Risk Assessment Studies
Report No. 50

Fatty Acid Esters of 3-monochloropropane-1,2-diol (3-MCPD) in Food

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Executive Summary

3-Monochloropropane-1,2-diol (3-MCPD) is a process contaminant which is formed during processing and manufacture of certain foods and ingredients. In 2006, the Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA) noted that fatty acid esters of 3-MCPD has been reported to be present in foods. Recent studies revealed that much of the 3-MCPD in foods is present as fatty acid esters and 3-MCPD fatty acid esters were found in a wide range of food products. Therefore, 3-MCPD fatty acid esters is a source of previously not recognized 3-MCPD.

2. There is currently lack of data about 3-MCPD fatty acid esters in foodstuffs at international scene. In 2010, the Codex Committee on Contaminants in Foods (CCCF) included 3-MCPD fatty acid esters in the priority list for evaluation by the JECFA for toxicological assessment and exposure assessment. The Centre for Food Safety (CFS), as a World Health Organization (WHO) Collaborating Centre for Risk Analysis of Chemicals in Food, conducted this study between 2011 and 2012 with a view to giving WHO an overview of the levels of 3-MCPD fatty acid esters in various foods in Hong Kong and assessing the potential health risk posed to the local population.

3. 3-MCPD would affect the kidney, the central nervous system and the male reproductive system of rats. JECFA established a provisional maximum tolerable daily intake (PMTDI) of 2 μg/kg bw/day for 3-MCPD. However, no safety reference value was established for its fatty acid esters. The mechanism(s) of

formation, metabolic pathways and toxicological properties of the intact 3-MCPD fatty acid esters are still unknown. It was reported that the primary toxicological concern of 3-MCPD fatty acid esters was its potential to release 3-MCPD *in vivo* during digestion in the gastrointestinal tract. In this study, health risk assessment of exposure to 3-MCPD fatty acid esters in adults was conducted by assuming that all 3-MCPD would be released from the esters by hydrolysis in the digestive system and the exposures would be compared to the PMTDI of 3-MCPD, having noted that this assumption may overestimate the actual dietary exposure to 3-MCPD. This approach was agreed by European Food Safety Authority (EFSA). As PMTDI does not apply to infants under the age of 12 weeks, this study report focused on the levels of 3-MCPD fatty acid esters in various local foods consumed by adults to assess the potential health risk of 3-MCPD fatty acid esters posed to adults.

4. Thermally processed foods and refined fats and oils (as such or as a component of other foodstuffs) are the most significant sources of 3-MCPD fatty acid esters for consumers. Therefore, this study focused on food items reported more likely to have higher 3-MCPD fatty acid esters levels. The results revealed that the levels of 3-MCPD fatty acid esters were higher in the food groups "Biscuits", "Fats and oils", "Snacks" and "Chinese pastry" with mean levels of 440, 390, 270 and 270 μg/kg respectively.

5. The dietary exposures to 3-MCPD fatty acid esters in the average and high adult consumers (95^{th} percentile) were 0.20 μg/kg bw/day (10% of the PMTDI of 3-MCPD) and 0.53 μg/kg bw/day (26 % of the PMTDI of 3-MCPD) respectively. Assuming that 100% of 3-MCPD was released from its fatty acid esters by

hydrolysis in the digestive system, the results suggested that both average and high consumers were unlikely to experience major toxicological effects of 3-MCPD.

6. By virtue of the dietary exposure to 3-MCPD fatty acid esters in adults alone, the findings of the current study did not provide sufficient justifications to warrant changes to the basic dietary advice on healthy eating. The public are recommended to maintain a balanced and varied diet, which includes a wide variety of fruits and vegetables. Since refined oil is reported as one of the major sources of 3-MCPD fatty acid esters, the public may reduce consumption of fats and oils to further reduce the exposure to 3-MCPD fatty acid esters. Members of the food trade are advised to find ways to reduce the levels of 3-MCPD fatty acid esters in refined fats and oils while not impairing the quality of their products.

OBJECTIVES

The Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department (FEHD) conducted a risk assessment study on fatty acid esters of 3-monochloropropane-1,2-diol (3-MCPD) in Food in 2011-2012, with a view to giving World Health Organization (WHO) an overview of the levels of 3-MCPD fatty acid esters in various foods in Hong Kong and assessing the potential health risk posed to the local population.

BACKGROUND

2. 3-MCPD is a process contaminant which is formed during processing and manufacture of certain foods and ingredients, such as acid hydrolysis, baking and roasting etc. It occurs in foods in its free (diol) form as well as in the bound esterified (with fatty acids) forms. 3-MCPD is originally discovered in acid hydrolysed vegetable protein (acid-HVP) and subsequently revealed its presence in soy sauces manufactured using acid-HVP as ingredient.[1]

3. This chemical has received attention in HKSAR since 1999 when a survey of soya sauce conducted in the United Kingdom by the former Ministry of Agriculture Fisheries and Food (MAFF) revealed that some local brands

contained 3-MCPD. In view of the findings, special studies on 3-MCPD in soya sauce as well as oyster sauce and related products were conducted jointly with the Consumer Council in 2002 and 2004 respectively. The CFS also conducted a risk assessment study, titled "Dietary Exposure to Chloropropanols of Secondary School Students" in 2007 to estimate the potential dietary exposures to chloropropanols including 3-MCPD. [2,3,4]

