

Risk Assessment Studies
Report No. 64

Chemical Hazard Evaluation

Ergot Alkaloids (EAs) in Food

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Centre for Food Safety
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EXECUTIVE SUMMARY

Ergot alkaloids (EAs) are mycotoxins produced by fungi, mainly members of the *Claviceps spp.* *Claviceps spp.* are known to infect some cereal grains such as rye, triticale, wheat, barley, millet and oats. During infection, the fungus colonises the ovaries and replaces the developing grains or seeds with alkaloid-containing sclerotia (ergots). EAs are predominantly contained in the ergots. If ergots are harvested together with the cereal grains, the grains and their products can also be contaminated with EAs.

2. In the Middle Ages, the consumption of EA-contaminated grains, flour or bread caused severe epidemics in Europe. Intoxicated people suffered from intense pain resulting from vasoconstriction and subsequent gangrene with loss of fingers, hands, feet and even entire limbs. The condition is rare today, primarily because the grain cleaning and milling processes have removed most of the ergots so that only very low levels of alkaloids remain in the grains and their products.

3. The Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA) established a group Tolerable Daily Intake (TDI) of 0.4 µg/kg body weight (bw) per day for the sum of total EAs in the diet in 2021.

4. This study serves (i) to determine the levels of EAs in selected foods

available in the local market; (ii) to estimate the dietary exposure to EAs of the Hong Kong adult population arising from the consumption of these foods; and (iii) to assess the associated health risk.

5. Cereal and cereal products, particularly rye containing products, were reported to be the main contributor to the dietary exposure of consumers to EAs in different overseas studies. This study, focusing on foods reportedly more likely to contain EAs, collected 339 samples from 8 food groups including “Cereal grains”, “Flour and starch”, “Pasta and noodles (raw and dried)”, “Pasta and noodles (raw and not dried)”, “Bread and rolls”, “Breakfast cereals”, “Other bakery wares” and “Cereal beverages”.

6. About 79% of samples (267 samples) were not detected with EAs. Among the samples with detectable EAs (72 samples, 21%), the levels of total EAs ranged from 0.54–6.5 µg/kg (lower-bound (LB) to upper-bound (UB)) to 1200 µg/kg. The results revealed that the levels of EAs were higher in the food groups “Breakfast cereals” and “Bread and rolls”, with the mean levels of total EAs of 30–35 µg/kg (LB–UB) and 12–16 µg/kg (LB–UB) respectively. When compared with the mean levels of total EAs reported by European Food Safety Authority (EFSA) in 2017, the results in this study were lower in general.

7. In this study, the dietary exposures to EAs of the average and high adult consumers (90th percentile) of the local population were 0.018–0.076 µg/kg bw/day (LB–UB) (4.4%–19% of TDI) and 0.036–0.12 µg/kg bw/day (LB–UB) (9.1%–29% of TDI) respectively. The results suggested that both

average and high adult consumers were unlikely to experience adverse effects of EAs. When compared with the mean dietary exposure to EAs across the European adult populations as reported by EFSA in 2017, the mean dietary exposure of the local adult population in this study was relatively low.

8. By virtue of the estimated dietary exposures to EAs in adults, the public are recommended to follow basic dietary advice on healthy eating and to maintain a balanced and varied diet.

9. Members of the trade (e.g. farmers, feed and food manufacturers) are advised to follow Codex Alimentarius Commission (Codex)'s "Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals" to reduce the levels of EAs, such as using separation techniques to clean the grains in order to remove ergots and their dust on the grain surface.

Ergot Alkaloids (EAs) in Food

OBJECTIVES

The Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department (FEHD) conducted a risk assessment study on ergot alkaloids (EAs) in Food in 2019–2021, with a view to providing an overview on the occurrence and levels of EAs in various foods in Hong Kong, estimating the dietary exposure to EAs of the local adult population, and assessing the associated potential health risk.

BACKGROUND

2. EAs are naturally occurring mycotoxins produced by several species of fungi in the genus *Claviceps* such as *Claviceps purpurea*, *africana*, *fusiformis*, *sorghii*, etc. In Europe, *C. purpurea* is the most widespread *Claviceps* species.¹ Infections are mostly prevalent in cereals and wild grasses.² The fungal hyphae invade the ovule of the host grass, and colonise the whole ovary. It was reported that the ovary is the only organ of the grass plant susceptible to infection.^{3, 4} The fungus replaces the developing grains or seeds with alkaloid-containing sclerotia^a. These sclerotia are dark, banana shaped, protruding from the regular grains of the ear. The sclerotia of *Claviceps* species are known as ergots.⁵

^a A sclerotium (plural sclerotia) is a compact mass of hardened fungal mycelium containing food reserves. One role of sclerotium is to survive environmental extremes.

