codex alimentarius commission

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
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DISCUSSION PAPER ON CHLOROPROPANOLS DERIVED FROM THE MANUFACTURE OF ACID-HVP AND THE HEAT PROCESSING OF FOODS

Governments and international organizations are invited to submit comments on the following subject matters no later than 25 March 2007, preferably in electronic format, for the attention of Ms. Tanja Åkesson, the Netherlands Secretariat of the Codex Committee on Contaminants in Foods, Fax No.:+31 70 3786141; E-mail:info@codexalimentarius.nl with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Fax +39.06.5705.4593; E-mail: Codex@fao.org).

BACKGROUND

1. The Codex Committee on Food Additives and Contaminants (CCFAC), at its 38th Session (ALINORM 06/29/12, para.176), agreed to establish an electronic working group for updating the discussion paper contained in CX/FAC 06/38/33[48]. The electronic working group led by the United Kingdom prepared this discussion paper in view of the results of the JECFA evaluation and other information relevant for discussion on the maximum levels, for circulation, comments and discussion at the First Session of the Codex Committee on Contaminants in Foods. The electronic working group includes Australia, Canada, China, European Community, Indonesia, Japan, Philippines, Poland, Republic of Korea, Thailand, United States, AIIBP, ICGMA, and IHPC.

2. The electronic working group, during the preparation of this discussion paper, changed the title to "Discussion paper on chloropropanols derived from the manufacture of acid-HVP and the heat processing of foods", in order to reflect the fact that 3-MCPD, 1,3-DCP and 2-3,DCP were discussed as well the different routes to formation of these chloropropanols. As agreed by the CCFAC, at its 38th session, the Committee is invited to reconsider the proposed draft maximum levels for 3-MCPD in liquid condiments containing acid-Hydrolyzed Vegetable Proteins (acid-HVPs) (excluding naturally fermented soy sauce) in the light of this revised discussion paper.

3. 3-MCPD is a member of the family of related compounds known as chloropropanols. 3-MCPD is also known as chlorohydrin, glycerol chlorohydrin, 3-chloropropan-1,2-diol and 1-chloropropane-2,3-dihydroxypropane.[8]

4. 3-MCPD (3-monochloropropane-1,2-diol) was originally identified as a contaminant of the savoury ingredient acid-HVP[1], which is produced by treating proteins from vegetables, such as soya beans with hydrochloric acid. As a result of the widespread use of acid-HVP, 3-MCPD has now been identified in many other foods and food ingredients, most notably soy sauce.[9,10,11,12,14,15,16,17]

5. The presence of 3-MCPD in soy sauce derived from acid-HVP appears to originate from contaminated acid-HVP, added at levels of up to 20 % as an ingredient[47], or the use of *in situ* acid hydrolysis during the manufacturing process.[29]

6. 3-MCPD can also form when food, such as cereal products, is heat-treated, such as by baking, roasting or toasting.[36] These foods do not use acid-HVP or products thereof as an ingredient and a separate mechanism of formation of 3-MCPD has only recently been proposed. As a result of certain processing or storage conditions, many foods contain low levels of 3-MCPD and other chloropropanols.[5]

7. A validated gas chromatography-mass spectrometry method (GC-MS) capable of measuring 3-MCPD in food and food ingredients at levels down to 0.01 mg/kg is available. This method has been accepted as a first action status method by AOAC International.[18]

3-MCPD

Toxicology

8. The available toxicology, mutagenicity and carcinogenicity data for 3-MCPD has been summarised previously by JECFA in 2001.[29]

9. JECFA also noted reports that fatty acid esters of 3-MCPD had been identified in a range of processed and unprocessed foods and that only a limited number of analyses have been reported but the amount of esterified 3-MCPD in many of the samples was higher than the amount of free (non-esterified) monochloropropanol in the same samples. There were insufficient data to enable either their intake or toxicological significance to be evaluated. It was recommended that studies be undertaken to determine the toxicological significance of esterified 3-MCPD

Risk assessment

10. The 57th Session of JECFA considered 3-MCPD and 1,3-DCP (1,3-dichloro-2-propanol), in June 2001.[29] The Committee assigned a provisional maximum tolerable daily intake (PMTDI) for 3-MCPD of 2 μg/kg bw on the basis of the lowest observed effect level (LOEL) and a safety factor of 500. The safety factor included a factor of 5 for extrapolation from a LOEL to a NOEL.