4. However, recent studies showed that elevated levels of 3-MCPD, particularly the fatty acid esters of 3-MCPD, were also found in a wide range of food products formulated without acid-HVP, e.g. French fries, toasted bread, salty crackers and roasted coffee etc. The reported concentrations of 3-MCPD fatty acid esters in some food were about hundred times higher than the 3-MCPD. 3-MCPD has been shown to release under certain processing conditions of these foods.[5] In addition, the Codex Committee on Contaminants in Foods (CCCF) included 3-MCPD fatty acid esters in the priority list for evaluation by The Joint Food and Agriculture Organization/ World Health Organization Expert Committee on Food Additives (JECFA) for toxicological assessment and exposure assessment in 2010. The CFS, as a WHO Collaborating Centre for Risk Analysis of Chemicals in Food, considered that there is a need to conduct a study to determine the 3-MCPD fatty acid esters in local foods and to estimate the potential health risk posed to the local population.

Source of exposure to 3-MCPD and its esters

3-MCPD

5. 3-MCPD belongs to a group of chemicals called chloropropanols. It

is the most widely occurring chloropropanol in foods, especially for foods that contain acid-HVP such as soya sauce, oyster sauce, fish sauce, instant noodle, garlic powder, spice mixture, mixes for soups, broths, sauces and gravies, snacks etc.[1,6]

6. Acid-HVPs are produced via the hydrolysis of various proteinaceous vegetable and animal materials with hydrochloric acid. They are used widely as flavour enhancers and as ingredients in processed savoury food products and pre-prepared meals. The occurrence of 3-MCPD in acid-HVP arises from the formation during the hydrochloric acid mediated hydrolysis step of the manufacturing process. During this hydrolytic stage the acid also reacts with residual lipids and phospholipids present in the raw material, resulting in the formation of 3-MCPD.[1]

7. 3-MCPD may also be formed in soy sauces, and related condiments without using acid-HVP as ingredient, if the manufacturing process of the sauce itself includes hydrochloric acid treatment of soybean meal. Generally, soy sauces made exclusively by means of fermentation do not contain 3-MCPD, or, if present, it only occurs in trace amounts. [1]

8. Very low levels of 3-MCPD may migrate into foods and beverages from packaging materials as 3-MCPD is present in certain types of epichlorohydrin-based wet strength resins used in paper (e.g. tea bag paper, coffee filters, absorbent meat padding) and cellulose casings.[6]

3-MCPD fatty acid esters

9. Recent studies revealed that much of the 3-MCPD found in foods is present as fatty acid esters. 3-MCPD fatty acid esters have been shown to be intermediates in the formation of 3-MCPD and therefore is a source of previously not recognized 3-MCPD.

10. Processed foods reported to contain 3-MCPD fatty acid esters includes edible oils and fat containing foodstuffs e.g. palm oil, infant milk substitute, French fries, salty crackers, sausage, toasted bread etc. Fatty acid esters of 3-MCPD arise in processed foods as primary reaction products of lipids and chloride. The reaction is promoted by high contents of fats and salts under high processing temperature. Some studies reported that refined oils contain higher levels of 3-MCPD fatty acid esters and suggested that the deodorisation step (the last step of refining, in which unwanted aromas and off- flavorings are removed) seems to be a critical step for the formation of 3-MCPD fatty acid esters during oil processing.[5]

11. The Federal Institute for Risk Assessment (BfR) in Germany stated that infant formula and follow-up formula based on dry powder (approximately 25% fat content), contain plant oils and sometimes animal oils. Since the added oils should be tasteless, they are almost always refined and therefore contain 3-MCPD fatty acid esters.[7] A study on occurrence of 3-MCPD fatty acid esters in infant and baby foods suggested that the concentration of 3-MCPD fatty acid esters in these products were proportional to the fat content in the products as refined vegetable oils used by manufactures contain 3-MCPD fatty acid esters depending on their origin and other factors.[8]

12. A study on the occurrence of 3-MCPD fatty acid esters in human breast milk reported that the mean level of 3-MCPD fatty acid esters for 12 breast milk samples was 35.5 μg/kg (ranged <11 – 76 μg/kg). It was deduced that various foodstuffs containing high level of 3-MCPD fatty acid esters might be the major sources of 3-MCPD fatty acid esters in breast milk. [9]

13. Workshops on "3-MCPD Esters in Food Products" and "MCPD and Glycidyl Esters in Food Products" were conducted in 2009 and 2011 respectively. It was concluded that although there is a lack of data about 3-MCPD esters for many foodstuffs, it is obvious that thermally processed foods and refined fats and oils (as such or as a component of other foodstuffs) are the most significant sources of 3-MCPD esters for consumers. In particular, refined palm oil in different kinds of foodstuffs is responsible for a significant part of exposure.[5, 10]