3. EAs are predominantly contained in the ergots.⁶ If ergots are harvested together with the cereal grains, the grains and their products can also be contaminated with EAs. Ergot is an important disease of cereals, which can lead to extensive financial losses to growers.⁷ The main types of cereal affected are rye and triticale (*Claviceps purpurea*), sorghum (*Claviceps africana*, *sorghii*, *sorghicola*) and pearl millet (*Claviceps fusiformis*). In spring seasons with longer moist and cool periods, wheat and barley might also be affected.⁸ Open-pollinated crops such as rye and triticale are more susceptible because of the easy access of the spores of the fungi into the flowering head.^{9, 10} Unlike other mycotoxins that are capable of forming post-harvest as a result of spoilage during storage, ergot only forms pre-harvest with EAs levels remaining relatively constant during storage.¹⁰

4. In the Middle Ages, the consumption of EA contaminated grains, flour or bread caused severe epidemics of the condition known as Holy Fire or St. Anthony's fire (so named for the burning sensation caused in victims' limbs) in Europe. It was reported that St. Anthony's fire was the major foodborne disease in human history between the Middle Ages to 20th century. More than 100 major outbreaks were recorded between the 8th and 16th century with as many as 40,000 deaths per incident. In the 20th century, some outbreaks were observed in Europe and Africa causing numerous deaths.¹¹ Intoxicated people suffered from intense pain resulting from vasoconstriction and subsequent gangrene with loss of fingers, hands, feet and even entire limbs.² The condition is now known as ergotism.^{5, 11} Ergotism is extremely rare today, primarily because the grain cleaning and milling processes have removed most of the ergots so that only very low levels of alkaloids remain in the grains

and their products.¹²

5. During the last decade, several places such as Canada¹³, United Kingdom (UK)^{14, 15, 16} and some European Union (EU) countries^{1, 5, 6} have conducted surveys on EAs in food. Apart from cereal grains (e.g. rye, wheat, barley, spelt, oat and their milling products), certain secondary cereal products including bread and rolls, breakfast cereals, pasta (raw), biscuits and fine bakery products were also covered in these surveys. In general, the reported levels of EAs in rye and rye products in these studies were higher than the levels in other cereals and their products.

6. There have been no reports of carryover of EAs to foods of animal origin.¹⁷ The European Food Safety Authority (EFSA) (2017) reported that the EAs levels were unquantified in samples of poultry, milk and milk product as well as other foods of plant origin such as fruits, vegetables, tree nuts, spices, *etc.*¹

7. EAs are relatively thermolabile, and some studies showed that baking or other cooking processes can reduce EA concentrations in food products.^{12, 18} Besides, reduction of EAs in cooked noodles or spaghetti products might also be due to leaching of EAs into the cooking water.⁵

8. Measures can be done to reduce the levels of EAs in cereal products. EAs are mainly present in ergot, therefore sorting and other cleaning methods early in grain processing will significantly reduce EA levels further down the food chain.⁸ However, even in the absence of physical sclerotia, alkaloids may still be detected in grain samples.^{6, 19} Ergot bodies have a softer, greasier and less dense structure than the grain

kernels, and there is a high probability that very fine ergot dust can be released via rubbing of the kernels and the sclerotia against each other when moving the lot containing ergot bodies. As the rubbed-off material has highly-adhesive properties, it sticks to the grain surface.⁸

Structure of ergot alkaloids

9. Most of the naturally occurring EAs show a tetracyclic ergoline ring system with a nitrogen atom at position 6 (Figure 1). In many EAs, this nitrogen is methylated, and the ring is substituted at C8 and possesses a double bond between C8 and C9 or C9 and C10.^{2, 5}

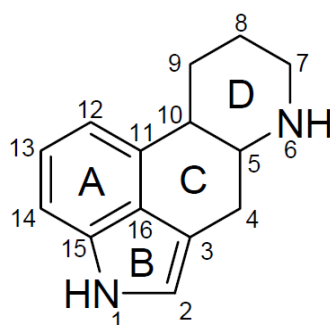


Figure 1: Ergoline ring system including numbering and assignment of rings.

