Risk Assessment Studies

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Sterigmatocystin in Food

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Sterigmatocystin in Food

EXECUTIVE SUMMARY

Sterigmatocystin (STC) is a mycotoxin that can be produced by many different fungal species. It is formed on food commodities that are spoiled by moulds during storage rather than on crops in the field. Some foods such as grains, grain-based products, cheese, coffee bean, spices, nuts and beer have been found to contain STC.

2. In animal studies, liver and kidneys are the main target organs of acute STC toxicity. Both European Food Safety Authority (EFSA) and Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that STC is genotoxic and carcinogenic. The International Agency for Research on Cancer (IARC) also classified STC as group 2B carcinogen, possibly carcinogenic to humans.

3. The lowest benchmark dose lower confidence limit for a 10% excess cancer risk ($BMDL_{10}$) of 0.16 mg/kg body weight (bw) per day for hepatic haemangiosarcoma in male rats treated with STC is applied to determine the Margin of Exposure (MOE) value in estimating the human health risk. The lower the MOE value, the greater is the possible effect on public health. EFSA considered that an MOE value of 10 000 or higher would be of low public health concern.

4. This study serves (i) to examine the levels of STC in selected food items available at local markets; (ii) to estimate the dietary exposure

to STC of the Hong Kong adult population arising from the consumption of these food items; and (iii) to assess the associated health risk.

Methods

5. A total of 331 samples which have been reported to contain STC from overseas studies were collected from the local retail market. These samples were classified into 12 different food groups, including "flour", "breakfast cereal", "dried spices", "grains", "pasta and noodles", "bakery and pastry items", "coffee beans", "starch substitutes", "peanuts and tree nuts", "cheese", "beer" and "cured meat".

Results

6. Of the 331 samples analysed, 32 samples (about 10%) were found to contain STC. They are coming from the food group "flour" (9 samples), "breakfast cereal" (7 samples), "dried spices" (6 samples), "grains" (3 samples), "pasta and noodles" (3 samples), "bakery and pastry items" (3 samples) and "coffee beans" (1 sample). Amongst the 32 samples detected with STC, 29 samples (about 91%) have a level of less than 1mcg/kg. STC was not detectable in all samples of the food groups "starch substitutes", "peanuts and tree nuts", "cheese", "beer" and "cured meat".

7. After evaluation, the UB dietary exposure estimates to STC arising from the collected food groups were 0.00017mcg/kg bw/day and

0.00033mcg/kg bw/day for average and high (90 percentile) consumers respectively. The calculated MOE values for average and high consumers were 940 000 and 480 000 respectively. Food group "pasta and noodles" was the major contributor to the dietary exposure of STC for local population.

Conclusion and Recommendations

8. In this study, STC was detected in only about 10% of samples collected.

9. The calculated MOE values for both average and high consumers were well above 10 000. Hence, health concern for the local adult population due to STC exposure from the selected food groups in this study is considered low.

10. STC is produced during storage of food commodities. STC contamination could be reduced by managing the storage conditions properly to prevent fungal infestation in food.

Risk Assessment Studies –

Sterigmatocystin in Food

OBJECTIVES

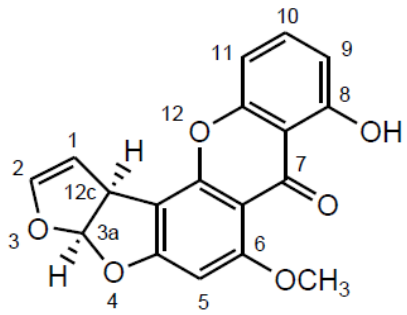
This study aims (i) to examine the levels of sterigmatocystin (STC) in selected food items available at local markets; (ii) to estimate the dietary exposure to STC of the Hong Kong adult population arising from the consumption of these food items; and (iii) to assess the associated health risk.

BACKGROUND

2. STC is a toxic fungal secondary metabolite (mycotoxin) that can be produced by many different fungal genera such as *Emericella*, *Aspergillus*, *Chaetomium*, *Botryotrichum* and *Humicola*[1,2]. Among the fungal species, *Aspergillus versicolor* is the major producing microbe[1,2,3,4].