Dietary exposure to 3-MCPD fatty acid esters

14. At present, adult's dietary exposure to 3-MCPD fatty acid esters in different countries is limited. The BfR estimated infant's exposure to 3-MCPD from its fatty acid esters (expressed as 3-MCPD) from infant milk based on ten samples of infant formulas and follow-up formula examined, under the assumption that 100% of 3-MCPD was released from its esters. Among the ten samples examined by BfR, the levels of 3-MCPD fatty acid esters in ready-to-drink infant and follow-up formula ranged 0.045 – 0.156 μg/ml and the estimated exposures to 3-MCPD fatty acid esters ranged 7.3 – 25 μg/kg bw/day (365% to 1250% of the PMTDI of 3-MCPD), by assuming that infants were given approximately 160 mL milk per kg body weight.[7] BfR

noted that the PMTDI does not apply to infants in the first months of life and concluded that no clear answer could be given to the question about the level of risk arising from the occurrence of 3-MCPD fatty acid esters in infant formula and follow-up formula.

Toxicity of 3-MCPD and its esters

15. The JECFA evaluated the safety of 3-MCPD in 2001 and re-evaluated in 2006. However, the toxicological data of 3-MCPD fatty acid esters are limited. In 2006, the JECFA commented that there were insufficient data to evaluate the intake or toxicological significance of 3-MCPD esters and there is no safety reference value for 3-MCPD fatty acid esters. It was reported that the primary toxicological concern of 3-MCPD fatty acid esters is its potential to release 3-MCPD *in vivo* during digestion in the gastrointestinal tract. However, the potential toxicological properties of intact 3-MCPD fatty acid esters, actual fate and metabolism, such as the degree of hydrolysis of 3-MCPD fatty acid esters during digestion, which amount of free 3-MCDP is released etc are still unknown.[5, 10, 11] The following provides the toxicological information of 3-MCPD and its esters.

3-MCPD

Kinetics and Metabolism

16. 3-MCPD has been shown to be widely distributed in body fluid and cross blood-brain barrier and blood-testis barrier. 3-MCPD was found to be detoxified by conjugation with glutathione and oxalic acid would be formed subsequently. Being a haloalcohol, there is ample evidence that it may

undergo microbial enzymatic reaction to form glycidol, which has been shown to be genotoxic *in vitro* and *in vivo*.[11]

Acute Toxicity

17. The reported oral median lethal dose (LD_{50}) value in rats was 150 mg/kg body weight (bw).[11]

Genotoxicity and Carcinogenicity

18. 3-MCPD was shown to be genotoxic in most *in vitro* assays but non-genotoxic in *in vivo* ones. JECFA raised questions about the relevancy of these *in vitro* tests because very high concentrations were used. JECFA concluded that 3-MCPD is not genotoxic *in vitro* at concentrations that are not toxic, which also applied to *in vivo* study.[11]

19. Although 3-MCPD was found to be associated with increased incidences of benign tumours in some organs in an animal study, such tumours were observed only at dose levels greater than those causing other toxic effects.[11]

20. The International Agency for Research on Cancer (IARC) classified 3-MCPD as Group 2B agent (Possibly carcinogenic to humans) as there is sufficient evidence showing that 3-MCPD is carcinogenic to experimental animals; but no data is currently were available for the carcinogenicity in human.

Other Chronic Toxicity

21. 3-MCPD was shown to affect the kidney, the central nervous system and the male reproductive system of rats. A decrease in the motility of human spermatozoa by 3-MCPD synergistically with copper ions has also been demonstrated *in vitro*.[11]

3-MCPD fatty acid esters

22. Although the toxicological properties of intact 3-MCPD fatty acid esters, actual fate and metabolism etc of 3-MCPD fatty acid esters were still unknown, a 90-days toxicological study of 3-MCPD and its diester (dipalmitate) suggested that dipalmitate might cause similar effects on kidney and the testes of free 3-MCPD in experimental animals. The most striking effects were seen on testes that almost devoid of cellularity were observed both in rats receiving free 3-MCPD and in those treated with 3-MCPD dipalmitate at the highest dose (156.75 mg/kg of 3-MCPD dipalmitate, equimolar dose of 29.5 mg/kg of free 3-MCPD). Microscopic evaluation of kidney of experimental animals treated with the highest dose of 3-MCPD and its dipalmitate highlighted degenerative lesions involving different tubular segments of one or more part of the kidney parenchyma.[12]

Safety Reference Value

23. JECFA established a provisional maximum tolerable daily intake (PMTDI) of 2 μg/kg bw/day for 3-MCPD on the basis of the lowest-observed-effect-level (LOEL) of 1.1 mg/kg bw/day for tubule

hyperplasia observed in the kidney of rats and a safety factor of 500 (100 for inter- and intra-species variation and an extra factor of 5 for extrapolation from a LOEL to a no-observed-effect-level (NOEL)).[11] JECFA retained this PMTDI in its re-evaluation in 2006.[13] However, no safety reference value was established for its fatty acid esters by JECFA.