10. EAs that have a double bond between C9 and C10 (known as ergolenes) undergo epimerisation, with respect to the centre of symmetry at C8, resulting in two epimers, ergopeptines (indicated by the suffix –ine) and ergopeptinines (indicated by the suffix –inine), respectively. These epimers differ in biological and physicochemical properties. The –ines isomers are biologically active, whereas the inines isomers are inactive. Both forms are found together in naturally contaminated samples. The conversion of the –ine to the –inine isomers occurs rapidly in aqueous solutions, and can reverse in some aqueous and organic solvents (Figure 2).^{2, 5}

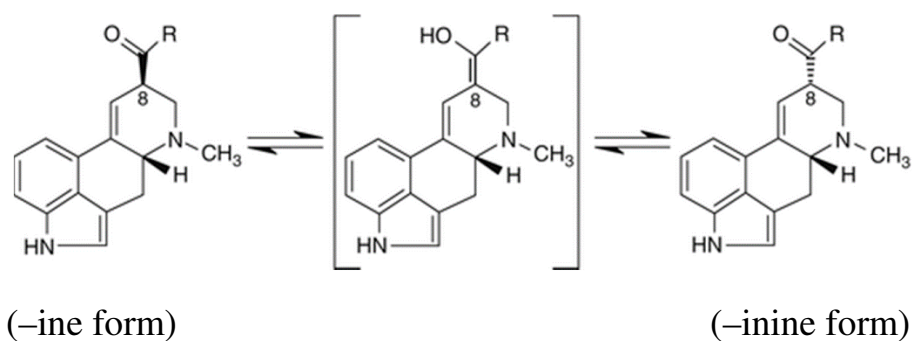


Figure 2: EAs containing C9 = C10 double bond readily epimerise at the centre of symmetry C-8.

11. The most prominent EAs produced by *Claviceps* species are ergometrine, ergotamine, ergosine, ergocristine, ergokryptine and ergocornine. The amount and pattern of these alkaloids varies between fungal strains, and depends on the host plant, the maturity of the sclerotia, the geographical region, and the prevailing weather conditions.^{2, 8, 9, 20} For example, cool conditions, and especially cool wet conditions that prolong the flowering period, will favour ergot infection. Among the rye varieties, the degree of susceptibility to ergot correlates with the level of pollen discharge.^{4, 10} A high pollen count increases the likelihood of fertilisation, leading to the closing of blossom more quickly, and the rejection of ergot spores. The concentration of EAs may also vary in different batches of grain or harvest year.^{10, 14}

Toxicity of ergot alkaloids

12. Ergot poisoning in humans is known as ergotism. Ergotism has two forms: gangrenous (e.g. itchy and burning skin, gangrene and loss of hands/feet), or convulsive (e.g. hallucinations, delirium and epileptic-type seizures).^{8, 21} It was reported that epidemics of ergotism usually

presented purely gangrenous or purely convulsive manifestations, although several mixed epidemics were reported.²²

Kinetics and metabolism

13. Data on toxicokinetics are sparse and are mainly limited to those EAs that are used as pharmaceuticals (e.g. ergometrine and ergotamine).

14. The available literature suggests that EAs are absorbed from the gastrointestinal tract, distributed readily in plasma and subjected to oxidative biotransformation, primarily by cytochrome P450 3A4, and some EAs (e.g. ergometrine) can subsequently be conjugated with glucuronic acid.⁵ Biliary excretion represents the main elimination pathway except in ruminants.^{5, 23}

Acute effects

15. Following oral ingestion of small quantities of EAs, acute symptoms such as vomiting, spasms, headaches, cardiovascular problems (e.g. hypertension or cardiac arrhythmia) and dysfunctions of the central nervous system can occur. Human data show that uterus contractions can be caused even by small intake quantities. These can in turn lead to uterus bleeding and miscarriage. Following consumption of high EA quantities, acute toxic effects such as circulatory disorders due to the vaso-constrictive effects on blood vessels, especially to the cardiac muscle but also to the kidneys and the extremities have been described. The symptoms can be accompanied by hallucinations, spasms and impaired sensations and paralysis and can, following respiratory or cardiac arrest, lead to death.⁶ Sublethal acute exposure induces signs of neurotoxicity, including restlessness, miosis or mydriasis, muscular

weakness, tremor and rigidity.

Developmental and reproductive toxicity

16. Chronic intake of moderate quantities of EAs can have a negative impact on reproduction (e.g. trigger miscarriage, lower birth weight and deficient lactation).⁶ Chronic oral ingestion of large quantities of EAs results in symptoms which correspond to acute ingestion of high quantities of EAs. This is known from observations of unwanted effects where certain EAs were used as active ingredients in medicines or where, following ingestion of cereal products containing high levels of ergot, people became ill.⁶

Genotoxicity and carcinogenicity

17. The International Agency for Research on Cancer (IARC) has not classified the carcinogenicity of EAs.

18. With the exception of ergotamine, only limited genotoxicity studies have been carried out on naturally occurring EAs. No mutagenic activity of ergotamine has been detected *in vitro*. Early studies showed that it had some chromosome damaging effects *in vitro* and *in vivo* although the latter were weak and inconsistent. Based on the available information on genotoxicity and carcinogenicity of EAs, the EFSA concluded that the observed tumours in rats fed crude ergot or ergotoxin were related to a non-genotoxic mode of action.⁵