3. STC shares its biosynthetic pathway with aflatoxins (AFs) and they are structurally closely related[1,5,6,7]. As such, STC is considered to have similar toxic effects as AFs, including genotoxicity and carcinogenicity[1,4]. However, studies suggested that STC is less potent comparing with AFs[1,4,5,6,8].

Figure 1. Chemical structure of sterigmatocystin[1]



4. STC is detected on stored food commodities that are spoiled by moulds rather than on crops in the field[1]. Human exposure can occur if there is contamination of grains and grain-based products by STC-producing fungi.

Occurrence in Food

5. In 2013, European Food Safety Authority (EFSA) summarised the occurrence of STC in foodstuffs that has been reported in the literature. Grains, grain-based products, cheese, coffee bean, spices, nuts and beer were found to contain STC[1].

6. In 2017, Joint FAO/WHO Expert Committee on Food Additives (JECFA) and Codex Committee on Contaminants in Food (CCCF) reviewed the STC occurrence in cereals and cereal products available in the Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme, commonly known as GEMS/Food. Positive samples were found in barley, buckwheat, maize,

oat, rice, rye, wheat and their products while the highest incidence was found in sorghum flour[5,8].

Toxicity

Kinetics and Metabolism

7. Information related to the toxicokinetics of STC is scare. According to the data obtained from animal studies, absorption and distribution of STC following oral administration could be influenced by sex and ages. So far, there is no consensus in the literatures about the pathways of metabolism. However, oral dose of STC was found to excrete unchanged or as hydroxylated metabolites via bile and urine[1,5,6,9].

Toxicity

8. In animal studies, the acute oral toxicity of STC (i.e. LD_{50} for rats) ranged from 120 to 166 mg/kg body weight (bw) which is relatively low and the main target organs of acute toxicity are the liver and kidneys[1,5]. STC is hepatotoxic in rat, mouse, monkey and guinea pig. Incidence of hepatocellular necrosis and haemorrhages increases with dose and duration of exposure. In the kidney, hyaline degeneration, tubular necrosis and haemorrhages are described in rats and/or vervet monkeys exposed to STC[1,5].

9. STC induces chromosomal damage both *in vitro* and *in vivo* in experimental animals[1,5]. Tumourigenicity of STC was also observed after oral, intraperitoneal, subcutaneous or dermal administration in the experimental animals. Premalignant and malignant lesions such as hepatocellular carcinomas, haemangiosarcomas in the liver, angiosarcomas in the brown fat, lung adenomas and incidental findings in other organs were reported[1,5,6].

10. Both EFSA and JECFA concluded that STC is genotoxic and carcinogenic. The International Agency for Research on Cancer (IARC) has also assessed the carcinogenic potential of STC and concluded that STC is possibly carcinogenic to humans (group 2B)[10].

Safety Reference Value

11. Health-based guidance values are not established for STC as no tolerable intake should be proposed for its genotoxicity and carcinogenicity. The Margin of Exposure (MOE) approach is used instead for assessing the human health risk[1,5,7,8].

12. In 2017, JECFA used a lower limit on the benchmark dose for a 10% excess cancer risk ($BMDL_{10}$) of 0.16 mg/kg bw per day for hepatic haemangiosarcoma in male rats treated with STC as the point of departure in the MOE approach to assess the safety concerns arising from the

presence of STC in food[5]. In general, an MOE value of 10 000 or higher would be of low concern from a public health point of view.

Regulatory Control

13. The Codex Alimentarius Committee (Codex) and other jurisdictions such as the United States, European Union, Australia, New Zealand and Mainland China have not established any standards for STC in food.

14. Instead, the Codex has established a code of practice for the prevention and reduction of mycotoxin contamination in cereals with an aim to provide a uniform guidance for countries to control and manage contamination by various mycotoxins[11].

15. In Hong Kong, there is no specific regulation of STC in foods. However, as stipulated in the Public Health and Municipal Services Ordinance (Cap 132), all food available for sale on the market must be fit for human consumption.

SCOPE OF STUDY

16. To estimate the dietary exposure to STC of Hong Kong adult population, this study analysed the levels of STC in selected food items which have been reported to be contaminated with STC from overseas studies. The food items were classified into 12 food groups, namely "flour", "breakfast cereal", "dried spices", "grains", "pasta and noodles", "bakery and pastry items", "coffee beans", "starch substitutes", "peanuts and tree nuts", "cheese", "beer" and "cured meat".