24. According to WHO, health-based guidance values such as PMTDI are not considered applicable to infants under the age of 12 weeks who might be at risk at lower levels of exposure.[14]

Regulatory control

25. Codex Alimentarius Commission (Codex) only established a maximum level of 0.4 mg/kg for 3-MCPD in "Liquid condiments containing acid-hydrolysed vegetable proteins (excluding naturally fermented soy sauce)".[15]

26. Codex has also established a "Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the production of Acid-Hydrolysed Vegetable Proteins (Acid-HVPs) and Products that Contain Acid-HVPs" in 2008.[1]

27. There is currently no specific regulatory control on the levels of 3-MCPD and its fatty acid esters in food in Hong Kong. The CFS had included the testing of 3-MCPD in its routine food surveillance programme and

adopted an action level of 1 mg/kg since 1999.

SCOPE OF STUDY

28. This study focused on foods which were reported more likely to have higher 3-MCPD fatty acid esters levels and popular in Hong Kong. Since 3-MCPD fatty acid esters are formed when fat- and salt-containing foods are processed at high temperatures during production, sampling criteria includes food items available in the market which contain fat and salt and might have undergone high heat treatments such as processing like frying, deep frying, roasting, baking etc. As PMTDI does not apply to infants under the age of 12 weeks, this study report focused on the levels of 3-MCPD fatty acid esters in various local foods consumed by adults.

METHODS

Sampling

29. A range of locally-available food items which contain fat and salt and might have undergone high heat treatments were taken for 3-MCPD fatty acid esters analysis in this study. The selection was based on the reported occurrence of 3-MCPD fatty acid esters in different food groups. A total of 300 individual samples were collected. Apart from instant noodle, only ready to eat, processed food items or foods need mixing with hot water only were collected. They were either pre-packaged foods or restaurant dishes. Food samples were purchased from various retail stores including both chain and independent stores and food premises include bakery shops, supermarket,

wet-market, restaurants and café etc.

Laboratory analysis

30. Laboratory analyses were conducted by the Food Research Laboratory (FRL) of the CFS.

31. The 3-MCPD fatty acid esters were analysed in individual samples as purchased, apart from instant noodles. The instant noodle samples were cooked according to the instruction on the food label and mixed with the seasoning powder for making the soup. About three minutes after finishing, the soup was discarded before further sample preparation.

32. Lipids in samples were extracted to hexane by homogenization. After that, the extract underwent enzymatic hydrolysis with *Candida Antarcticalipase A*. 3-MCPD released from the 3-MCPD fatty acid esters were derivatized by phenylboronic acid and then determined by gas chromatography - mass spectrometry. Deuterium-labelled 3-MCPD esters were used as internal standard. The concentration of 3-MCPD fatty acid esters in samples were expressed as 3-MCPD. The limits of detection (LOD) varied among different food categories (1 – 20 μg/kg) as the sample masses taken for analysis varied between different food items examined (Annex 1).[16]

Food consumption data

33. The food consumption data from the Hong Kong Population-based Food Consumption Survey 2005-2007 (the Survey) was used for estimating

dietary exposure to 3-MCPD fatty acid esters.[17]

34. Due to the nature and limitation of the Survey, some consumption data might have been underestimated. For example, the consumption amount of oil, sugar, salt and some condiments, as it was difficult for respondents to recall and report the actual amount consumed, especially if he/she was not the one responsible for preparing the dishes. Moreover, the oil, sugar, salt and condiments in mixed food items, such as oil in spring rolls and butter in cocktail buns, had not been taken into account.

35. Since the consumption data of oils in the Survey might be underestimated, per capita oil consumption from Hong Kong Edible Oils Association (HKEOA) was also used to estimate and compare the dietary exposure to 3-MCPD fatty acid esters due to oil consumption.

Estimation of dietary exposure

36. Dietary exposure to 3-MCPD from its fatty acid esters was obtained by combining the weighted population consumption data from 24-hr recalls and the detected levels of 3-MCPD fatty acid esters in food items in this study. 1/2 LOD was assigned to the non-detect (ND) samples for the calculation of mean levels of 3-MCPD fatty acid esters in foods. The mean and 95th percentile exposures were used to represent the average and high consumers respectively.

RESULTS AND DISCUSSION

3-MCPD fatty acid esters levels

37. Results of 3-MCPD fatty acid esters (expressed as 3-MCPD) in food consumed by adults under different food groups were listed in Table 1. The levels of 3-MCPD fatty acid esters in individual food categories were listed in Annex 1.

Table 1: Results of 3-MCPD fatty acid esters in different food groups

Food Group	Number of Samples	3-MCPD fatty acid esters level (µg/kg), expressed as 3-MCPD	
		Mean*	Minimum – Maximum
Breakfast cereal	20	7	ND# - 43
Noodles	20	53	ND - 210
Biscuit	25	440	50 - 860
Meat, and its products	30	19	ND - 280
Poultry, and its products	15	23	ND - 160
Fish, and its products	15	77	ND - 280
Nuts and seeds	15	5	ND for all samples
Fats and oils	20	390	ND - 2500
Condiments and sauces	15	75	ND - 490
Snacks	25	270	9 - 1000
Bakery wares	35	120	ND - 410
Chinese pastry	20	270	ND - 1200
Dairy products	15	17	ND - 230
Soup and non-alcoholic beverages	20	12	ND - 61

*Mean levels below 10 µg/kg had been rounded to one significant figure and levels equal to or above 10 µg /kg had been rounded to two significant figures.