Health-based guidance values

19. In 2012, the EFSA established a group Acute Reference Dose

(ARfD) of 1 µg/kg body weight (bw), and a group Tolerable Daily Intake (TDI) of 0.6 µg/kg bw per day for the sum of the EAs (ergometrine, ergosine, ergocornine, ergotamine, ergocristine, ergocryptine (α- and β-isomers) and their corresponding –inine (S)-epimers). Equal relative potency for all EAs was assumed as the available data did not allow determination of relative potencies.⁵

20. The Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA) evaluated EAs in 2021. JECFA considered that the available data were insufficient to establish toxic equivalency factors (TEFs) for different EAs. Hence, it was appropriate to establish a group ARfD and a group TDI for the simple sum of total EAs, and JECFA established the group ARfD and the group TDI at the same value of 0.4 µg/kg bw per day for the sum of total EAs in the diet.²⁴

Regulatory control

21. In 2017, the Codex Committee on Contaminants in Food (CCCCF) amended the “Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals” (COP) with the incorporation of an annex which advises farmers and producers on good agricultural and manufacturing practices to reduce *Claviceps* infection and EA contamination of cereals.²⁵

22. Codex Alimentarius Commission (Codex)^{26, 27}, EU²⁸, the United States^{29, 30, 31}, Canada³², Australia and New Zealand³³, and mainland China³⁴ have established maximum levels (MLs) for ergot sclerotia in certain cereals.

23. There is no specific local regulation on EAs in food. Nevertheless, as stipulated in the Public Health and Municipal Services Ordinance (Cap 132), all foods for sale in Hong Kong must be fit for human consumption.

SCOPE OF STUDY

24. EAs were in the priority list of contaminants for evaluation by JECFA in 2017–2019. The CFS, as a World Health Organization (WHO) Collaborating Centre for Risk Analysis of Chemicals in Food, considered that there is a need to conduct a study to determine the EAs in local foods, and to estimate the potential health risk posed to the local population.

25. This study focused on foodstuffs in the local market which were reportedly more likely to contain EAs. These foodstuffs were classified into 8 different food groups which included “Cereal grains”, “Flour and starch”, “Bread and rolls”, “Breakfast cereals”, “Pasta and noodles (raw and dried)”, “Pasta and noodles (raw and not dried)”, “Other bakery wares” and “Cereal beverages”.

METHODS

Sampling

26. A range of locally-available food items which contained cereals were analysed in this study. The selection was based on the reported occurrence of EAs in different food groups in the literature. A total of 339 samples were collected. Food samples were purchased from various retail stores (including those in wet markets) such as bakery shops, supermarkets, restaurants, cafés, *etc.* between June and September 2019.

Laboratory analysis

27. Laboratory analyses were conducted by the Food Research Laboratory (FRL) of the CFS. Samples collected were sent to the FRL for testing of EAs on individual sample basis. The testing included the following 12 EAs: ergocristine, ergotamine, ergocryptine^b, ergometrine, ergosine and ergocornine; and their –inine forms.

28. Each sample was extracted with a mixture of acetonitrile and ammonium carbonate solution. The sample extract was then purified by a MycoSep[®] ergot column. Levels of EAs in the sample were determined by ultra-performance liquid chromatography-tandem mass spectrometry. The limit of detection (LOD) of all 12 EAs was 0.5 µg/kg whereas the limit of quantification (LOQ) was 2 µg/kg.

Data interpretation

29. For the calculation of the total EAs in a sample, the levels of all 12 EAs detected in the sample were summed up. In situations where samples with some or all EAs below LOD (i.e. non detected (ND)), the true values for these results may actually be any values between zero and the LOD. In these situations, the substitution method (i.e. the lower-bound (LB) and upper-bound (UB) approach) as recommended in the “Principles and Methods for the Risk Assessment of Chemicals in Food” was used for expressing “ND” results.³⁵ A value of zero and the

^b α-ergocryptine and β-ergocryptine were analysed separately.

value of LOD were assigned to the results of “ND” for all EAs in each sample for the calculation of the total EAs at the LB and UB levels respectively.

Food consumption data

30. The food consumption data from the Hong Kong Population-based Food Consumption Survey 2005–2007 were used for estimating dietary exposures to EAs.³⁶

Estimation of dietary exposures

31. In this study, although food items under some food groups^c were non-ready-to-eat, the reported levels of EAs in all foods were used to estimate the dietary exposure. Hence, the dietary exposure to EAs of the local adult population was obtained by combining the weighted population consumption data from 24-hour recalls and the sum of EAs of foods in different food groups in this study.

32. In addition, different food items were grouped into food groups to better illustrate their contribution to the total dietary exposure to EAs.

33. The dietary exposure was performed with the aid of an in-house developed web-based computer system, Exposure Assessment System

^c The food groups “Cereal grains”, “Flour and starch”, “Pasta and noodles (raw and dried)” and “Pasta and noodles (raw and not dried)” were non-ready-to-eat.

