Risk Assessment Studies

Report No. 29

<u>Chemical Hazard Evaluation</u>

DIETARY EXPOSURE TO CHLOROPROPANOLS OF SECONDARY SCHOOL STUDENTS

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Abstract

This study examined the levels of two types of chloropropanols, namely 3-monochloropropan-1,2-diol (3-MCPD) and 1,3-dichloro-2-propanol (1,3-DCP), in a wide range of food items, estimated the dietary exposure to the above two chloropropanols of secondary school students in Hong Kong and assessed the associated health risks based on the available data.

Dietary exposure to chloropropanols was estimated using the local food consumption data obtained from secondary school students in 2000 and the concentrations of 3-MCPD and 1,3-DCP in food samples taken from the local market. Laboratory analysis for 3-MCPD and 1,3-DCP was conducted by the Food Research Laboratory of the Centre for Food Safety.

The dietary exposure to 3-MCPD for an average consumer of secondary school student was estimated to be 0.063 – 0.150 μg/kg bw/day whilst that for the high consumer was 0.152 – 0.300 μg/kg bw/day. Both estimates fell below the provisional maximum tolerable daily intake of 2 μg/kg bw established by JECFA and amounted to less than 20% of this safety reference value. The dietary exposure to 1,3-DCP for an average consumer of secondary school student was estimated to be 0.003 – 0.019 μg/kg bw/day whilst that for the high consumer was 0.009 – 0.040 μg/kg bw/day. The resulting margin of exposures were of low concern for human health.

It could be concluded that both the average and high consumers of the secondary school students were unlikely to experience major toxicological effects of 3-MCPD and 1,3-DCP.

The results also showed that the food group “cereal and their products”, particularly instant noodle, was the main dietary source of 3-MCPD. This might due to the fact that the soup base for instant noodle might contain acid-HVP as a savoury ingredient. As the dietary exposure to 3-MCPD upon consumption of instant noodle soup had not been taken into account in this study, the exposure estimates were expected to be higher for those consumers of the instant noodle soup. On the other hand, “meat, poultry and their products”, particularly sausage, was the main dietary source of 1,3-DCP.

The trade is advised to reduce the levels of chloropropanols in food as far as is technically achievable. Members of the public are advised to maintain a balanced diet so as to avoid excessive exposure to contaminants from a small range of food items.

Dietary Exposure to Chloropropanols of Secondary School Students

OBJECTIVES

This study aims to examine the levels of two types of chloropropanols, namely 3-monochloropropan-1,2-diol (3-MCPD) and 1,3-dichloro-2-propanol (1,3-DCP), in a wide range of food items and to estimate the potential dietary exposure to these chloropropanols of secondary school students in Hong Kong. The associated health risks will be assessed based on the estimations.

INTRODUCTION

2. In recent years there has been increasing interest in chloropropanols (also known as chlorinated propanols) globally. These chemicals have 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.[1]

3. Certain chloropropanols, including 3-MCPD and 1,3-DCP, were originally identified as contaminants of the savoury ingredient, acid-hydrolysed vegetable protein (acid-HVP), which is formed by treating defatted vegetable proteins with hydrochloric acid. Because of the wide application of acid-HVP,

3-MCPD and 1,3-DCP have been identified in many other foods, particularly sauces and condiments such as soya sauce and oyster sauce. 3-MCPD and 1,3-DCP can also form in food as a result of heat processing (e.g., baking of cereal products), as well as other processing or storage conditions, but the exact mechanisms for their formation have not been fully understood.[2,3,4]

4. To address the food safety concern of chloropropanols, food safety authorities have conducted toxicological evaluation and dietary surveys of chloropropanols in food. The Joint Food and Agriculture Organization (FAO) / World Health Organization (WHO) Expert Committee on Food Additives (JECFA) evaluated the safety of 3-MCPD and 1,3-DCP in 2001 and re-evaluated the two contaminants in 2006. The Codex Alimentarius Commission (Codex) has been discussing the issue and proposing relevant standard and code of practice since 2000. On the other hand, food authorities from places such as the member countries of the European Commission[5] and Australia[6] have been collecting data on levels of chloropropanols in different food items and conducting estimates on dietary exposure.

5. In response, FEHD has included the testing of 3-MCPD in its routine food surveillance programme and adopted an action level of 1 mg/kg since 1999. 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 results showed that the levels of 3-MCPD in all samples fell below the action level.[7,8] Lacking local data on the levels of chloropropanols in other food items, dietary exposure estimates could not be determined and the associated health risks to the local population are not clear. A study on

chloropropanols in food is therefore needed to examine the situation in the local scene.