11. The 67th Session of JECFA held in June 2006 re-evaluated 3-MCPD. The committee retained the PMTDI of 2 μg/kg bw due to there being no new pivotal toxicological studies available since the last evaluation[80]. ECFA also noted that the reduction in the concentration of 3-MCPD in soy sauce and related products made with acid-HVP could substantially reduce the intake of this contaminant by certain consumers of this condiment[80].

1,3-DCP

Toxicology

12. The available toxicology, mutagenicity and carcinogenicity data for 1,3-DCP has been summarised previously by JECFA in 2001.[29]
The 67th Session of JECFA reviewed two new *in vivo* genotoxicity studies. A rat bone marrow micronucleus test and a rat liver UDS assay were reported and both yielded negative results. As toxicity was not demonstrated in these tissues the level of exposure was unclear.

13. JECFA concluded that the critical effect of 1,3-DCP is carcinogenicity. The Committee also concurred that it was not possible to exclude a genotoxic mechanism for the tumours arising in the two-year carcinogenicity study due to limitations in the new *in vivo* genotoxicity studies.[22] Benchmark Dose i.e BMDL analysis was performed on data from the two-year carcinogenicity study and, based on the margins of exposure, the Committee concluded that the estimated intakes of 1,3-DCP were of low concern for human health.

Risk assessment

14. The 57th Session of JECFA concluded that 1,3-DCP was hepatotoxic, induced a variety of tumours in various organs in the rat, and was genotoxic *in vitro*. In 2001, JECFA considered it inappropriate to set a tolerable intake on the basis of; the significant increases in incidence of both benign and malignant neoplasms in at least three independent tissues and; the unequivocal evidence that 1,3-DCP interacts with chromosomes or DNA in bacterial or *in vitro* mammalian systems.[29]

15. Soy sauces that contain high levels of 3-MCPD can also contain 1,3-DCP.[13,16,17] In the data collated in the EC Scientific Co-operation (SCOOP) task,[42] 282 soy sauce samples were analysed for both 3-MCPD and 1,3-DCP. Approximately 20% of these samples contained quantifiable levels of both 3-MCPD and 1,3-DCP. None of the samples contained 1,3-DCP in the absence of 3-MCPD. Levels of 1,3-DCP were always lower than those for 3-MCPD in the same sample. The EC SCOOP report considered that the ratio of 3-MCPD to 1,3-DCP concentration was not consistent and no correlation could be proposed. JECFA reviewed the available data in its 2006 evaluation and concluded that there appears to be a linear relationship between the concentrations of 1,3-DCP and 3-MCPD (although the data to support this was limited) but this was not demonstrated at low concentrations. JECFA concluded that additional occurrence data is needed to confirm any type of relationship between the concentrations of 3-MCPD and 1,3-DCP.

16. Data from a United States survey of chloropropanols in soy sauces and related products carried out in 2003,[47] suggest that soy sauce and related products with 3-mcpd levels of greater than 10 mg/kg could be suspected to contain 1,3-DCP levels ranging from approximately 0.250 to 10 mg/kg. The ratios of 3-MCPD to 1,3-DCP concentrations varied, indicating no close correlation between 3-mcpd and 1,3-DCP (r^2 = 0.7346); however, some apparent trends are evident. Many of the soy sauces and related products manufactured in Asia contained very high 3-MCPD and 1,3-DCP levels. In contrast similar products manufactured in the USA contained low or undetectable 3-MCPD and 1,3-DCP levels.

17. In its 2006 evaluation, JECFA concluded that the available evidence suggests that 1,3-DCP occurs at lower levels than 3-MCPD in soy sauce and related products and also in acid-HVP food ingredients but not in meat products where levels of 1,3-DCP are generally higher than the levels of 3-MCPD.[80]

18. JECFA concluded that based on national estimates, an intake of 0.051μg/kg bw per day of 1,3-DCP could be taken to represent the average for the general population and 0.136 μg/kg bw per day to represent high consumers which includes young children. Comparison of these means and high level intakes with the lowest $BMDL_{10}$ of 3.3 mg/kg bw per day, which was the $BMDL_{10}$ for incidence data on tumour bearing animals for all treatment-affected locations, indicates margins of exposure of approximately 65000 and 24000 respectively. Based on these margins of exposure JECFA concluded that the estimated intake of 1,3-DCP were of low concern for human health