(EASY). The mean and 90th percentile exposure levels were used to represent the dietary exposures of average and high consumers of the local population respectively. The estimated exposures were compared with the TDI established by JECFA in 2021.

RESULTS AND DISCUSSION

Occurrence of ergot alkaloids

34. A total of 339 food samples were collected in this study which were grouped under 8 food groups, including “Cereal grains”, “Flour and starch”, “Pasta and noodles (raw and dried)”, “Pasta and noodles (raw and not dried)”, “Bread and rolls”, “Breakfast cereals”, “Other bakery wares” and “Cereal beverages”. Among the 339 samples analysed, EAs were not detected in 267 samples (79%). Only 72 samples (21%) were reported to have at least one detectable EA (\geq LOD).

35. The mean levels of total EAs of different food groups were summarised in Table 1. EAs were not detected in all samples in “Cereal beverages”. Among the 72 samples with detectable EAs, more than one-third were from the food group “Bread and rolls” (26 samples, 36%).

36. The mean levels of total EAs in food groups other than “Cereal beverages” ranged from 0.49–6.8 $\mu\text{g}/\text{kg}$ (LB–UB) to 30–35 $\mu\text{g}/\text{kg}$ (LB–UB). The food group “Breakfast cereals” had the highest mean level of total EAs (30–35 $\mu\text{g}/\text{kg}$, LB–UB), followed by “Bread and rolls” (12–16 $\mu\text{g}/\text{kg}$, LB–UB).

37. The levels of total EAs in different food categories were listed in the annex. The highest level of total EAs (i.e. 1200 $\mu\text{g}/\text{kg}$) was found in a wheat germ sample under the food group “Breakfast cereal”, followed

by a sample of barley grain (i.e. 540 µg/kg) and a sample of shrimp noodles (i.e. 180 µg/kg). A total of 3 wheat germ samples were collected in this study, and their total EAs levels were 22–23 µg/kg (LB–UB), 170 µg/kg and 1200 µg/kg respectively.

Table 1: Results of total EAs in different food groups

Food group	Number of samples		Mean of total EAs level (µg/kg) [range]			
	Collected	<LOD (%)	Lower bound		Upper bound	
Breakfast cereals	50	41 (82%)	30	[0 – 1200]	35	[6.5 – 1200]
Bread & rolls	51	25 (49%)	12	[0 – 71]	16	[6.5 – 71]
Cereal grains	64	62 (97%)	8.4	[0 – 540]	15	[6.5 – 540]
Pasta & noodles (raw & dried)	30	20 (67%)	8.2	[0 – 180]	14	[6.5 – 180]
Other bakery wares	45	33 (73%)	7.0	[0 – 130]	13	[6.5 – 130]
Flour & starch	54	43 (80%)	6.5	[0 – 160]	12	[6.5 – 160]
Pasta & noodles (raw & not dried)	27	25 (93%)	0.49	[0 – 8.0]	6.8	[6.5 – 12]
Cereal beverages	18	18 (100%)	0	[0 – 0]	6.5	[6.5 – 6.5]
Total	339	267 (79%)				

38. Among the 72 samples with detectable EAs, about one-fourth (20 samples, 28%) were known to contain rye. In general, the mean levels of total EAs were higher in rye-containing products within their respective food groups. For example, the mean levels of total EAs of rye flour and rye crispbread were 90–90 µg/kg (LB–UB) and 53–56 µg/kg (LB–UB) respectively, while the mean levels of total EAs of their respective food groups “Flour and starch” and “Other bakery wares” were 6.5–12 µg/kg (LB–UB) and 7.0–13 µg/kg (LB–UB) respectively.

Dietary exposure to ergot alkaloids

39. The dietary exposures to EAs for an average and high (90th percentile) adult consumers in Hong Kong (bw 61.25 kg) were estimated to be 0.018–0.076 µg/kg bw/day (LB–UB) (4.4%–19% of TDI) and 0.036–0.12 µg/kg bw/day (LB–UB) (9.1%–29% of TDI) respectively. The results suggested that both average and high consumers were unlikely to experience adverse effects of EAs.

Major food contributor

40. Contributions of food groups to overall LB dietary exposure to EAs for an average consumer of the adult population were listed in Table 2. The LB was considered to be better reflecting the actual food group contribution to overall EAs exposure since it was not influenced by the high numbers of samples with results below the LOD in some food groups. The percentages of TDI of EAs were also calculated using the LB estimation.

