to 250 µg/kg from 01/07/2028.

In addition, maximum levels have been set for milling products of barley, wheat, spelt and oats (with an ash content of at least 900 mg/100 g), for barley, wheat, spelt and oat grains placed on the market for the final consumer, for wheat gluten and for processed cereal-based foods for infants and young children.

### **What measures are taken to prevent the occurrence of ergot alkaloids?**

In the mills, ergot is removed using various technical measures. However, under certain circumstances, e.g. due to climatic conditions such as periods of drought, the shape or colour of the ergot can change. Due to these changes, the ergot is not detected by routine cleaning techniques. This can result in increased levels of ergot alkaloids in cereal products. The BfR therefore recommends the consistent application of agricultural and technological Good Manufacturing Practices (GMP) with the aim of minimising the levels of ergot alkaloids in cereal products. The focus here is on measures taken by all economic operators along the entire value chain, from the selection of seeds and cultivation to the selection of raw materials and the technological processing of the grain.

To this end, the Federal Ministry of Nutrition and Agriculture (BMEL) initiated a working group coordinated by the Max Rubner-Institute (MRI) and with the participation of experts from federal authorities and associations, which developed "[Recommendations for action to minimise ergot and ergot alkaloids in cereals](#)" (in German only) in 2014 and updated them in 2023. The revised version of the recommendations for action has been published on the MRI website.

There is also a "[Code of practice for the prevention and reduction of mycotoxin contamination in cereals](#)" of the Codex Alimentarius, which includes recommendations for the prevention and reduction of ergot and ergot alkaloid contamination in cereals.

### **Further information on ergot alkaloids and moulds**

BfR-Opinion: Assessment of health risks from ergot alkaloids in selected cereal products

<https://www.bfr.bund.de/cm/349/assessment-of-health-risks-from-ergot-alkaloids-in-selected-cereal-products.pdf>

Mould in foods – health risks and how to avoid them

<https://www.bfr.bund.de/cm/349/mould-in-foods-health-risks-and-how-to-avoid-them.pdf>

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