2,3-DCP

Toxicology

19. In 2001 and 2004 the UK Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM), considered the available mutagenicity data on 2,3-DCP[84,85]. The data included noted three positive in vitro assays and two in vivo studies performed to OECD guidelines; a rat bone-marrow micronucleus test and a rat liver unscheduled DNA synthesis assay. The Committee considered the in vivo studies to be negative and therefore provided evidence that 2,3-DCP is not an in vivo mutagen [85].

20. There is a lack of toxicokinetic and general toxicity data for this compound. The US Environmental Protection Agency (EPA) IRIS datasheet No. 0465, mentions a rat oral sub-chronic study, conducted by the EPA in 1989, which found Myocardial degeneration, hepatotoxicity and nephrotoxicity with a NOAEL of 10 mg/kg bw/day.[86] Omura et al. (1995), reported that 2,3-DCP is more toxic than 1,3-DCP to the testes and kidneys, though it is less hepatotoxic. [87]

ROUTES OF FORMATION OF 3-MCPD

1) Acid hydrolysis

21. Commercially, hydrolysis is carried out using 4-6M hydrochloric acid at 100°C-130°C for 4-24 hours, followed by neutralisation with sodium hydroxide.[27] 3-MCPD is formed during this process from the reaction of the acid with residual vegetable oil. Hydrochloric acid and triacylglycerols and to a smaller extent, phospholipids and glycerol, in the raw materials are the main precursors of chloropropanols.[2,4] The raw materials include soybean flour, soyabean meal, wheat, (including wheat gluten), maize, rapeseed (canola) meal and potato.[27,4]

2) Heat processing (not originating from HVP)

22. 3-MCPD also occurs in the absence of acid-HVP. It appears to form from lipids and sodium chloride, (present naturally or added), during normal manufacturing and cooking processes, such as baking and grilling. Phospholipids or glycerol are thought to be the major precursors of 3-MCPD in foods such as bread, bakery wares, and malt. The moisture content of food influences the process, since glycerol appears to be the major precursor in foods with a low water content (<15%), and other precursors, such as lecithin, for foods with a higher water contents. Mono or di-esters of fatty acids of 3-MCPD can also be present, which might provide an additional source of 3-MCPD.[5]

23. The amount of glycerol available for conversion to 3-MCPD is dependent on the raw ingredients and conditions prior to processing. For example, components of barley or wheat grains are sufficient to promote 3-MCPD synthesis. However, the glycerol content of dough is dependent on the age of the flour (fresh or stored), the amount of yeast added and the proof time.[5] When bread is toasted, high temperatures act directly on the large bread surface, which allow for high temperature hydrolysis of triglycerides. The resulting glycerol is a precursor for 3-MCPD formation.[65]

24. The major factors affecting 3-MCPD formation are temperature and pH. 3-MCPD is formed at temperatures above 170^{o}C and is unstable above pH 6.0. Indeed, sodium bicarbonate, amongst other factors, appears to inhibit the formation, or accelerate the degradation, of 3-MCPD in model systems.[5] But, it should be noted that increasing the pH in model breads, whilst reducing the 3-MCPD concentration, resulted in an increase in acrylamide.[6]

25. Additives can also contribute to the 3-MCPD level. For example, the addition of the flour improver, diacetyltartaric and fatty acid esters of glycerol (DATEM), to dough, can increase the amount of 3-MCPD in the final product. [5]

3) Fatty Acid Esters of 3-MCPD (bound 3-MCPD)

26. These esters represent a new source of 3-MCPD in foods, as 3-MCPD could be released from them *in vivo,* by lipase catalysed hydrolysis reaction.[71] Research carried out in the Czech Republic shows that 3-MCPD occurs in foodstuffs both in its free form and in the form of fatty acids esters. Fatty acid esters of 3-MCPD were first identified in model mixtures of hydrochloric acid with triacylglycerols, phospholipids, soybean oil and lipids isolated from soybean meal and wheat gluten.[70] They are also known to occur in foods where hydrogenated/refined vegetable oils are used in their manufacture. As with 3-MCPD, they occur in foods processed at high temperatures , having low water content , high levels of sodium chloride and stored for long periods.[71]

27. In studies carried out on bread, significant levels of 3-MCPD were released from bread treated with bakery grade lipase. 3-MCPD is released from the bound form by hydrolysis of the esters by these enzymes during the baking process. Lipases have also been found to be responsible for the generation of 3-MCPD in baked cereal products especially in white bread and its crust.[66].