#ND = Non-detect . 1/2 LOD was assigned to the ND samples for the calculation of mean levels of 3-MCPD fatty acid esters.

38. On the whole, vast majority of thermally processed foods and/or foods containing relatively more fats and oils had detected levels of 3-MCPD fatty acid esters. For example, the food groups “Biscuits”, “Fats and oils”,

"Snacks" and "Chinese pastry" contained relatively higher levels of 3-MCPD fatty acid esters with mean levels of 440, 390, 270 and 270 μg/kg respectively.

39. The mean levels of 3-MCPD fatty acid esters in some food groups were relatively low. They included "Nuts and seeds" (all samples with 3-MCPD fatty acid esters not detected) and "Breakfast cereal" (mean 7 μg/kg, ranged ND - 43 μg/kg).

40. It was reported that refined fats and oils are the most significant sources of 3-MCPD fatty acid esters for consumers. The levels of 3-MCPD fatty acid esters in different kinds of vegetable oils were listed in Table 2.

Table 2: Results of 3-MCPD fatty acid esters in different vegetable oils

Oils	Number of Samples	3-MCPD fatty acid esters level (μg/kg), expressed as 3-MCPD	
		Mean*	Minimum – Maximum
Peanut oil	3	570	500 - 650
Canola oil	3	110	100 - 130
Corn oil	3	280	120 - 470
Olive oil	3	390	250 - 640
Grape seed oil	3	1200	390 – 2500
Extra virgin olive oil	1	10	ND#

*Mean levels above 10 μg /kg had been rounded to two significant figures.

#ND = Non-detect . 1/2 LOD was assigned to the ND samples for the calculation of mean levels of 3-MCPD fatty acid esters.

41. In this study, only the sample of "extra virgin olive oil" had 3-MCPD fatty acid esters level not detected among vegetable oils collected. Other vegetable oil samples contained 3-MCPD fatty acid esters levels ranged 100 - 2500 μg/kg, which were lower than reported levels of 3-MCPD fatty acid esters

in refined vegetable fats and oils in other countries (<200 – 21500 μg/kg).[18] The refined oil containing relatively higher 3-MCPD fatty acid esters levels in this study were grape seed oil (390 – 2500 μg/kg) and peanut oil (500 – 650 μg/kg). These results tally with other studies reports that refined vegetable oils and fats contained considerable amount of 3-MCPD fatty acid esters and only oil that had not undergone any heat treatment (e.g. native olive oil) did not contain the substance. For animal fats, the butter samples collected in this study had 3-MCPD fatty acid esters levels not detected, which was tally with the report that animal fats are usually not refined. [5]

Comparison on levels of 3-MCPD fatty acid esters in foods in other country.

42. There is currently lack of data about 3-MCPD fatty acid esters in foodstuffs at international scene. Table 3 showed the reported levels of 3-MCPD fatty acid esters for French fries, potato chips, bread, biscuits, breakfast cereals etc in United Kingdom (UK) retail foods reported by UK Food Standard Agency (FSA) in 2008. The highest reported level was 1186 μg/kg in potato crisps.[19]

Dietary exposure to 3-MCPD from its fatty acid esters

43. JECFA established a PMTDI of 2 μg/kg bw/day for 3-MCPD only. No safety reference value was established for its fatty acid esters. It was reported that the primary toxicological concern of 3-MCPD fatty acid esters is its potential to release 3-MCPD *in vivo* during digestion in the gastrointestinal tract. The BfR has assessed the detected levels of 3-MCPD fatty acid esters in

foods, based its risk assessment on toxicological data on 3-MCPD, under the assumption that 100% of 3-MCPD was released from its esters. Scientific Panel on Contaminants in the Food Chain (CONTAM) of European Food Safety Authority (EFSA) agreed with the assumption made by the BfR and concluded that there was no scientific evidence at present to dispute this figure and agreed with the estimate of 100 % release of 3-MCPD from its esters in humans.[20] In this study, health risk assessment of exposure to 3-MCPD fatty acid esters in adults was conducted by assuming that all 3-MCPD would be released from the esters by hydrolysis in the digestive system and the exposures would be compared to the PMTDI of 3-MCPD, having noted that this assumption may overestimate the actual dietary exposure to 3-MCPD.

Table 3: Comparison on levels of 3-MCPD fatty acid esters in certain foods in Hong Kong and UK

Food Product	**This study (2011)**		**UK FSA Survey (2008)**	
	3-MCPD fatty acid esters (μg/kg)		**3-MCPD fatty acid esters (μg/kg)**	
	No. of samples	**Mean* (range)**	**No. of samples**	**Mean (range)**
French fries	8	120 (37-300)	20	105 (35-397)
Potato crisps	10	340(22-660)	20	198 (48-1186)
Bread	10	87 (2-230)	5	27 (ND – 42)
Breakfast cereals	20	7 (ND#-43)	5	12 (11-12)
Biscuits	25	440 (50-860)	8 (including infant biscuits)	443 (110-696)
Chicken	7	43 (ND-160)	2 (coated)	342 (260-423)
Soups	5	3 (ND-7)	1 (vegetable soups)	ND
Vegetable crisps	3 (cornnuts)	550 (16-1000)	1	157

*Mean levels below 10 μg/kg had been rounded to one significant figure and levels equal to or above 10 μg /kg had been rounded to two significant figures.