HAZARD IDENTIFICATION

3-MCPD

6. 3-MCPD is also known as chlorohydrin, glycerol chlorohydrin, 3-chloropropan-1,2-diol and 1-chloropropane-2,3-dihydroxypropane.[4] It is present in a wide range of food items due to routes and mechanisms discussed below:

<u>Acid-hydrolysis</u>

7. The most well-known route of formation of 3-MCPD is the hydrolysis of vegetable protein using concentrated hydrochloric acid. The raw materials are usually derived from soya flour, soya meal, wheat, corn, rapeseed meal and potato. Hydrochloric acid as well as triacylglycerols, phospholipids and glycerol in the raw materials have been demonstrated to be the precursors of chloropropanols.[4]

8. Liquid seasoning condiments such as soya sauce, oyster sauce, fish sauce, etc., which have been produced using an acid treatment or included acid-HVP as an ingredient, have been found to contain 3-MCPD. Other food products that may contain acid-HVP, for example, instant noodle, garlic powder, spice mixture, mixes for soups, broths, sauces and gravies, snacks such as potato

chips, as well as composite foods such as hamburgers, have also been reported to contain 3-MCPD.[4]

Heat processing

9. 3-MCPD has been found to occur in a wide range of other food items without the presence of the ingredient acid-HVP. It appears that the presence of lipids and sodium chloride contribute to the formation of 3-MCPD during normal heat processing steps such as baking, grilling and roasting. The most studied model is bread-making. Factors affecting the formation of 3-MCPD in bread include moisture content, temperature, pH as well as the types of esters of fatty acids and food additives present in the food. The presence of glycerol at low moisture content, lecithin at high moisture content, mono- or di-esters of fatty acids of 3-MCPD, temperatures above 170^{o}C, flour improver such as diacetyltartaric acid and fatty acid esters of glycerol have been shown to promote the 3-MCPD formation. On the other hand, relatively high pH (above pH 6.0) and the presence of sodium bicarbonate have been found to inhibit its formation. In contrast, the levels of acrylamide in these bakery products were found to increase with increasing pH value.[4]

Fatty acid esters of 3-MCPD

10. Recent studies found that fatty acid esters of 3-MCPD, i.e., bound 3-MCPD, were found in various foodstuffs such as pickled olives, roasted and green coffee, crisp bread, soda crackers, potato crisps and French fries, salami, certain types of ham, smoked and pickled fish, as well as some cheeses. 3-MCPD has been shown to release under certain processing conditions, such as enzymatic hydrolysis by bakery grade lipase during the baking process.[4]

Epichlorohydrin-based resins

11. The presence of 3-MCPD in some of food may be contributed by its migration from certain types of epichlorohydrin-based wet strength resins used in paper and cellulose casings, e.g., sausage casings, tea bags and coffee filter paper.[4]

Other routes

12. A number of smoked foods was also found containing 3-MCPD. However, the parameters that affect 3-MCPD generation in these products are still being studied. The exact mechanism for the formation of 3-MCPD in different foods in fact has not been fully understood yet. Salami, though reported to have 3-MCPD up to 29 mg/kg, was found not containing acid-HVP as a food ingredient and not demonstrating to have the evidence of lipid hydrolysis to release 3-MCPD from its esters during storage.[4]

Other types of chloropropanols

13. Another type of well-known chloropropanol is 1,3-DCP. It has been reported that the levels of 1,3-DCP in acid-HVP food ingredients, soya sauce and related products are generally lower than those of 3-MCPD. In addition to sauces, 3-MCPD and 1,3-DCP have been found in cooked minced beef, ham and sausage. However, 1,3-DCP alone has also been detected in raw minced beef, ham and sausage meat. It has been suggested that more than one route is involved in the formation of 1,3-DCP and the exact mechanism is still under exploration.[4,6]

HAZARD CHARACTERISATION

14. JECFA[2,3] has evaluated the safety of the two types of chloropropanols of most concern, i.e., 3-MCPD and 1,3-DCP. The toxicological significance of other types of chloropropanols, including the fatty acid esters of 3-MCPD, has not been determined yet. The safety of 3-MCPD and 1,3-DCP is briefly summarised below.

3-MCPD

Kinetics and metabolism

15. 3-MCPD has been shown to be widely distributed in body fluid and cross blood-brain barrier and blood-testis barrier. Upon intraperitoneal administration of 3-MCPD, about 30% was shown to exhale as carbon dioxide whereas 8.5% was excreted unchanged in the urine. 3-MCPD was also found to be detoxified by conjugation with glutathione and oxalic acid would be formed subsequently. On the other hand, 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*.[2]

Acute effects

16. The reported oral median lethal dose (LD_{50}) value in rats was 150 mg/kg body weight (bw).[2]

Genotoxicity and carcinogenicity

17. 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 and *in vivo*.[2]

18. 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.[2]

Other chronic effects

19. 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*.[2]

Safety reference value

20. 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)).[2] JECFA retained this PMTDI in its re-evaluation in 2006.[9]

1,3-DCP

Kinetics and metabolism

21. The studies on kinetics and metabolism for 1,3-DCP were limited. Animal studies found that about 5% or less of an oral dose of 1,3-DCP was excreted in the urine. 1,3-DCP was also found to be conjugated with glutathione and oxalic acid would be formed subsequently.[3]

Acute effects

22. The reported oral LD_{50} values in rats ranged from 120 to 140 mg/kg bw.[3]

Genotoxicity and carcinogenicity

23. JECFA in 2001 considered that 1,3-DCP was clearly mutagenic and genotoxic in various bacterial and mammalian test systems *in vitro* and there was no data on intact mammalian organisms or humans. Regarding its carcinogenicity, an animal study demonstrated that 1,3-DCP increased the incidences of both benign and malignant neoplasms in at least three independent tissues in rats.[3]