28. Analysis of 20 samples of selected retail products (Table 1) showed all samples contained free 3-MCPD in the range 9.6 – 82.7 μg/kg food[71].

Table 1: Levels of free and bound 3-MCPD in foodstuffs[66],[71]

Foodstuff	Free 3-MCPD µg/kg	Bound 3-MCPD mg/kg fat	Bound3-MCPD mg/kg
Pickled Olives	13.93	< 3.30	< 0.28
Roated Coffee	16.15	< 3.30	< 0.33
Roasted Peanuts-	22.10	nd	Nd
Light malt (pilsner type)	9.55	< 3.30	< 0.05
Dark malt	27.90	36.51	0.58
Crisp bread	11.05	6.31	0.42
Salty crackers	10.72	12.52	0.14
Doughnuts	16.58	3.95	1.21
Potato crisps	14.48	< 3.30	< 1.21
French fries	15.41	36.77	6.10
Soft salami	14.03	< 3.30	< 0.93
Fermented salami	47.63	< 3.30	< 1.49
Smoked ham	23.18	< 3.30	< 1.62
Bologna ham	26.24	nd	nd
Grilled chicken	26.04	< 3.30	< 0.43
Smoked mackerel	18.62	< 3.30	< 0.53
Pickled herring	28.19	3.57	0.28
Parmesan cheese	82.67	nd	nd
Processed cheese	29.83	< 3.30	< 0.77
Feta cheese	12.98	< 3.30	< 0.58
Roasted ground coffee	<0.009 – 16.1	1.7 – 3.0	0.21 – 0.39
Roasted Instant Coffee (soluble)	<0.009 – 18.5	2.7 – 5.2	0.006
Roasted Green Coffee	10.1 – 18.2	<0.009* – 1.9	<0.009* – 0.22
Green Coffee	<0.003* <0.009*	<0.003*	<0.003*

Nd= not detected i.e below LOD <3.30 mg/kg fat = below LOQ

** for coffee <0.003mg/kg = nd i.e below LOD, <0.009mg/kg = trace levels i.e below LOQ*

4) **Epichlorohydrin**

29. 3-MCPD can migrate from certain types of epichlorohydrin-based wet strength resins used in paper and cellulose casings, for example sausage casings, tea bags and coffee filter paper. European Commission Directive 2002/72/EC came into force in 2002 as an international measure to minimise exposure to 3-MCPD from this source and sets a limit maximum permitted quantity of the 'residual' epichlorohydrin in the finished material of 1 mg/kg[3], so 3-MCPD present in food from contact with casings or wrappings should be minimal in foods produced in the EU.

OCCURRENCE OF CHLOROPROPANOLS IN HEAT PROCESSED FOODS

Cereal products

Bread and bakery wares

30. 3-MCPD can be detected in breads and other cereal products. Savoury biscuits appear to account for some of the highest levels of 3-MCPD reported, followed by doughnuts, bread and sweet biscuits.[36] 3-MCPD has also been measured at levels of up to 0.2 mg/kg in cake.[42]

31. Recent research funded by the UK Food Standards Agency has reported the formation of up to 0.1 mg/kg 3-MCPD in bread.[63] An investigation of toasted bread revealed that up to 1 mg/kg of 3-MCPD is formed in toast.[30] Indeed, for foods, excluding soy sauces and acid-HVPs, toasted bread had the highest mean level of 3-MCPD.[31]

32. 3-MCPD has also been reported in commercial breadcrumbs for coating at 0.014 mg/kg[42]. Crust of white bread has been found to have high levels of 3-MCPD at 0.48 mg/kg[75].