#ND = Non-detect . 1/2 LOD was assigned to the ND samples for the calculation of mean levels of 3-MCPD fatty acid esters.

Adult's dietary exposure to 3-MCPD from its fatty acid esters

44. The estimated dietary exposures to 3-MCPD fatty acid esters of an

average and high (95th percentile) adult consumers in Hong Kong (body weight 61.25 kg) were 0.20 μg/kg bw/day (10% of the PMTDI of 3-MCPD) and 0.53 μg/kg bw/day (26 % of the PMTDI of 3-MCPD) respectively. Assuming that all 3-MCPD would be released from the esters by hydrolysis in the digestive system, the results suggested that both average and high consumers were unlikely to experience major toxicological effects of 3-MCPD. Exposure to 3-MCPD fatty acid esters attributed by different food groups were listed in Table 4.

45. Assuming that all 3-MCPD would be released from the esters by hydrolysis in the digestive system, each food groups contributed less than 5% of the PMTDI of 3-MCPD. The food groups "Bakery wares", "Noodles" and "Biscuit" contributed relatively more on the exposure to 3-MCPD fatty acid esters. The food groups "Bakery wares" and "Noodles" had relatively higher contribution due to larger consumption amount (35.06 g/day and 83.70 g/day respectively) whereas the food group "Biscuit" was due to higher levels of 3-MCPD fatty acid esters in samples (mean levels 440 μg/kg).

46. It was reported that thermally processed foods and refined fats and oils (as such or as a component of other foodstuffs) are the most significant sources of 3-MCPD fatty acid esters for consumers. However, the local consumption data of edible fats and oils may be underestimated since consumers may not be able to report the amount of oil consumed accurately. Therefore oil consumption pattern from HKEOA (2007) was used to estimate and compare the dietary exposure to 3-MCPD fatty acid esters due to oil consumption. HKEOA estimated the oil consumption/capita using the edible oil usage data

and the Hong Kong population in 2007. The estimated oil consumption amount was 11.22 kg per annum (30.74 g/day), which was about 11.5 times the average daily consumption amount of the food items under the food group "Fats and oils" in this study (2.67 g/day).

Table 4: Adult's dietary exposure to 3-MCPD fatty acid esters from different food groups

Food Group	Average exposure to 3-MCPD fatty acid esters (ng/kg bw/day)*	Percentage of PMTDI of 3-MCPD (%)*
Breakfast cereal	0.3	0.01
Noodles	48	2
Biscuit	29	1
Meat, and its products	7	0.4
Poultry, and its products	9	0.4
Fish, and its products	19	0.9
Nuts and seeds	0.1	0
Fats and oils	13	0.7
Condiments and sauces	3	0.1
Snacks	9	0.5
Bakery wares	48	2
Chinese pastry	6	0.3
Dairy products	3	0.1
Soup and non-alcoholic beverages	9	0.4
Total	200	10

*average exposure and percentage of PMTDI values below 10 had been rounded to one significant figure and values equal to or above 10 had been rounded to two significant figures.

47. Using the oil consumption data estimated by HKEOA (2007) and the detected levels of 3-MCPD fatty acid esters in the food group "Fats and oils", the exposure to 3-MCPD fatty acid esters would be increased from 13 ng/kg

bw/day (0.7 % PMTDI of 3-MCPD) to about 150 ng/kg bw/day (8 % PMTDI of 3-MCPD) upon consumption of fats and oils.

48. Currently, the most complete set of information on occurrence of 3-MCPD fatty acid esters in foods are data for several oils. There is an inequality of data on 3-MCPD fatty acid esters across food groups with little information on cereals and bread, milk and milk products, frying oils and mixtures, animal fats and oils and composite processed foods. Therefore dietary exposure to 3-MCPD fatty acid esters in different countries was limited and comparison on local dietary exposure to 3-MCPD fatty acid esters was not feasible.[10]

Comparison on dietary exposure to free 3-MCPD of secondary school students and adult's dietary exposure to 3-MCPD from its fatty acid ester

49. This study aims to give an overview of the levels of 3-MCPD fatty acid esters in various foods in Hong Kong. Therefore, the levels of free 3-MCPD in foods were not analysed. Nevertheless, the CFS conducted special studies on 3-MCPD in soya sauce as well as oyster sauce and related products jointly with the Consumer Council in 2002 and 2004 respectively and a risk assessment study, titled "Dietary Exposure to Chloropropanols of Secondary School Students" in 2007, to estimated the potential dietary exposures to free 3-MCPD in secondary school students. [2,3,4]

50. The levels of free 3-MCPD in different food groups in these studies and the levels of 3-MCPD fatty acid esters in corresponding food groups in this study were summarised in Annex 2.

51. Previous study results revealed that the exposure to free 3-MCPD for average consumer of secondary school student was estimated to be 0.063 – 0.150 μg/kg bw/day (3- 8% PMTDI of 3-MCPD) whilst that for the high consumer was 0.152 – 0.300 μg/kg bw/day (8 – 15% PMTDI of 3-MCPD). In this study, the estimated dietary exposure to 3-MCPD fatty acid esters of an average and high adult consumers in Hong Kong was 0.20 μg/kg bw/day (10% of the PMTDI of 3-MCPD) and 0.53 μg/kg bw/day (26 % of the PMTDI of 3-MCPD) respectively.