41. Compared with other food groups, “Bread and rolls” had the highest contribution to the overall exposure to EAs. Nonetheless, the results revealed that none of the food group was identified as a significant source of dietary exposure to EAs for the local population as the percentage contributions were all less than 5% of the TDI of EAs.³⁷

Table 2: Dietary exposures to EAs for an average consumer from different food groups

Food Group	Average exposure to EAs (LB) (µg/kg bw/day)	% Contribution to dietary exposure* (%)	Percentage of TDI of EAs# (%)
Bread & rolls	0.0072	41	1.8
Pasta & noodles (raw & dried)	0.0057	33	1.4
Flour & starch	0.0019	11	0.47
Other bakery wares	0.0017	9.9	0.43
Breakfast cereals	0.00060	3.4	0.15
Cereal grains	0.00036	2.1	0.091
Pasta & noodles (raw & not dried)	0.000086	0.49	0.021
Cereal beverages	0	0	0
Total	0.018	100	4.4

*May not sum to total due to rounding.

#The LB estimation of total EAs was used; the percentages were calculated using the TDI (i.e. 0.4 µg/kg bw per day) established by JECFA in 2021

International comparison

Comparison of levels of EAs in local foods with other study

42. Table 3 compared the reported mean levels of total EAs in certain food groups/items between this study and the EFSA (2017) report.¹ In general, the mean levels of total EAs in this study were lower than the mean levels of similar food products reported by EFSA (2017). However, direct comparison of data has to be done with caution because of the differences in research methodology, methods of chemical analysis as well as methods of treating results below LOD and LOQ.

43. In the EFSA report, the mean levels of EAs of rye and rye-containing commodities were generally higher than that of the other

cereal grains (e.g. wheat, spelt, oats and corn) and their derived processed products.¹ The results of this study, in general, tallied with this finding.

Table 3: Comparison of mean levels of total EAs in certain foods in Hong Kong and EU*

Food Product	This study		EFSA 2017	
	Number of samples	Mean levels of total EAs (LB – UB)	Number of samples	Mean levels of total EAs (LB – UB)
		(µg/kg)		(µg/kg)
Rye grains	1	0.60 – 6.6	321	148.7 – 203.1
Wheat grains	6	0 – 6.5	248	20.0 – 132.8
Barley grain	6	90 – 95	48	38.1 – 55.8
Spelt grain	3	0 – 6.5	20	28.0 – 180.5
Oats grain	6	0 – 6.5	29	32.7 – 70.8
Rye milling products	3	90 – 90	394	198.0 – 239.4
Wheat milling products	6	7.7 – 12	293	12.0 – 87.2
Corn milling products	3	0 – 6.5	132	0.3 – 227.9
Oat milling products	1	0 – 6.5	14	1.9 – 72.7
Spelt milling products	3	3.0 – 8.3	26	34.0 – 148.8
Rye bread & rolls	3	1.2 – 6.7	181	29.2 – 66.8
Mixed wheat and rye bread & rolls	6	25 – 27	201	32.8 – 82.0
Wheat bread & rolls	33	11 – 16	19	5.9 – 29.3
Multigrain bread & rolls	6	12 – 16	51	10.5 – 25.9
Other bread	3	4.0 – 9.2	22	14.0 – 67.6
Rye flakes	3	24 – 25	15	34.6 – 83.4
Oat flakes	6	0 – 6.5	52	2.9 – 100.1
Wheat flakes	3	0 – 6.5	8	1.1 – 68.1
Mixed cereal flakes	21	0.55 – 6.8	3	19.2 – 19.8
Crisp bread (contains rye)	3	53 – 56	32 (rye, wholemeal)	10.2 – 50.4
			62 (rye, light)	12.9 – 82.7
Biscuits (cookies)	3	0 – 6.5	39	2.9 – 16.7

*The values of LOD/LOQ and the approaches of treating results below LOD/LOQ between the report of EFSA and this study were different.

Comparison of local dietary exposures to EAs with other study

44. At present, data on dietary exposures to EAs are limited. There is a lack of data on the exposure to EAs in other places such as Canada, Australia, New Zealand, *etc.*¹⁷ The EFSA estimated the dietary exposures to EAs for the European populations in 2017.¹ The report concluded that the mean estimates of chronic and acute dietary exposure to the sum of EAs, for all age groups across European dietary surveys, were all below the group ARfD and the group TDI established by the EFSA.¹ Table 4 compared the dietary exposures to EAs for adults in Hong Kong and EU. The mean dietary exposure for the local adult population in this study was relatively low when compared with the findings reported by EFSA in 2017.

Table 4: Comparison of dietary exposure estimates to EAs for adults between this study and EFSA (2017)

		EFSA (2017)*	This study#
Mean dietary exposure	LB	0.01 – 0.05 (2.5 – 13% TDI [®])	0.018 (4.4% TDI)
(µg/kg bw/day)	UB	0.06 – 0.18 (15 – 45% TDI)	0.076 (19% TDI)

*Analytical results of foods that were non-ready-to-eat (e.g. dried foods) were adjusted with the use of conversion factors to obtain a more accurate exposure estimates.