33. Dough ingredients have been found to influence the level of 3-MCPD in bread. Addition of fat (1% in relation to flour) was found to increase the level of 3-MCPD in bread although higher fat content (2-5%) did not have any additional effect.[30]

34. Commercially used baking agents contain a range of ingredients and have been found to be crucial for promoting the formation of 3-MCPD. When commercial baking agents are used in the preparation of dough, the sucrose content apparently has the largest contribution to 3-MCPD formation.[30] It is therefore feasible for manufacturers to influence 3-MCPD formation in bread by varying the baking agent used.

35. The addition of yeast to dough and length of proofing is also known to enhance the production of 3-MCPD during baking of the bread. Products made with old or more rancid flour will have more 3-MCPD. In leavened cereal products, glycerol is formed as a by-product of yeast fermentation and it is this that reacts with chloride ions from added cooking salt to generate 3-MCPD during baking[63] Studies have shown 3-MCPD levels to increase with increase in proof time in yeasted dough.[66]

Malt

36. 3-MCPD has been detected in malts, malt flours and malt extracts.[10,11] Concentrations of up to 0.8 mg/kg have been recorded for malt.[42.] 3-MCPD has been found in roasted cereals and dark speciality malts which are used to impart colour and flavour to most dark beers and some lagers. The concentration of 3-MCPD has been found to parallel the degree of roasting given to the barley with the darker malts having the greatest concentration.[67]

Batter

37. Frying laboratory-produced batters can generate up to 0.1 mg/kg 3-MCPD, but the few commercial batters tested did not appear to contain detectable 3-MCPD when fried.[7,42] But, some battered products can contain 3-MCPD since 0.009 mg/kg 3-MCPD has been reported in a sample of battered and fried fish fillets.[42]

Meat and fish

38. There is no evidence for direct 3-MCPD formation during salami manufacture, but salami can also contain high concentrations of 3-MCPD esters, a potential source of 3-MCPD.[5] However, 3-MCPD levels of up to 29 mg/kg have been reported for salami samples[66]. This may have originated from acid HVP which although not identified as a food ingredient may still have been present in the salami. Salami fat was found to contain significant amounts of esterified 3-MCPD although no evidence could be found to show that the action of lipases present in the spices, bacterial culture and endogenous to the meat were responsible for the increase in free 3-MCPD during storage.[66]

39. The 3-MCPD content of smoked fish increases with the length of time the product is smoked although there is no similar correlation for smoked bacon. In kippers, an increase in the concentration of the brine used for curing led to an increase in the 3-MCPD content of the product.[5]

40. In products such as salted bacon, 3-MCPD levels increased on cooking. In low temperature salted products such as anchovies the evidence suggests that fish visceral enzymes have a part to play, either in releasing 3-MCPD from esters or in the direct synthesis of 3-MCPD from glycerol/glycerides.[5]

41. Low concentrations of 3-MCPD and 1-3-DCP have been detected in cooked minced beef, ham and sausages. But 1,3-DCP has also been detected in raw minced beef, ham and sausage meat, in the absence of 3-MCPD.[8] This suggests that there must be more than one route of formation of 1-3-DCP. The mechanism for this formation has not been identified.[44]

Cheese

42. 3-MCPD has been detected in some samples of processed cheese, cheese alternatives, Feta and Parmesan. Some cheeses were also shown to contain significant amounts of 3-MCPD esters.[5] In some cases this might be due to the migration of 3-MCPD from paper and cellulose casings.

43. Grilling and toasting produced substantial increases in the 3-MCPD content of some cheeses, resulting in levels of up to about 0.1 mg/kg. Microwave cooking can also produce elevated 3-MCPD levels in some cheeses.[7]

44. Table 2 contains a list of products and ingredients identified as containing 3-MCPD.[42] These products do not appear to contain acid-HVP and therefore the 3-MCPD is thought to originate from another source. Maximum levels recorded in these products have been included.

Smoked Foods

45. It was discovered in a recent study carried out in Germany, that smoked sausages and hams manufactured using fresh smoke contain high levels of 3-MCPD.[73] However the level of 3-MCPD found is dependent on the type of wood used and the length of time in the smoking chamber. Peppered sausages smoked at 28ºC were found to contain 3-MCPD at 0.133 mg/kg. A sample scraped from the wall of the smoking chamber contained 3-MCPD at 18 times (i.e 2.455mg/kg), the level found in the smoked sausages.[73] Liquid smoke flavourings used in smoked sausage manufacture, were also found to be high in 3-MCPD. The results for 6 commercially available preparations, showed 3-MCPD levels ranging from 0.2 to 0.76 mg/kg. Further work is required in this area to assess the influence of parameters mentioned above on 3-MCPD generation in smoked food products.