Other chronic effects

24. 1,3-DCP was found to affect the kidney and the liver of rats. It has also been reported to be hepatotoxic in humans upon occupational exposure.[3]

Safety reference value

25. JECFA in 2001 concluded that it would be inappropriate to estimate a

tolerable intake for 1,3-DCP because of the nature of the toxicity.[3] In 2006, JECFA concluded that carcinogenicity is the critical effect of 1,3-DCP and its genotoxicity cannot be excluded. After the analysis of the cancer dose-response data by dose-response modelling, a benchmark dose lower confidence limit[a] of a 10% incidence ($BMDL_{10}$) value of 3.3 mg/kg bw/day was identified. JECFA has made use of this $BMDL_{10}$ value for calculating the margin of exposure[b] (MOE) for the evaluation of risks for the estimated intakes of 1,3-DCP in its evaluation in 2006.[9]

EXPOSURE ASSESSMENT

Dietary exposure estimates from foods other than sauces

Scope of study

26. To estimate the dietary exposures to 3-MCPD and 1,3-DCP from foods other than sauces, eight major food groups, namely (i) cereals and their products, (ii) vegetables and their products, (iii) fruits, (iv) fish, shellfish and their products, (v) meat, poultry, and their products, (vi) egg and their products, (vii) dairy products, as well as (viii) snacks, were covered. The selection was based on the reported occurrence of 3-MCPD and 1,3-DCP in these food groups and the consumption patterns.

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[a] The benchmark dose lower confidence limit (BMDL) is the lower one-sided confidence limit of the benchmark dose (BMD) for a predetermined level of response (usually for the carcinogenic response(s) of relevance to human health), called the benchmark response (BMR), such as a 5 or 10% incidence. It can be used as a starting point for hazard characterization for chemical that is genotoxic and carcinogenic and when the available data are suitable for dose-response modelling.

[b] Margin of exposure (MOE) is the ratio of the BMDL to the estimated intake of a compound in humans. It is used to prioritise different contaminants that are genotoxic and carcinogenic for further risk management.

<u>Methodology</u>

Food consumption data

27. The food consumption data in this study was extracted from the Food Consumption Survey conducted in local secondary school students in 2000 by the FEHD. In the survey, a stratified three-stage sampling plan was used, with a sampling frame of 472 secondary schools and more than 380,000 students, covering almost all the local secondary schools. A total of 967 students from 27 schools participated in the survey yielding a response rate of 77% at the school level and 96% at the student level. The mean body weight of the participated students was 52.0 kg.[10]

Sampling plan

28. Food samples were taken from the local market according to the above eight food groups. Food items were selected based on the results of the Food Consumption Survey and the likely occurrence of 3-MCPD and 1,3-DCP. Three samples of each food item were taken randomly from different sources for laboratory analysis.

Laboratory analysis

29. Sample preparation and laboratory analysis were conducted by the Food Research Laboratory of the Centre for Food Safety. Food samples were treated and analysed as consumed so as to give a better estimate of the levels of 3-MCPD and 1,3-DCP that might be consumed. In view of lacking consumption data on instant noodle soup, the instant noodle samples were cooked according to the instruction on the food label and the soup was discarded

before further sample preparation. As 3-MCPD may be formed during heat processing, selected beef, pork, chicken and fish samples were steamed and shallow-fried respectively to simulate the possible levels of 3-MCPD formed under low temperature (i.e. boiling, steaming, stewing, etc.) and high temperature (i.e. frying, grilling, braising, etc.) cooking processes. During the estimation of dietary exposures, the levels of chloropropanols for that particular food item were approximated in the proportions of the popularity of different cooking methods being employed in the preparation of that particular food item, based on the data collected in the Food Consumption Survey.[10]

30. 3-MCPD and 1,3-DCP in prepared food samples were extracted with concentrated sodium chloride solution, followed by separation and purification by liquid-liquid extraction. A portion of concentrated sample extract was subject to derivatization with heptafluorobutyrylimidazole (HFBI) and then analysis by gas chromatography / mass spectrometry (GC/MS). The limits of detection (LODs) for 3-MCPD and 1,3-DCP were 2.5 μg/kg (ppb) and 0.5 μg/kg (ppb) respectively. The adopted LODs are comparable to those used by authorities in the international arena for dietary exposure assessment and are in fact lower than the ones adopted in Australia.[6]

31. When the analytical value was below the LOD, the true value of 3-MCPD or 1,3-DCP in the food sample could be anywhere between zero and the LOD. The treatment for these results was particularly important when a large percentage of the analytical results of a particular food group fell below the LOD. While it may not be appropriate to assume a zero concentration for all samples with analytical values below LOD, assigning these non-detects a value

of LOD, would, however, grossly overestimate the dietary exposure. In this study, recommendation from WHO regarding evaluation of low-level of contamination of food was followed when treating analytical value below LOD.[11]

Estimation of dietary exposure

32. Daily dietary exposures to 3-MCPD and 1,3-DCP from an individual food item were obtained by combining the consumption data and the levels of 3-MCPD and 1,3-DCP of that food item. Total exposure for each secondary school student was obtained by summing exposures from all food items. The mean and the 95th percentile of the daily exposure levels were used to represent the dietary exposure for average and high consumers respectively.