METHODOLOGY AND LABORATORY ANALYSIS

Methodology

17. Food samples were collected between June and September 2018 from various retail outlets such as supermarkets, wet markets, grocery stores, bakery shops and cafés. The list of food items analysed is provided in Appendix I. All samples except the 8 flour items (i.e. rice flour, wheat flour, corn flour, buckwheat flour, glutinous flour, rye flour, sorghum flour and flour mix) were prepared in the form of food as consumed prior to analysis of STC. The analytical results were then combined with food consumption information captured from the Hong Kong Population-based Food Consumption Survey (2005-2007) to obtain the dietary exposures of local adult population.

The estimation of dietary exposures was performed with the aid of an in-house developed web-based computer system, Exposure Assessment System (EASY). The mean and 90th percentile exposure levels were used to represent the dietary exposure levels of average and high consumers of the local population respectively. The MOE value was calculated by dividing the $BMDL_{10}$ of 0.16 mg/kg bw per day by the estimated dietary exposure to STC from food.

Laboratory Analysis

18. Laboratory analysis of STC was conducted by the Food Research Laboratory (FRL) of CFS. All samples were tested on an individual samples basis for the presence of STC.

19. Level of STC in food samples were analysed by ultra-performance liquid chromatography - tandem mass spectroscopy (UPLC-MS/MS). The sample was extracted by shaking with aqueous acetonitrile solution. The sample extract was then purified by immunoaffinity column. After sample purification, the sample solution was concentrated and subjected to instrumental analysis. Limits of detection (LODs) of STC were 0.05 mcg/kg and 0.005 mcg/kg for solid and liquid samples respectively.

Treatment of Analytical Values Below the LOD

20. In this study, analytical results were treated by the lower bound (LB) and upper bound (UB) approach, i.e. results below the LOD were assigned as zero or the value of LOD for the LB and UB respectively. This approach compares the two extreme scenarios, based on the consideration that the true value for results smaller than LOD may actually be any value between zero and the LOD. The LB scenario assumes the chemical is absent whilst the UB scenario assumes that the chemical is present at the level of the LOD.

RESULTS AND DISCUSSION

Occurrence of Sterigmatocystin

21. Of the 331 samples analysed, 32 samples (about 10%) were detected with STC. In other words, 299 samples (about 90%) were not detected with any STC.

22. Among these 32 samples, more than two-third (i.e. 22 samples; about 69%) were from food groups “flour” (9 samples), “breakfast cereal” (7 samples) and “dried spices” (6 samples). Other food samples containing STC include “grains” (3 samples), “pasta and noodles” (3 samples), “bakery and pastry items” (3 samples) and “coffee beans” (1 sample). In contrast, all samples in food groups “starch substitutes”, “peanuts and tree nuts”, “cheese”, “beer” and “cured meat” were not detected with STC.

23. 29 out of 32 samples (about 91%) were found to contain STC at levels less than 1 mcg/kg. The mean STC concentration of food samples are shown in Appendix I.

24. The mean concentrations of STC in different food groups are summarized in Table 1, ranging from 0.0043mcg/kg to 4.9mcg/kg at LB and 0.0051mcg/kg to 5.0mcg/kg at UB.

Table 1. Mean Concentration of STC (mcg/kg) in Different Food Groups

Food Group	**No. of samples**	**% of samples <LOD**	**Mean of STC (mcg/kg) [range] ***			
			LB		**UB**	
Flour	44	80	4.9	[0-210]	5.0	[0.05-210]
Dried Spices	13	54	0.15	[0.087]	0.18	[0.05-0.87]
Pasta and Noodles	48	94	0.023	[0-0.74]	0.07	[0.05-0.74]
Breakfast Cereal	48	85	0.022	[0-0.21]	0.064	[0.05-0.21]
Grains	58	95	0.0072	[0-0.21]	0.055	[0.05-0.21]
Coffee Beans	12	92	0.0066	[0-0.079]	0.052	[0.05-0.079]
Bakery and Pastry Items	48	94	0.0043	[0-0.082]	0.051	[0.05-0.082]
Starch Substitute	12		< LOD in all samples			
Peanuts and Tree Nuts	12		< LOD in all samples			
Cheese	12		< LOD in all samples			
Beer	12		< LOD in all samples			
Cured Meat	12		< LOD in all samples			
Total	331	90				

* Rounded to 2 significant figures.