46. In another study a number of smoked foods i.e cheeses, meat, barbecue sauce were found to contain 3-MCPD. Levels ranged from <0.002 - 0.02mg/kg.[66] Cooked bacon samples were found to contain more 3-MCPD than the uncooked samples. Levels in the cooked samples ranged from 0.01 - 0.05mg/kg. [66]

Roasted Coffee

47. 3-MCPD has been found in roasted coffee at a level of 0.01 - 0.018 mg/kg. The highest level was found in a sample of instant coffee and in products where the roasting had been prolonged for a period of time. Green coffees contained only traces of free 3-MCPD. The final colour of the roasted coffee beans is directly linked to the 3-MCPD formation, the darker beans having the greatest concentration. The level of bound 3-MCPD varied between 6 µg/kg (soluble coffees) and 0.390 mg/kg (decaffeinated coffee) and exceeded the free 3-MCPD level between 8 and 33 times[68]. Chloride from salt and lipids (precursors of 3-MCPD) naturally present in coffee beans are responsible for 3-MCPD formation during the roasting process.

Table 2: Products found to contain 3-MCPD that does not originate from acid-HVP

	Codex Food Grouping	Range of 3-MCPD (quantifiable, mg/kg)	Number in Sample	Number quantifiable
1.6	Cheese	0.02 - 0.1	123	12
2.2	Fat emulsions mainly of type water in oil (comprises spreads, butters, margarine)	0.006 - 0.01	12	1
5.2	Sugar based Confectionery including hard and soft candy, nougats etc	0.020 - 0.023	15	2
6.2	Flours and Starch	0.014 - 0.029	11	4
6.3	Breakfast Cereals	0.07	45	1
6.4	Pasta and Noodles	0.003 – 0.023	6	5
7.1.1	Breads & Rolls	0.001 - 0.57	975	533
7.1.2	Crackers excluding sweet crackers	0.01 - 0.26	169	115
7.1.3	Baked Cereal Products	0.011 - 0.11	59	40
7.1.4	Bread Type Products, including Bread stuffing and bread crumbs	0.01 - 0.15	20	8
7.2.3	Other fine baked products including doughnuts, scones and muffins	0.01 - 0.11	98	44
7.2.1	Cakes, cookies and pies (eg fruit filled or custard type)	0.003 - 0.21	107	33
7.2.2	Biscuits	0.01 - 0.28	460	196
8.1	Fresh meat, in whole pieces or cuts or comminuted	0.006 – 1.9	106	19
8.2	Processed meat in whole pieces or cuts	0.003 - 0.10	130	47
	Smoked meat products	0.009 - 0.13	34	30
	Salami	0.011 – 29	27	16
8.3	Comminuted processed meat	0.003 – 1.8	176	72
21	Meat Extract	0.014 - 0.55	16	5
9.1	Fresh Fish	0.003 – 0.033	12	12
9.3	Semi Preserved Fish	0.009 – 0.021	3	3
9.4	Fully preserved fish and fish products, including molluscs, crustaceans, and echinoderms	0.012 - 0.19	18	8
13.3,13.4,13.5	Dietetic Foods and Formulae	0.01 - 0.41	33	14
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	0.01 – 0.38	58	27
14.2.1	Beer & Malt Beverages	0.003 - 0.02	104	8
15.1	Snacks including potato chips	0.006 – 0.04	66	13
22.2	Malt extract	0.005 - 0.85	31	17
23	Modified Starched Dextrins	0.012 - 0.49	9	2
26 Includes	Other ingredients Flavourings	0.019 - 0.025 0.025	11 2	2 1
16 Includes	Composite foods Pizza	0.004 - 0.11 0.004 - 0.09	134 83	57 31

OCCURRENCE OF 3-MCPD IN ACID-HVP CONTAINING FOODS

Acid-HVP

48. Hydrolysed vegetable protein is a savoury flavouring product. It is produced by the hydrolysis of protein sources such as soybean flour, wheat or maize. Traditionally the hydrolysis is carried out using an acid, often hydrochloric acid.[27] Acid HVP is a widely used ingredient of foods such as soy sauces, soups, prepared meals, savoury snacks, gravy mixes and instant noodles.