LIMITATIONS

52. Although more 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 laboratory resources. In this study, only popular local food items that were reported more likely to contain higher amount of 3-MCPD fatty acid esters were sampled. Furthermore, as the numbers of replicates were limited in this study and batch-to-batch variations in 3-MCPD fatty acid esters levels may be fluctuated even for the same product, the results of this study represented only a snapshot of the 3-MCPD fatty acid esters levels in certain local foods.

53. In addition, food consumption data for oil was underestimated in the Survey and consumption data were not available for all foods sampled. If no exact match was available, the consumption data of the next-closest food category would be used for estimation. For example, the consumption data of "Partly/ semi-skimmed dried milk" was used for the food item "high- calcium

low-fat milk powder" for calculating exposures to 3-MCPD fatty acid esters.

54. Moreover, there are some information gaps on 3-MCPD fatty acid esters, including the mechanism(s) of formation, percentage release of 3-MCPD from its esters, metabolic pathways and toxicological properties of the intact 3-MCPD fatty acid esters etc. Due to the approximations above, the net effect of these factors on over-estimation or under-estimation on the estimated exposure was uncertain.

CONCLUSIONS AND RECOMMENDATIONS

55. 3-MCPD fatty acid esters are found in processed foods which contain edible oils and fats and salt. The study showed that vast majority of thermally processed foods and/or foods containing fats and oils had detected levels of 3-MCPD fatty acid esters and the food groups "Biscuits", "Fats and oils", "Snacks" and "Chinese pastry" contained relatively higher levels.

56. The estimated exposures to 3-MCPD from its fatty acid esters in the local average and high adult consumers were below the PMTDI of 3-MCPD, suggesting that both average and high consumers were unlikely to experience major toxicological effects of 3-MCPD.

57. By virtue of the dietary exposure to 3-MCPD fatty acid esters in adults alone, the findings of the current study did not provide sufficient justifications to warrant changes to the basic dietary advice on healthy eating. The public

are recommended to maintain a balanced and varied diet, which includes a wide variety of fruits and vegetables. Since refined oil is reported as one of the major sources of 3-MCPD fatty acid esters, the public may reduce consumption of fats and oils to further reduce the exposure to 3-MCPD fatty acid esters.

58. Members of the food trade are advised to find ways to reduce the level of 3-MCPD fatty acid esters in refined fats and oils while not impairing the quality of their products. The methods may include removal of precursors from the raw material e.g. remove chloride by washing, optimisation of the oil refining process and removal of 3-MCPD-esters from the product. However, all these possibilities needed to be assessed in the future.

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Annex 1

Results of 3-MCPD fatty acid esters in different food categories consumed by adults

	No. of samples	3-MCPD fatty acid esters level (μg/kg), expressed as 3-MCPD		
		Mean*	range	LOD
Breakfast cereal:	**20**	**7**	**ND[#] - 43**	**1 - 4**
Oatmeal	6	3	ND - 6	1 - 2
Corn flakes	3	2	ND - 6	1 - 2
Wheat bran breakfast cereal	3	4	ND - 6	1 - 2
Other Breakfast Cereal	8	14	ND - 43	1 - 4
Noodles:	**20**	**53**	**ND - 210**	**1 - 5**
Instant noodles (cooked)	6	81	ND - 210	1 - 2
Rice noodles/ Rice vermicelli	4	3	ND - 11	1
Flat noodles/ "Ho Fan"/"Lai Fan"	3	49	ND - 110	1
Other noodles	7	59	ND - 200	1 - 5
Biscuit:	**25**	**440**	**50-860**	**2 - 13**
Cheese cracker	2	540	280 - 800	5 -6
Saltine crackers	5	510	200 - 850	2 - 13
Sandwich crackers	2	450	200 - 690	5 -12
Wafer biscuit	4	240	50 - 610	4 -7
Chocolate coated/filled biscuit	4	250	130 - 400	4 - 6
Digestive biscuit	2	580	650 - 720	4 - 6
Other biscuit	6	540	250 - 860	4 - 8
Meat, and its products:	**30**	**19**	**ND-280**	**1 - 6**
Dried beef/ Beef jerky	2	12	6 - 17	1
Corned beef	2	26	ND - 50	2
Beef ball/beef salami	4	0.9	ND for all samples	1 - 3
Beef flank	2	2	ND for all samples	1 - 6
Roasted beef/ ribs of veal	3	16	3 - 36	1 - 6
Fried beef steak	2	12	9 - 14	1 - 2
Roasted/ barbeque pork (including Siu Mei)	4	78	3 - 280	2 - 3
Fried pork chop	2	27	22 - 32	1 - 2
Ham/Chinese ham (hind leg include buttock)	3	1	ND for all samples	1 - 3
Pork sausage/patties	3	4	ND - 10	2 -5
Other processed pork products	3	15	ND - 30	2 - 4
Poultry, and its products:	**15**	**23**	**ND-160**	**1 - 5**