#Analytical results of all samples (including non-ready-to-eat foods) were used, without adjustment, for the estimation of the dietary exposure.

[®]The percentages were calculated using the TDI (i.e. 0.4 µg/kg bw per day) established by JECFA in 2021.

LIMITATIONS

45. In the Hong Kong Population-based Food Consumption Survey (2005–2007), a set of two non-consecutive days of 24-hour dietary intake questionnaires was used to obtain food consumption information among individuals in Hong Kong. Some food items which were less commonly consumed might not be captured in the Survey. For example, rye flour samples were collected in this study but consumption data were not available. Therefore, the data of rye flour samples were not taken into account for the dietary exposure estimation. Nevertheless, since food items not being captured in the Survey were non-staple food, their contribution to the dietary exposure to EAs in the general population is probably low.

46. The foods under the food groups “Cereal grains”, “Flour and starch”, “Pasta and noodles (raw and dried)” and “Pasta and noodles (raw and not dried)” were non-ready-to-eat. In the real-life situation, these foods would be processed or cooked before consumption. After cooking, the concentrations of EAs in these foods would decrease due to the processing effect including the change in water content of the foods. Hence, the use of the reported levels of EAs of these non-ready-to-eat foods for the estimation of the dietary exposure to EAs would inevitably be an overestimation. Nonetheless, the overestimation would reasonably not affect the conclusion of the study.

47. The results of this study represented only a snapshot of the EAs

levels in certain local foods. More accuracy and precision in exposure estimation could be achieved with more samples analysed if resources allow.

CONCLUSIONS AND RECOMMENDATIONS

48. EAs are naturally occurring mycotoxins produced by fungi, mainly members of the *Claviceps spp.* In this study, 79% of samples were not detected with EAs, and only 72 samples were found to contain at least one detectable EAs. The food group “Breakfast cereals” contained the highest mean levels of EAs, followed by “Bread and rolls”.

49. The estimated exposures to EAs in the local average and high adult consumers were well below the TDI established by JECFA, suggesting that both average and high consumers were unlikely to experience adverse effects of EAs.

50. By virtue of the estimated dietary exposures to EAs in adults, the public are recommended to follow the basic dietary advice on healthy eating, and to maintain a balanced and varied diet.

51. Members of the trade (e.g. farmers, feed and food manufacturers, *etc.*) are advised to follow Codex’s COP to reduce the levels of EAs, such as using separation techniques to clean the grains in order to remove ergots and their dust on the grain surface.

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ANNEX

Results of total EAs in different food categories

	Number of samples	Number of samples with individual EAs \geq LOD* (%)	Mean of total EAs level ($\mu\text{g}/\text{kg}$) [range] [#]			
			Lower bound		Upper bound	
Cereal grains	64	2 (3.1%)	8.4	[0 – 540]	15	[6.5 – 540]
White rice	6					
Brown rice	3					
Red rice	3				< LOD in all samples	
Wheat	6					
Spelt	3					
Barley	6	1	90	[0 – 540]	95	[6.5 – 540]
Oats	6					
Sorghum	3					
Corn	3					
Buckwheat	3				< LOD in all samples	
Millet	3					
Glutinous rice	3					
Rye	1	1	0.6	[0.60 – 0.60]	6.6	[6.6 – 6.6]
"Treasure" congee	1					
Quinoa	3				< LOD in all samples	
Other/ mixed cereal grains	11					
Flour & starch	54	11 (20%)	6.5	[0 – 160]	12	[6.5 – 160]
Rice flour	3				< LOD in all samples	
Wheat flour	6	4	7.7	[0 – 21]	12	[6.5 – 22]
Spelt flour	3	1	3.0	[0 – 9.0]	8.3	[6.5 – 12]
Corn flour	3					
Glutinous rice flour	3				< LOD in all samples	
Rye flour	3	3	90	[13 – 160]	90	[13 – 160]
Corn starch	3					
Wheat starch	3					
Self raising flour	3				< LOD in all samples	
Barley flour	2					
Cake mix/ pancake mix	4	2	1.3	[0 – 4.6]	6.8	[6.5 – 7.6]
Buckwheat flour	3					
Sorghum flour	3				< LOD in all samples	