33. The estimated exposure level of 3-MCPD was then compared with the PMTDI established by JECFA, whereas that of 1,3-DCP was combined with the $BMDL_{10}$ value recommended by JECFA for calculating the respective MOEs.

<u>Results of exposure assessment</u>

Food consumption data

34. Food consumption data for the nine food groups are given in Table 1.

Table 1: Food Consumption Pattern for Secondary School Students

Food groups	Mean consumption (g/day)
Cereal and their products	493.2
Vegetables and their products	313.6
Fruits	310.2
Fish, shellfish and their products	121.7
Meat, poultry and their products	187.0
Egg and their products	14.1
Dairy products	142.6
Snacks	26.7

Concentrations of chloropropanols in food

35. A total of 318 individual food samples were tested for 3-MCPD and 1,3-DCP. The test results for each food group are summarised in Table 2 whereas those for individual food samples are presented in Annex.

Table 2: Concentrations of 3-MCPD and 1,3-DCP in Foods

Food groups	No. of samples	3-MCPD			1,3-DCP		
		No. of detects	% of detects	Concentration range (μg/kg)	No. of detects	% of detects	Concentration range (μg/kg)
Cereal and their products	57	31	54	< LOD – 23	0	0	–
Vegetables and their products	39	0	0	–	0	0	–
Fruits	21	0	0	–	0	0	–
Fish, shellfish and their products	66	15	23	< LOD – 33	9	14	< LOD – 6.0
Meat, poultry and their products	87	46	53	< LOD – 32	6	7	< LOD – 9.5
Egg and their products	12	0	0	–	0	0	–
Dairy products	12	0	0	–	0	0	–
Snack	24	9	38	< LOD – 66	0	0	–
Total	**318**	**101**	**31**		**15**	**5**	

LODs for 3-MCPD and 1,3-DCP were 2.5 μg/kg (ppb) and 0.5 μg/kg (ppb) respectively.

36. 3-MCPD was detected in food groups “cereal and their products”, “fish, shellfish and their products”, “meat, poultry and their products” and “snack”, but not in food groups “vegetable and their products”, “fruits”, “egg and their products” and “dairy products”. On the other hand, 1,3-DCP was only detected in low levels in “meat, poultry and their products” and “fish, shellfish and their products”, but not in other food groups. Association between the formation of 3-MCPD and 1,3-DCP was not observed.

37. According to the WHO’s recommendation on evaluation of low-level of contamination of food,[11] two estimates using 0 and LOD for all the results less than LOD are produced when greater than 60% but smaller and equal to 80% of

results are below LOD and with at least 25 results quantified. The same recommendation is also applied to the condition when greater than 80% of test results fall below LOD. In our study, 68% of test results for 3-MCPD were below LOD and 85% of test results for 1,3-DCP were below LOD. The concentrations of 3-MCPD and 1,3-DCP for each food group and hence the dietary exposure estimates for these two contaminants were therefore presented in range. The upper bound was calculated by setting analytical values below LOD to LOD while the lower bound was calculated by setting analytical value below LOD to zero.

Dietary exposure to 3-MCPD

38. The dietary exposure to 3-MCPD for the average consumer of secondary school student was estimated to be **0.058 – 0.139 μg/kg bw/day**. The main dietary source of 3-MCPD was "cereal and cereal products" which contributed to 40-56% of the total exposure. Dietary exposure to 3-MCPD from different food groups are shown in Table 3.

Table 3: Dietary Exposure to 3-MCPD for Average Consumer of Secondary School Student (μg/kg bw/day) (% contribution)

Food groups	Lower bound	Upper bound
Cereal and their products	0.032 (56%)	0.055 (40%)
Vegetables	0.000 (0%)	0.019 (14%)
Fruits	0.000 (0%)	0.019 (13%)
Fish, shellfish and their products	0.002 (4%)	0.009 (6%)
Meat, poultry and their products	0.021 (36%)	0.024 (17%)
Egg and their products	0.000 (0%)	0.001 (1%)
Dairy products	0.000 (0%)	0.009 (6%)
Snack	0.002 (4%)	0.003 (2%)
Total	**0.058**	**0.139**

39. Further analysis was undertaken to estimate the risk that high consumers might be exposed to. The 95th percentile exposure level of the secondary school students was used to represent the dietary exposure to 3-MCPD for a high consumer and was estimated to be **0.147 – 0.289 μg/kg bw/day** (Table 4).

Table 4: Comparison between PMTDI Established by JECFA and Dietary Exposures to 3-MCPD from Foods Other Than Sauces for Average and High Consumers of Secondary School Students (μg/kg bw/day) (% of PMTDI)

JECFA PMTDI (μg/kg bw/day)	Average consumer	High consumer
2	0.058 (3%) to 0.139 (7%)	0.147 (7%) to 0.289 (14%)

Dietary exposure to 1,3-DCP

40. Dietary exposure to 1,3-DCP for the average consumer of secondary school student was estimated to be **0.003 – 0.019 μg/kg bw/day**. The main dietary source of 1,3-DCP at the lower bound was "meat, poultry and their products" and that at the upper bound was "cereal and their products". Dietary exposure to 1,3-DCP from different food groups are shown in Table 5.