Dietary Exposure to Sterigmatocystin

25. The dietary exposure estimates to STC of local population arising from the collected food items and the corresponding MOE values are shown in Table 2. Using LB and UB concentrations, the dietary exposures were estimated to range from 0.000012 to 0.00017mcg/kg bw/day and 0.000025 to 0.00033mcg/kg bw/day for average and high consumers respectively. The calculated MOE values by using the $BMDL_{10}$ of 0.16 mg/kg bw per day were in the ranges of 13 000 000 – 940 000 (LB – UB) and 6 400 000 – 480 000 (LB – UB) for average and high consumers respectively. These MOE values are well above 10 000, indicating a low public health concern.

Table 2. Dietary Exposure to STC of Local Population and the Corresponding MOE values

	Average consumers	**High consumers**
Dietary Exposure (mcg/kg bw/day) (LB – UB)	0.000012 – 0.00017	0.000025 – 0.00033
MOE (LB-UB)	13 000 000 – 940 000	6 400 000 – 480 000

26. Further analysis of dietary exposure of individual age-gender population subgroups was shown in table 3. All the MOE values for average and high consumers were well above 10 000, which indicated a low health concern for all age-gender subgroups.

Table 3. Dietary Exposure to STC by Age-Gender Groups of Local Population

Age-Gender Group	**Dietary Exposure (mcg/kg bw/day)**	
	Average consumers (LB –UB)	High consumers (LB – UB)
Male aged 20-29	0.000013 – 0.00015	0.000032 – 0.00032
Female aged 20-29	0.000017 – 0.00019	0.000049 – 0.00037
Male aged 30-39	0.000012 – 0.00015	0.000033 – 0.00029
Female aged 30-39	0.000016 – 0.00019	0.000044 – 0.00036
Male aged 40-49	0.0000091 – 0.00015	0.000014 – 0.00030
Female aged 40-49	0.000014 – 0.00018	0.000037 – 0.00037
Male aged 50-59	0.000010 – 0.00016	0.000015 – 0.00034
Female aged 50-59	0.000011 – 0.00017	0.000019 – 0.00032
Male aged 60-69	0.0000086 – 0.00015	0.000013 – 0.00031
Female aged 60-69	0.0000095 – 0.00017	0.000018 – 0.00034
Male aged 70-84	0.0000069 – 0.00014	0.000012 – 0.00030
Female aged 70-84	0.0000094 – 0.00016	0.000019 – 0.00033

Major Food Contributor

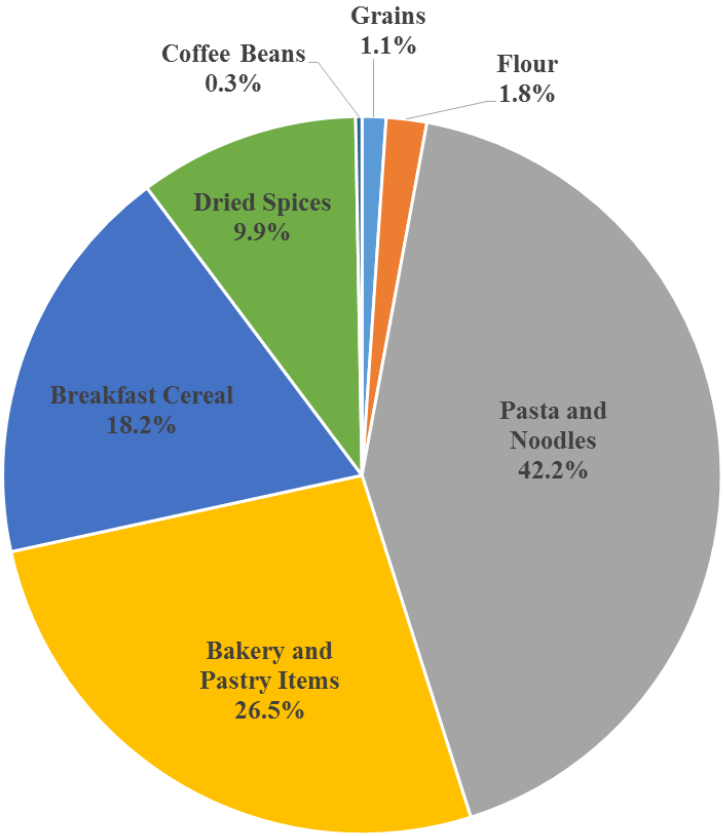
27. Relative contribution of food groups to the overall STC dietary exposure at LB estimation for an average consumer of local adult population is shown in Table 4 and Figure 2. The LB is considered to better reflect the actual food group contribution to the overall STC exposure since it is not influenced by the high numbers of samples below the LOD in some food groups.