49. In a survey also carried out in China of 45 samples of instant noodles, 3-MCPD was detected in 36 samples. The levels ranges from 0.004 - 3.61 mg/kg, 3 samples had levels exceeding 1 mg/kg. 1, 3-DCP and 2,3-DCP were not found in any of the samples[69]

Soy sauce

50. Soy sauce can be manufactured by a range of processes, including traditional fermentation and processes which involve the use of an acid treatment or include acid-HVP as an ingredient. It is known that such acid treatments can generate chloropropanols, unless the processing conditions are well controlled.

51. Soy sauces which are traditionally fermented are unlikely to contain 3-MCPD,[29] although the addition of 3-MCPD containing ingredients such as acid-HVP can give rise to the presence of 3-MCPD in products described as fermented, if labeling legislation of the country concerned allows the use of such terms.

52. Several countries world-wide have identified that there are many liquid seasoning condiments similar to soy sauce (such as fish sauce, oyster sauce, mushroom sauce, meat seasoning sauces etc.) which can contain 3-MCPD and other chloropropanols, either as a result of processing or from the use of processed ingredients.[42]

53. Japan has provided information on soy sauce production. Data on soy sauce made with acid-HVPs were compared with soy sauce made from traditional fermentation and the data demonstrated that very low levels occurred in traditionally fermented soy sauce with levels ranging from <0.004 – 0.008mg/kg, whereas soy sauce made with acid-HVP had levels ranging from <0.004 – 7.8mg/kg.[82]

54. In the data collated by JECFA in 2001, 3-MCPD had been detected at concentrations in excess of 1 mg/kg in acid-HVP and soy sauces. In acid HVP and soy sauces a range of concentrations has been reported, from below the limit of quantification (0.01 mg/kg) up to 100 mg/kg in some samples of acid-HVP and more than 300 mg/kg in some samples of soy sauce.[29]

55. In Canada a nationwide investigation of 3-MCPD in various soy, mushroom and oyster-flavoured sauces is being conducted**.** In 2004-2005, 45 samples of imported soy sauces were analyzed for 3-MCPD and for 1,3-DCP. The samples comprised soy sauces marketed as plain, vegetarian, seasoning, oyster, mushroom, light or dark. 3-MCPD was not detected in 33 of the samples. In a further 3 samples, the level of 3-MCPD (range 0.02 to 0.63 mg/kg), was above the detection limit but below the current maximum level in Canada, i.e. 1 mg/kg.[81] At such levels of 3-MCPD the chloropropanol 1,3-DCP was not detected.

56. Nine samples from the Canadian survey[81] contained 3-MCPD above 1 mg/kg, the values ranged from 2.97 to 812 mg/kg (mean, 194.25 mg/kg). Eight of these also contained with 1,3-DCP and, in two cases, some very high values for 1,3-DCP were noted. As indicated previously, 1,3-DCP was not detected (LOD = 5 ppb) in any of the samples containing less than 1 mg 3-MCPD/kg (on a liquid basis). The country of origin was a more consistent factor in observations of contaminated sauces than were other variables such as the type of sauce examined or whether or not the sauce was fermented.

57. In a survey of 103 soy sauces carried out in China, 42 samples had no 3-MCPD i.e below the LOD of 0.006 mg/kg, 23 had levels of 3-MCPD ranging from 0.001 – 0.020 mg/kg and 17 samples had levels of 3-MCPD in excess of 1 mg/kg. 2-MCPD was detected at levels between 0.01 – 1.93 mg/kg (with 8 samples exceeding 1 mg/kg). 1,3-DCP and 2,3-DCP were detected in 6 samples at concentrations between 0.004 and 0.21 mg/kg. In addition to soy sauce, the flavouring sauce of instant noodles is one of the major intake sources of chloropropanols in Asia.[69]

58. In a survey of 13 soy sauces and 4 acid-HVP samples again carried out in China, 3-MCPD was found in 11 of the soy sauce samples at levels ranging from 0.078 – 4.68 mg/kg, and in all of the acid-HVP samples at levels between 0.17 and 27.500 mg/kg.[72]

59. Table 3 contains a list of products identified as containing quantifiable levels of 3-MCPD. This 3-MCPD probably originates from acid-HVP in the product, which has been added or generated *in situ*.