Table 5: Dietary Exposure to 1,3-DCP for Average Consumer of Secondary School Student μg/kg bw/day (% contribution)

Food groups	**Lower bound**	**Upper bound**
Cereal and their products	0.000 (0%)	0.005 (26%)
Vegetables and their products	0.000 (0%)	0.003 (17%)
Fruits	0.000 (0%)	0.003 (16%)
Fish, shellfish and their products	0.001 (24%)	0.002 (10%)
Meat, poultry and their products	0.002 (76%)	0.004 (21%)
Egg and their products	0.000 (0%)	0.000 (1%)
Dairy products	0.000 (0%)	0.002 (8%)
Snack	0.000 (0%)	0.000 (2%)
Total	**0.003**	**0.019**

41. The 95th percentile exposure level of the secondary school students was used to represent the dietary exposure to 1,3-DCP for a high consumer and was estimated to be **0.009 – 0.040 μg/kg bw/day**.

Dietary exposure estimates from sauces

3-MCPD

42. According to the literature, the main dietary sources of 3-MCPD for the general population, particularly in Asian, are soya sauce and oyster sauce. Dietary exposures to 3-MCPD from soya sauce and oyster sauce were therefore estimated based on the assumptions stated below.

Levels of 3-MCPD in soya sauce and oyster sauces

43. Previous joint studies conducted by the FEHD and the Consumer Council revealed that the average level of 3-MCPD in soya sauce ranged from 7μg/kg (lower bound) to 16μg/kg (upper bound) with a highest reported level of 260μg/kg and that in oyster sauce ranged from 3 μg/kg (lower bound) to 5μg/kg (upper bound) with a highest reported level of 29μg/kg.[7,8]

Food consumption pattern for sauces

44. Data on the consumption pattern for sauces and condiments is limited in Hong Kong[c]. JECFA once reported that the per-capita consumption of soya sauce in Japan was about 30 g per person per day (which has been considered to be overestimated) whilst an email communication with National Food Research Institute in Japan indicated that the soya sauce sold to the Japanese market in 2001 was 771 286 kilolitres (i.e., ~ 17 millilitres per person per day). In the Mainland, it was reported that the average consumption of soya sauce for people

[c] According to Hong Kong Merchandise Trade Statistics reported by the Census and Statistics Department of HKSARG, 2,336,281 kg of soya sauce was imported and 372,922 kg was exported/re-exported from Hong Kong. However, the exact consumption pattern for soya sauce or the amount of soya sauce available for retail in Hong Kong is not available, due to the lack of data on the volume of local production.

resided in the urban area was 10.7 g/day in 2002.[12]

45. As the consumption pattern for oyster sauce is not available, it is assumed that its consumption pattern would be about half of that for soya sauce.

Dietary exposure

46. The resulting average dietary exposure of 3-MCPD of a 52-kg secondary school student upon consumption of soya sauce and oyster sauce are estimated using the average levels of 3-MCPD in soya sauce and oyster sauce. The possible dietary exposure to 3-MCPD for those consumers who are loyal to particular brand of products was estimated using the highest reported levels of 3-MCPD in soya sauce and oyster sauce. (Table 6)

Table 6. Dietary Exposure to 3-MCPD from Soya Sauce and Oyster Sauce of a 52-kg Secondary School Student (μg/kg bw/day) (%PMTDI)

	Average exposure		**Highest Exposure for consumer of particular brand of product**
	Lower bound	**Upper bound**	
Scenario 1 - Soya sauce: 30 g Oyster sauce: 15 g	0.005 (0.2%)	0.011 (0.5%)	0.158 (7.9%)
Scenario 2 - Soya sauce: 10.7 g Oyster sauce: 5.4 g	0.002 (0.1%)	0.004 (0.2%)	0.057 (2.8%)

47. Even under the most extreme scenario, i.e., a 52-kg secondary school

student who was loyal to a particular brand of product and consumed 30 g soya sauce and 15 g oyster sauce per day, the resulting exposure to 3-MCPD was estimated to be 0.158 μg/kg bw/day, which amounted to less than 8% of the PMTDI.

48. In this study, the average exposure estimates under scenario 1 would be combined with those from foods other than soya and oyster sauces to give a rough estimates of the overall exposures to 3-MCPD from the diet (see para. 50). These values were likely to be overestimated as the highest reported consumption pattern of sauces was used under scenario 1.

<u>1,3-DCP</u>

49. Soya sauce has been considered as one of the main dietary source of 1,3-DCP for the general population who consumes soya sauce. However, the dietary exposure to 1,3-DCP due to sauce consumption could not be estimated due to the lack of data on 1,3-DCP in soya sauce in Hong Kong.

Overall exposure to 3-MCPD

50. The dietary exposure to 3-MCPD for the average and high consumers of secondary school student was estimated to be **0.063 – 0.150 μg/kg bw/day** and **0.152 – 0.300 μg/kg bw/day** respectively (Table 7).