Table 4. Average Dietary Exposure to STC of Local Population and the Percentage Contribution of Different Food Groups

Food Item	**Dietary Exposure (mcg/kg bw/day)**	**% Contribution to Dietary Exposure***
Pasta & Noodles	0.0000051	42.5%
Bakery & Pastry Items	0.0000032	26.7%
Breakfast Cereal	0.0000022	18.3%
Dried Spices	0.0000012	10.0%
Flour	0.00000022	1.8%
Grains	0.00000013	1.1%
Coffee Beans	0.000000034	0.3%
Starch Substitute	NA	NA
Peanuts & Tree Nuts	NA	NA
Cheese	NA	NA
Beer	NA	NA
Cured Meat	NA	NA
Total	0.000012	100%

*May not sum to total due to rounding

Figure 2. Relative Contribution of Food Groups to the Overall LB Dietary Exposure to STC among Local Adult Population in Average



28. In this study, “pasta and noodles” was the major contributor to the overall exposure to STC, accounting for 42.2% (i.e. 0.0000051mcg/kg bw/day at the LB) of the total exposure. This observation could be explained by having a higher consumption amount of food under the “pasta and noodles” food group by the Hong Kong adult population.

International Comparison

29. As a consequence of limited information on occurrence of STC in food, few dietary exposure evaluations were published internationally[1,5]. In 2017, JECFA carried out the first dietary exposure assessment and calculated the MOE values in five World Health Organization's Regions where consumption and contamination data were available. The five Regions were Africa, Americas, Eastern Mediterranean, Europe and Western Pacific (Table 5). It showed that all calculated MOE values in the aforesaid Regions were higher than 10 000 except for Africa, where sorghum was a staple food grain for African and was found commonly contaminated with STC[5]. Comparing to the results of current study with that of JECFA, the dietary exposure to STC of the local population was much lower.

Table 5. International Comparison of Dietary Exposure to STC and MOE values

		African Region	Region of the Americas	Eastern Mediterranean Region	European Region	Western Pacific Region	Hong Kong
Mean Exposure (mcg/kg bw/day)	LB	0.016	0.0003	0.0003	0	0	0.000012
	UB	0.017	0.0063	0.0035	0.022	0.0005	0.00017
MOE	LB	10 000	530 000	530 000	NA	NA	13 000 000
	UB	9 400	25 000	46 000	NA	NA	940 000
High Exposure (mcg/kg bw/day)	LB	0.032	0.0006	0.0006	0	0	0.000025
	UB	0.034	0.013	0.007	0.044	0.001	0.00033
MOE	LB	5 000	270 000	270 000	NA	NA	6 400 000
	UB	4 700	12 000	23 000	NA	NA	480 000

Uncertainties and Limitations of the Study

30. While higher accuracy and precision in exposure estimation could be achieved with more samples analysed, compromises had to be made in relation to the use of finite resources. In this study, only selected food items that were reported more likely to contain STC were sampled. Furthermore, the results of this study could only represent a snapshot of STC levels in certain locally available foods.

31. 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 covered by the respondents and hence not being captured in the survey. In this study, food samples including buckwheat, corn flour, sorghum flour, buckwheat flour and flour mix for which no consumption data available were not taken in 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 of STC in the general population is probably low.

CONCLUSIONS AND RECOMMENDATIONS

32. In this study, only about 10% of samples (32 out of 331 samples) collected were found to contain STC. The levels detected in majority (i.e. 29 samples; about 91%) of these samples were less than 1mcg/kg. Food group "pasta and noodles" was the major contributor to the dietary exposure of STC for local population.

