

Sources of EAs exposure

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43. The European Union (EU) established maximum levels (ML) of ergot sclerotia and of EAs in Commission Regulation (EU) 2021/1399, effective as of January 2022. The ML of ergot sclerotia permitted in unprocessed cereals, with the exception of maize, rye and rice, is 0.2 g/kg. For unprocessed rye, the limit

was 0.5 g/kg, further reduced to 0.2 g/kg in July 2024. For milled products derived from barley, wheat, spelt or oats with an ash content of less than 900 mg/100 g, a limit of 100 µg EAs/kg applies, which was further reduced to 50 µg/kg in July 2024. For the same types of grain products with a higher ash content or sold directly to the end consumer, the maximum level of EAs was set at 150 µg/kg. The maximum level of EAs in wheat gluten is 400 µg/kg. As an open pollination species, rye is generally more susceptible to infestation, which is reflected in a higher ML. Milled rye products are subject to an EAs limit of 500 µg/kg, which was further reduced to 250 µg/kg in July 2024. A ML of 20 µg/kg for EAs in grain-based food for infants and toddlers has also been introduced. The levels brought in by the EU for EAs as well as any subsequent changes to these limits do not apply in Great Britain (GB), however they do apply in Northern Ireland (NI).

44. EFSA's estimated chronic dietary exposure to EAs in the adult population was between 0.007 and 0.08 µg/kg bw per day for average consumers and 0.014 and 0.19 µg/kg bw per day for high consumers. The estimated acute dietary exposure in the adult population ranged between 0.02 and 0.23 µg/kg bw per day for average consumers, and between 0.06 and 0.73 µg/kg bw per day for high consumers. The highest exposure (chronic and acute) was in countries with relatively high consumption of rye bread and rolls. Assessment of the dietary exposure to EAs in specific groups of the population indicated no significant differences between vegetarians and the general population. However, a slightly higher dietary exposure to EAs was noted in consumers of unprocessed grains compared to the general population (EFSA, 2012).

45. The German Federal Institute for Risk Assessment (BfR) based their risk assessment of EAs on the consumption of rye flour contaminated with ergotamine and ergometrine. The BfR estimated that on average, ergotamine accounted for a maximum of 46 % of the total alkaloid content. The consumption of 250 g of the most contaminated rye flour would result in an intake of 834 µg ergotamine per day per person (BfR, 2004).

46. Caraballo et al. (2019) reported concentrations of EAs of up to 47 µg/kg in grains and grain-based composites. Despite effective cleaning procedures, surveys of Swiss, Canadian, Danish, and German cereals, cereal products and rye flours detected levels of EAs, with concentrations of up to 7.3 mg/kg (German rye flour) (Krska and Crews, 2008). Arroyo-Manzanares (2017) carried out an extensive survey on European products and tested 1,065 samples of cereals and cereal products (rye, wheat, and multigrain-based food that contain rye and wheat) intended for human consumption, as well as a number of animal feeds. In total, 59 % of samples tested positive for EAs, with EAs present in 84 % of rye

food, 67 % of wheat food and 48 % of multigrain-based food. Levels overall ranged from 1 to 12,340 µg/kg, but while the highest frequencies of contamination were observed for food samples, feed samples accounted for the highest levels of ergot alkaloids. Storm et al. (2008) detected EAs in Danish rye flour samples with an average and maximum concentration of 46 µg/kg and 234 µg/kg, respectively. Crews et al. (2009) detected EAs in 25 of 28 samples, including all 11 types of rye crispbreads with concentration up to 340 µg/kg, while Müller et al. (2009) found EAs in 92 % of tested rye products with a maximum content of 740 µg/kg. Reinhold et al. (2011) tested 500 food samples from Germany, approximately 50 % of which were positive for EAs, with a highest concentration of 1,063 µg/kg. A more recent survey by Bryła et al. (2015) detected EAs in 83 % of tested rye grain, 94 % of rye flour, and 100 % of rye bran and flake samples. Ergocryptine, ergocristine, and ergotamine were the most common EAs detected in the majority of surveys and foods sampled. A study by Dusemund et al. (2006) concluded that ergometrine contributed 5 % of the total alkaloid content and that consumption of 250 g of the most contaminated rye flour would result in an intake of 91 µg ergometrine per day per person.