Table 7: Comparison between PMTDI Established by JECFA and Overall Dietary Exposures to 3-MCPD for Average and High Consumers of Secondary School Students (μg/kg bw/day) (% of PMTDI)

Sources of exposure	Average consumer	High consumer
Foods other than sauces	0.058 to 0.139	0.147 to 0.289
Soya sauce and oyster sauce	0.005 to 0.011	0.005 to 0.011
Overall exposure	0.063 (3%) to 0.150 (8%)	0.152 (8%) to 0.300 (15%)

RISK CHARACTERISATION

3-MCPD

Dietary exposure

51. The dietary exposure to 3-MCPD for an average consumer of secondary school student was estimated to be 0.063 – 0.150 μg/kg bw/day whilst that for the high consumer was 0.152 – 0.300 μg/kg bw/day. These exposures amounted to 3 – 8 % and 8 – 15 % of the PMTDI respectively. Exposures to 3-MCPD for both average and high consumers of secondary school student fell below the PMTDI established by JECFA.

52. The above dietary exposure estimates therefore suggested the average and high consumers of secondary school students were unlikely to experience major toxicological effects of 3-MCPD.

Major dietary sources

53. In this study, the main dietary source of 3-MCPD was “cereal and their

products" and this was followed by "meat, poultry and their products". Even though sauces have been previously reported to be the main dietary source of 3-MCPD, it only contributed to 3-17% of the overall dietary exposure in this study, and its dietary exposure estimate was lower than those from "cereal and their products" and "meat, poultry and their products".

54. Among those "foods other than sauces" with detectable amount of 3-MCPD, instant noodle was the largest contributor to total dietary exposure to 3-MCPD, i.e., 0.012 μg/kg bw/day, which was higher than those contributed by soya sauce and oyster sauce. This might be due to its relatively high level of 3-MCPD (average: 18 μg/kg) and consumption pattern as well as the fact that the soup base for instant noodle might contain acid-HVP as a savoury ingredient. As the dietary exposure to 3-MCPD upon consumption of instant noodle soup had not been taken into account in this study, the exposure is expected to be higher for those consumers of the instant noodle soup.

55. On the other hand, besides soya sauce, seaweed under the food group "snack" had the highest reported concentration of 3-MCPD (average: 56 μg/kg). However, its relatively low consumption pattern made it accountable for less than 1% of total dietary exposure to 3-MCPD. Ready-to-eat seaweed may contain acid-HVP as a savoury ingredient.

1,3-DCP

Dietary exposure

56. The dietary exposure to 1,3-DCP for an average consumer of secondary

school student was estimated to be 0.003 – 0.019 μg/kg bw/day whilst that for the high consumer was 0.009 – 0.040 μg/kg bw/day. The resulting MOEs for an average consumer ranged from 174 000 to 1 100 000 whereas those for high consumers ranged from 84 000 to 355 000, taking into account the $BMDL_{10}$ value of 3.3 mg/kg bw/day (Table 8). Such MOE values suggested that the estimated exposures to 1,3-DCP for both average and high consumers of secondary school students were of low concern for human health.

Table 8: MOEs for Dietary Exposures to 1,3-DCP for Average and High Consumers of Secondary School Students

$BMDL_{10}$ (mg/kg bw/day)	**Average consumer**	**High consumer**
3.3	174 000 – 1 100 000	84 000 – 355 000

Major dietary sources

57. In this study, the main dietary sources of 1,3-DCP at the lower bound was "meat, poultry and their products" and that at the upper bound was "cereal and their products". Nevertheless, it should be noted that 1,3-DCP was not detected in any food items under the food group "cereal and their products". The high consumption pattern for "cereal and their products" and the low concentration in other detected items probably made "cereal and their products" the main contributor at upper bound estimate. On the other hand, the LOD for 1,3-DCP might also affect the dietary exposure estimates. However, the LOD for 1,3-DCP adopted in our study was comparable to those used by authorities in the international arena for dietary exposure assessment and was in fact lower

than the one adopted in Australia.

58. For the food group "meat, poultry and their products", only two food items, namely sausage and roast pork, were detected with 1,3-DCP. Even though roast pork has the highest level of 1,3-DCP (average: 9.3 μg/kg), its relatively small amount of consumption made sausage the largest contributor, i.e., 11% (upper bound) to 67% (lower bound) of the total dietary exposure. Unlike the results of other overseas studies, 1,3-DCP was not detected in any minced beef and ham samples in this study.[4]

International comparison

59. Studies on dietary exposures to 3-MCPD and 1,3-DCP conducted overseas were reviewed and summarised in Table 9.

Table 9. A Comparison of Average Daily Exposure to 3-MCPD and 1,3-DCP (µg/kg bw/day)

Places	3-MCPD	1,3-DCP
Australia[6]	0.16-0.20*	0.012-0.041*
Denmark[5]	0.101*	NA
Finland[5]	0.200*	NA
France[5]	0.107*	NA
Hong Kong	0.063-0.150†	0.003-0.019†
Ireland[5]	0.196*	NA
Netherlands[5]	0.158*	NA
Sweden[5]	0.047*	NA
UK[13]	0.10‡	NA

* Estimated dietary exposure to 3-MCPD from various food sources, including soya and oyster sauces.

† The exposure data in Hong Kong is extracted from our current study.

‡ The data was derived from the total diet study in 2001 with no clear indication whether the exposure from sauces and related products was included.