33. The calculated MOE values to STC for average and high consumers were in the ranges of 13 000 000 – 940 000 (LB – UB) and 6 400 000 – 480 000 (LB – UB) respectively. MOE values above 10 000 indicates a low health concern for the adult population in Hong Kong.

34. STC is produced during storage of food commodities which means that prevention and control should focus on postharvest stages at both industrial and consumer levels. STC contamination could be reduced by managing the storage conditions properly, such as in cool and dry places, to prevent fungal infestation in food.

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Appendix I

Mean Levels of Sterigmatocystin (mcg/kg) Detected in Food Samples Collected in the Current Study

Food Item	**No. of samples**	**% of samples <LOD**	**Mean of STC (mcg/kg) [range]***			
			Lower bound		Upper bound	
Grains	**58**	**95**	**0.0072**	**[0-0.21]**	**0.055**	**[0.05-0.21]**
White Rice	12		< LOD in all samples			
Brown Rice	6					
Red Rice	6					
Wheat	6	67	0.045	[0-0.21]	0.078	[0.05-0.21]
Oat	6		< LOD in all samples			
Barley	6					
Buckwheat[#]	6	83	0.025	[0-0.15]	0.067	[0.05-0.15]
Corn	6		< LOD in all samples			
Sorghum	3					
Rye	1					
Flour	**44**	**80**	**4.9**	**[0-210]**	**5.0**	**[0.05-210]**
Rice Flour	6	83	0.033	[0-0.2]	0.075	[0.05-0.2]
Wheat Flour	6		< LOD in all samples			
Corn Flour[#]	6	83	0.35	[0-2.1]	0.39	[0.05-2.1]
Buckwheat Flour[#]	6	33	35.0	[0-210]	35.0	[0.05-210]
Glutinous Rice Flour	6	83	0.0092	[0-0.055]	0.051	[0.05-0.055]
Rye Flour	6		< LOD in all samples			
Sorghum Flour[#]	2	50	1.5	[0-3.0]	1.5	[0.05-3]
Flour Mix[#]	6	83	0.25	[0-0.15]	0.067	[0.05-0.15]
Pasta and Noodles	**48**	**94**	**0.023**	**[0-0.74]**	**0.070**	**[0.05-0.74]**
Pasta / Spaghetti	12		< LOD in all samples			
Japanese Noodles	12	75	0.093	[0-0.74]	0.13	[0.05-0.74]
Rice Noodles	12		< LOD in all samples			
Dumpling Wrapping	12					
Bakery and Pastry Items	**48**	**94**	**0.0043**	**[0-0.082]**	**0.051**	**[0.05-0.082]**
Bread	20	95	0.0041	[0-0.082]	0.052	[0.05-0.082]
Biscuits and Crackers	12	83	0.011	[0-0.069]	0.052	[0.05-0.069]
Cake and Other Pastry Products	16		< LOD in all samples			
Breakfast Cereal	**48**	**85**	**0.022**	**[0-0.21]**	**0.064**	**[0.05-0.21]**

Corn Flakes	12	< LOD in all samples				
Oatmeal	12	92	0.0083	[0-0.1]	0.054	[0.05-0.1]
Muesli	12	92	0.0078	[0-0.094]	0.054	[0.05-0.094]
Other breakfast cereals	12	67	0.070	[0-0.21]	0.099	[0..05-0.21]
Starch Substitute	**12**	**< LOD in all samples**				
Cornstarch	6	< LOD in all samples				
Wheat starch	6					
Peanuts & Tree Nuts	**12**	**< LOD in all samples**				
Cheeses	**12**	**< LOD in all samples**				
Dried Spices	**13**	**50**	**0.15**	**[0-0.87]**	**0.18**	**[0.05-0.87]**
Black Pepper	6	0	0.33	[0.086-0.87]	0.33	[0.086-0.87]
Chilli	7	< LOD in all samples				
Beer	**12**	**< LOD in all samples**				
Coffee beans	**12**	**92**	**0.0066**	**[0-0.079]**	**0.052**	**[0.05-0.079]**
Cured Meat	**12**	**< LOD in all samples**				
Chinese-styled cured meat	6	< LOD in all samples				
Western-styled cured meat	6					

* Rounded to 2 significant figures.

Analytical results of food items, where appropriated consumption data are not available in the Population-based Food Consumption Survey, were not included in the dietary exposure assessment.