Quinoa flour	3					
Pearl millet flour	3					
Other flour	6	1	3.2	[0 – 19]	8.8	[6.5 – 20]
<u>Pasta & noodles (raw & dried)</u>	<u>30</u>	<u>10 (33%)</u>	<u>8.2</u>	<u>[0 – 180]</u>	<u>14</u>	<u>[6.5 – 180]</u>
Spaghetti	3					
Macaroni	3					< LOD in all samples
Soba (Japanese)	3	1	0.43	[0 – 1.3]	6.6	[6.5 – 6.8]
Instant noodles	3	1	7.3	[0 – 22]	12	[6.5 – 24]
Egg noodles	3	2	3.7	[0 – 5.7]	8.5	[6.5 – 10]
Rice noodles/ rice vermicelli	3					< LOD in all samples
Shrimp noodles	3	2	64	[0 – 180]	67	[6.5 – 180]
Other pasta/ noodles (raw & dried)	3					< LOD in all samples
"E-fu noodles"	3	3	3.5	[0.89 – 5.5]	8.4	[6.9 – 9.5]
Couscous	3	1	3.3	[0 – 9.9]	8.3	[6.5 – 12]
<u>Pasta & noodles (raw & not dried)</u>	<u>27</u>	<u>2 (7.4%)</u>	<u>0.49</u>	<u>[0 – 8.0]</u>	<u>6.8</u>	<u>[6.5 – 12]</u>
"Ho Fan"	3					
Udon	3					
Shanghai noodles	3					< LOD in all samples
Ramen (Japanese)	3					
"Lai Fan"	3					
"Yau Mian"	3	2	4.4	[0 – 8.0]	9.2	[6.5 – 12]
Vietnamese rice noodles	3					
Dumpling wrappings	3					
Shanghai new year pudding	2					< LOD in all samples
Silver pin noodles	1					
<u>Bread & rolls</u>	<u>51</u>	<u>26 (51%)</u>	<u>12</u>	<u>[0 – 71]</u>	<u>16</u>	<u>[6.5 – 71]</u>
Wheat bread	3	1	14	[0 – 42]	18	[6.5 – 42]
White bread	6	5	15	[0 – 44]	18	[6.5 – 44]
Rye bread	3	1	1.2	[0 – 3.5]	6.7	[6.5 – 7.0]
Plain roll/ bun	3					< LOD in all samples
Multigrain bread (contains rye)	6	6	25	[3.2 – 52]	27	[8.2 – 52]
Multigrain bread (uncertain if contains rye)	6	4	12	[0 – 62]	16	[6.5 – 62]
French bread/ Baguette/	3	2	2.1	[0 – 3.6]	7.7	[6.5 – 8.6]

Vienna bread (includes sourdough)						
Raisin bread	3	1	23	[0 – 69]	27	[6.5 – 69]
Hotdog bun	2	1	4.8	[0 – 9.6]	9.3	[6.5 – 12]
Hamburger bun	4	2	35	[0 – 71]	38	[6.5 – 71]
Bagel	3	1	0.90	[0 – 2.7]	7.1	[6.5 – 8.2]
Chinese steamed bun	3					
Pineapple bun	3					
English muffin	3	2	4.0	[0 – 6.6]	9.2	[6.5 – 11]
Breakfast cereals	50	9 (18%)	30	[0 – 1200]	35	[6.5 – 1200]
Corn flake	3					
Oat flakes	6					
Wheat germ	3	3	460	[22 – 1200]	460	[23 – 1200]
Muesli	5					
Wheat flakes	3					
Quinoa flakes	3					
Rice flakes	3	1	3.2	[0 – 9.6]	8.3	[6.5 – 12]
Buckwheat flakes	2					
Spelt flakes	2					
Rye flakes	3	3	24	[20 – 27]	25	[21 – 27]
Mixed breakfast cereals	17	2	0.69	[0 – 11]	6.9	[6.5 – 13]
Other bakery wares	45	12 (27%)	7.0	[0 – 130]	13	[6.5 – 130]
Cookie	3					
Brownie	3					
Saltine crackers	3	1	1.1	[0 – 3.2]	7.1	[6.5 – 8.2]
Wheat cracker	3	1	14	[0 – 42]	18	[6.5 – 42]
Digestive biscuit	3					
Wafer biscuit	3					
Corn chips	3	1	0.37	[0 – 1.1]	6.7	[6.5 – 7.1]
Muffin	3	2	2.2	[0 – 3.4]	7.4	[6.5 – 7.8]
Cakes	3					
Pancake	3					
Pastry	3					
Egg roll	3					
Croissant	3	3	32	[9.5 – 53]	33	[13 – 53]
Rye Crisp bread	3	2	53	[0 – 130]	56	[6.5 – 130]
Other crackers	3	2	2.6	[0 – 5.2]	7.8	[6.5 – 8.7]
Cereal beverages	18	0 (0%)	0	[0 – 0]	6.5	[6.5 – 6.5]

Beer	7	
Rye Beer	2	
Rice milk	3	< LOD in all samples
Malt	3	
Other cereal beverages	3	

*LOD = Limit of detection

#A value of zero and the value of LOD were assigned to "ND" results of individual EAs for the calculation of total EAs at LB and UB respectively.