NA denotes not available.

60. It can be seen that dietary exposure to 3-MCPD estimated in our study is about the same order of magnitude when compared to exposure estimates obtained from overseas studies whereas that for 1,3-DCP (without taken into account the 1,3-DCP exposure from sauces) is lower than the Australian study. This comparison gives the reader a rough idea of the local situation relative to the international picture, but it should be noted that direct comparison of data between different studies has to be done with caution due to the differences in time when the studies were carried out, research methodology, food group categorisation (particularly whether the exposures from sauces and condiments were included), methods of collection of consumption data, methods of chloropropanols analyses and methods of treating results below the detection limits.

LIMITATION OF THE EXPOSURE ASSESSMENT STUDY

61. The methodology for collecting food consumption data may influence the accuracy of the estimates on dietary exposure. In the Food Consumption Survey, the food consumption pattern of secondary school students was collected using a food frequency questionnaire. Although the questionnaire was very comprehensive, it was not possible to cover every single food item, some of which might be relevant to exposure to chloropropanols, particularly sauces and condiments, instant noodle soup, etc. Furthermore, only the data of consumption pattern for secondary school students is available.

62. Three samples for each food item were collected for laboratory analysis. Although about 300 samples were taken in this study, increasing the number of sample for each food item for laboratory analysis could provide a more precise estimate of the average concentrations of 3-MCPD and 1,3-DCP for a particular food item. However, the number of samples taken have to be balanced with the required resources and number of food items to be included.

63. On the other hand, the assessment of dietary exposure to 1,3-DCP was not comprehensive in this study because of the lack of data on the level of 1,3-DCP in sauces.

CONCLUSION AND RECOMMENDATION

64. The dietary exposure to 3-MCPD for an average consumer of secondary school student was estimated to be 0.063 – 0.150 μg/kg bw/day whilst that for the high consumer was 0.152 – 0.300 μg/kg bw/day. Both estimates fell below the safety reference value (i.e., < 20% of the PMTDI) established by JECFA. It could be concluded that both the average and high consumers of the secondary school students were unlikely to experience major toxicological effects of 3-MCPD.

65. The food group "cereal and their products", particularly instant noodle, was identified as the main dietary source of 3-MCPD.

66. The dietary exposure to 1,3-DCP for an average consumer of secondary school student was estimated to be 0.003 – 0.019 μg/kg bw/day whilst that for the high consumer was 0.009 – 0.040 μg/kg bw/day. The resulting MOEs were of low concern for human health.

67. Among the food groups with detected amount of 1,3-DCP, the food group "meat, poultry and their products", particularly sausage, was identified as the main dietary source of 1,3-DCP.

68. Results of our previous studies and routine surveillance programme indicated the local trade has put much effort in reducing the levels of chloropropanols in sauces and condiments since 1999. Nevertheless, the trade is advised to continue observing good manufacturing practice and reducing the

levels of chloropropanols in food as far as is technically achievable. Generally speaking, there are three main approaches in minimising the formation of 3-MCPD in acid-HVP: (i) careful control of the acid hydrolysis step; (ii) subsequent neutralisation to minimise 3-MCPD formation; and (iii) the use of sulphuric acid instead of hydrochloric acid during the hydrolysis.[14]

69. Codex is currently developing a Code of Practice for the Reduction of 3-MCPD during the Production of Acid-HVPs and Products that Contain Acid-HVPs.[15] Even though the intake estimates indicate that 3-MCPD and 1,3-DCP are not of immediate health concern, further research studies by the industries and academia deem necessary to explore the exact mechanisms for the formation of chloropropanols in other foods that do not contain acid-HVP and to propose ways to further reduce the levels of these contaminants.

70. The public is advised to maintain a balanced diet so as to avoid excessive exposure to chemical contaminants from a small range of food items.

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<u>Annex</u>

Levels of 3-MCPD and 1,3-DCP in Individual Food Items

Food Group	Food Item	Number of Samples	3-MCPD (μg/kg)		1,3-DCP (μg/kg)	
			Number of detects	Range	Number of detects	Range
Cereal and their products	Rice	3	0	-	0	-
	Congee	3	0	-	0	-
	Rice noodle	3	0	-	0	-
	Flatten noodle	3	2	< LOD – 9	0	-
	Wheat noodle	3	0	-	0	-
	Instant noodle	3	3	14 – 23	0	-
	Bread, white	3	3	8 – 13	0	-
	Bread, wheat	3	3	11 – 23	0	-
	Plain roll	3	3	10 – 20	0	-
	Sausage roll	3	3	9 – 10	0	-
	Sweet roll	3	2	< LOD – 8	0	-
	Soda cracker	3	3	17 – 22	0	-
	Spring onion cracker	3	0	-	0	-
	Paper wrapped cake	3	3	4 – 8	0	-
	Egg tart	3	3	8 – 14	0	-
	Egg roll	3	0	-	0	-
	Wafers	3	0	-	0	-
	Pertz	3	0	-	0	-
	Hamburger	3	3	11 – 20	0	-
Vegetable and their products	Flowering cabbage	3	0	-	0	-
	Chinese broccoli	3	0	-	0	-
	Bak choi	3	0	-	0	-
	Broccoli	3	0	-	0	-
	Winter melon	3	0	-	0	-
	Wax gourd	3	0	-	0	-
	Tomato	3	0	-	0	-
	Potato	3	0	-	0	-
	French fries	3	0	-	0	-
	Carrot	3	0	-	0	-
	Winter mushroom	3	0	-	0	-
	Pickled vegetables	3	0	-	0	-
	Tofu	3	0	-	0	-
Fruits	Apple	3	0	-	0	-
	Orange	3	0	-	0	-
	Banana	3	0	-	0	-
	Pear	3	0	-	0	-
	Watermelon	3	0	-	0	-
	Honeydew melon	3	0	-	0	-
	Cantaloupe	3	0	-	0	-
Fish, shellfish and their products	Golden thread, steamed	3	0	-	0	-
	Golden thread, shallow-fried	3	0	-	0	-
	Sole fillet, steamed	3	0	-	0	-