Fried/ deep fried chicken leg/wing	3	42	ND - 91	3 - 4
Chicken nugget	2	85	9 - 160	3
Other chicken products	3	2	ND - 3	1 - 2
"Lo shui" poultry	3	7	ND - 13	3 - 5
Roasted poultry	4	7	ND - 24	3 - 5
Fish, and its products:	**15**	**77**	**ND-280**	**1 - 7**
Canned fish	3	79	ND - 230	1 - 5
Fish fillet/ fish patty/ fish ball	5	30	3 - 74	1 - 2
Deep fried fish	2	220	150 - 280	4 - 5
Roasted fish	2	66	21 - 110	1 - 2
Other processed fish products	3	66	5 - 140	2 - 7
Nuts and seeds:	**15**	**5**	**ND for all samples**	**1 - 17**
Nuts	12	5	ND for all samples	1 - 17
Seeds	3	6	ND for all samples	9 - 15
Fats and oils:	**20**	**390**	**ND - 2500**	**10 - 20**
Butter	2	8	ND for all samples	16
Peanut oil	3	570	500 - 650	20
Canola oil	3	110	100 - 130	20
Corn oil	3	280	120 - 470	20
Olive oil	3	390	250 - 640	20
Extra Virgin Olive oil	1	10	ND	20
Grape seed oil	3	1200	390 - 2500	20
Other fats and oils	2	85	76 - 93	10 - 20
Condiments and sauces:	**15**	**75**	**ND - 490**	**1 - 20**
Oil based sauces	3	350	160 - 490	5 - 20
Other condiments and sauces	8	9	ND - 43	1 - 11
Soya sauce	2	0.5	ND for all samples	1
Oyster Sauce	2	0.5	ND for all samples	1
Snacks:	**25**	**270**	**9 - 1000**	**1 - 16**
Fried Potato (e.g.French fries,Hush brown)	8	120	37 - 300	2 - 6
Cornnuts	3	550	16 - 1000	7 - 16
Potato chips	10	340	22 - 660	5 - 14
Shrimp flavoured chips/ Prawn crackers	4	180	9 - 500	1 - 8
Bakery wares:	**35**	**120**	**ND - 410**	**1-6**
White bread	5	42	2 - 160	1 - 2
Other bread	5	130	64 - 230	1 - 2
Cookie/ Brownie	5	60	ND - 270	4 - 5
Cake	3	44	4 - 110	3 -4

Swiss roll	3	170	26 - 250	3- 5
Pie	3	280	140 - 410	2 -4
Tart	7	170	ND - 300	2 - 6
Muffin	4	84	5 - 190	2 - 5
Chinese pastry:	**20**	**270**	**ND - 1200**	**1 -20**
Chinese pastry	20	270	ND - 1200	1 -20
Dairy products:	**15**	**17**	**ND - 230**	**1 - 7**
Milk	4	0.5	ND for all samples	1
Cream	3	3	ND for all samples	1 - 7
Cheese	3	2	ND for all samples	2 -5
Ice-cream	2	120	8 - 230	1 - 3
Other dairy products	3	0.5	ND for all samples	1
Soup and non-alcoholic beverages:	**20**	**12**	**ND - 61**	**1 -5**
Chocolate powder	3	9	ND - 21	1 - 2
Coffee	5	15	1 - 61	1
Coffee Powder	5	12	ND - 36	1 - 5
Other beverage powder	2	27	5 - 49	1 - 2
Canned soup	5	3	ND - 7	1

*Mean levels below 10 µg/kg have been rounded to one significant figure and levels equal to or above 10 µg /kg have been rounded to two significant figures.

#ND = Non-detect . 1/2 LOD was assigned to the ND samples for the calculation of mean levels of 3-MCPD fatty acid esters.

Annex 2

Levels of free 3-MCPD in different food groups in previous studies[2, 3, 4] and levels of 3-MCPD fatty acid esters in corresponding food groups in this study

Food groups	No. of samples	Free 3-MCPD level (**previous studies**) Range (μg/kg)*	Food groups	No. of samples	3-MCPD fatty acid esters level (**this study**) Range (μg/kg)*
Cereal and their products	57	ND - 23	Breakfast cereal	20	ND[#] - 43
			Noodles	20	ND - 210
			Biscuit	25	50 - 860
			Bakery wares	35	ND - 410
Vegetable and their products	39	ND for all samples	-	-	-
Fruits	21	ND for all samples	-	-	-
Fish, shellfish and their products	66	ND - 33	Fish, and its products	15	ND -280
Meat, poultry and their products	87	ND - 32	Meat, and its products	30	ND - 280
			Poultry, and its products	15	ND - 160
Egg and their products	12	ND for all samples	-	-	-
Dairy products	12	ND for all samples	Dairy products	15	ND - 230
Snack	24	ND -66	Snacks	25	9 - 1000
			Nuts and seeds	15	ND for all samples
Soya sauces	40	ND - 260	Condiments and sauces	15	ND - 490
Condiments and sauces, other than soya sauces	40	ND - 170			

* Levels below 10 μg/kg have been rounded to one significant figure and levels equal to or above 10 μg /kg have been rounded to two significant figures.

#ND = Non-detect .