Food Group	Food Item	Number of Samples	3-MCPD (μg/kg)		1,3-DCP (μg/kg)	
			Number of detects	Range	Number of detects	Range
	Sole fillet, shallow-fried	3	0	-	0	-
	Mud carp / dace, minced, steamed	3	0	-	0	-
	Mud carp / dace, minced, shallow-fried	3	0	-	0	-
	Green grouper, steamed	3	0	-	0	-
	Japanese eel, grilled	3	3	7 – 33	0	-
	Tuna, canned	3	0	-	0	-
	Salmon, raw	3	0	-	0	-
	Salmon fillet, shallow-fried	3	3	5 – 7	0	-
	Oyster, steamed	3	0	-	0	-
	Mussel, steamed	3	0	-	0	-
	Shrimp, steamed	3	0	-	0	-
	Shrimp meat, shallow-fried	3	0	-	0	-
	Crab, steamed	3	3	3 – 9	3	3.5 – 5.0
	Crab, stir-fried	3	3	3 – 10	3	2.5 – 6.0
	Salted fish, steamed	3	3	9 – 21	3	3.0 – 3.5
	Fish ball	3	0	-	0	-
	Octopus ball	3	0	-	0	-
	Marinated octopus / cuttlefish / squid	3	0	-	0	-
	Other octopus / cuttlefish, squid, cooked	3	0	-	0	-
Meat, poultry and their products	Pork, shredded, steamed	3	0	-	0	-
	Pork, shredded, stir-fried	3	3	6 – 9	0	-
	Pork, minced, steamed	3	0	-	0	-
	Pork, minced, stir-fried	3	3	9 – 15	0	-
	Beef, shredded, steamed	3	3	5 – 9	0	-
	Beef, shredded, stir-fried	3	3	9 – 32	0	-
	Beef, minced, steamed	3	1	< LOD – 4	0	-
	Beef, minced, stir-fried	3	3	9 – 14	0	-
	Chicken, steamed	3	0	-	0	-
	Chicken, stir-fried	3	3	4	0	-
	Barbequed pork	3	3	6 – 28	0	-
	Roasted pork	3	3	6 – 19	3	9.0 – 9.5
	Roasted duck / goose	3	2	< LOD – 7	0	-
	Marinated duck / goose	3	3	11 – 14	0	-
	Pork liver, cooked	3	2	< LOD – 14	0	-
	Other pig's offal, cooked	3	0	-	0	-
	Marinated beef tripe	3	0	-	0	-
	Marinated beef lights	3	0	-	0	-
	Marinated beef milt	3	0	-	0	-
	Marinated beef intestine	3	0	-	0	-
	Pork ball	3	0	-	0	-
	Beef ball	3	3	4 – 6	0	-
	Luncheon meat	3	2	< LOD – 9	0	-

Food Group	Food Item	Number of Samples	3-MCPD (μg/kg)		1,3-DCP (μg/kg)	
			Number of detects	Range	Number of detects	Range
	Ham	3	2	0 – 22	0	-
	Sausage	3	0	-	3	4.5 – 5.0
	Big red sausage	3	1	0 – 27	0	-
	Chinese sausage	3	0	-	0	-
	Liver sausage	3	3	5 – 10	0	-
	Preserved pork	3	3	9 – 15	0	-
Egg and their products	Egg white, steamed	3	0	-	0	-
	Egg white, fried	3	0	-	0	-
	Egg yolk, steamed	3	0	-	0	-
	Egg yolk, fried	3	0	-	0	-
	Limed duck egg	3	0	-	0	-
	Salted duck egg	3	0	-	0	-
Dairy products	Milk	3	0	-	0	-
	Cheese	3	0	-	0	-
	Yoghurt	3	0	-	0	-
	Ice-cream	3	0	-	0	-
Snack	Potato chips	3	3	6 – 11	0	-
	Prawn crackers	3	3	25 – 33	0	-
	Seaweed, ready-to-eat	3	3	50 – 66	0	-
	Peanuts	3	0	-	0	-
	Chocolate	3	0	-	0	-
	Hard candy	3	0	-	0	-
	Kumquat	3	0	-	0	-
	Orange peel	3	0	-	0	-

LODs for 3-MCPD and 1,3-DCP were 2.5 μg/kg (ppb) and 0.5 μg/kg (ppb) respectively.