Table 3: Products containing acid-hydrolysed vegetable protein

	Codex Food Grouping	**Range of 3-MCPD (quantifiable, mg/kg)**	**Number in Sample**	**Number quantifiable**
	2.3. – Fat emulsions other than 2.2.	0.006 - 1.5	19	12
Includes	Instant noodle oil	0.013 - 1.5	19	12
	4.2.2.2. – Dried vegetables	0.011 - 0.69	33	28
Includes	Garlic – agglutinated	0.020 - 0.69	6	6
	Granulated garlic	0.024 - 0.34	5	5
	Garlic powder	0.028 - 0.03	2	2
	Granulated onion	0.016 - 0.02	2	2
	6.4. – Pasta and noodles and like products	0.011 - 300	157	52
Includes	Instant noodles (not noodle soups)	0.011 - 300	157	52
	Noodles[69]	.004 – 3.610	45	36
	12.2. – Herbs, spices, seasonings and condiments	0.002 - 8.5	252	184
Includes	Spice mixture (inc. pork) (where data available).	0.01 - 8.5	11	5
	Instant noodle seasoning (where data available).	0.01 - 5.3	185	143
	Dried stock (where data available).	0.01 - 0.45	11	7
	12.5.2. – Mixes for soups and broths	0.002 - 0.20	87	47
	12. 6.2. – Emulsified sauces	0.01 - 51	108	5
	12.6.3. – Mixes for sauces and gravies	0.012 - 0.44	40	13
Includes	Soy sauce powder	0.088 - 0.44	2	2
	Curry sauce powder	0.04	1	1
	Gravy powder	0.01	1	1
	12.6.4. – Soy sauce/soy sauce based products (where data available).	0.001 - 1779	3368	1169
	Soy sauce[69]	0.01 – 0.020 >0.02	103	23 38
	Soy sauce[74]	0.01 – 17.0	316	44
	Soy Sauce[72]	0.078 – 4.68 (µg/kg)	13	11
	12.6.4.1. – Emulsified sauces	0.017 - 2.0	22	5
Includes	Chicken marinade	0.017 - 2.0	6	3
	12.6.4.2. – Dark soy sauce	0.013 - 112	215	59
	12.6.4.4. – Light soy sauce	0.011 - 1779	238	88
	12.6.4.6. - Mushroom soy sauce	0.013 - 108	175	104
	12.6.4.7. - Oyster sauce	0.003 - 8.8	153	36
	Oyster Sauce[74]	0.02 – 0.1	102	18
	12.6.4.8. – Raw fish soy sauce	0.018 - 0.46	18	9
	12.6.4.11. – Seasoning sauce	0.011 - 940	87	37
	12.6.4.12. – Shrimp flavour soy sauce	0.025 - 20	8	4
	12.6.4.13 – Soy sauce	0.001 - 1015	1125	434
Includes	Schweinfleisch sauce	79	1	1
	12.6.4.15 – Teriyaki sauce	51	15	1
	12.6.4.16. – Thick soy sauce	0.02 - 19	30	3
	12.6.4.17. –Thin soy sauce	0.011 - 11	37	8
	12.6.4.18 – Vegetarian oyster sauce	0.028 - 4.0	5	2
	12.6.(misc) – Sauces and like products (miscellaneous)	0.002 – 17	294	85
Includes	Grill oil (where data available).	0.093 - 0.16	8	4
	15.1 – Snacks including potato chips.	0.01 – 0.04	60	7
	16 – Composite foods	0.004 - 0.11	113	36
Includes	Meat free burger	0.011	2	1
	20.0. – HVPs	0.01 - 1.0	99	37

DIETARY EXPOSURE TO 3-MCPD

60. There have been many dietary exposure estimates to 3-MCPD. Some of these estimates take into account all dietary sources of 3-MCPD (i.e., foods that contain 3-MCPD as a result of thermal processing as well as those foods that contain acid-HVP derived 3-MCPD). A short account of these dietary exposure estimates now follows.

61. The SCOOP task 3.2.9,[42] carried out in Europe, reported upper bound mean 3-MCPD levels of 9.16 mg/kg for soy sauce and soy sauce related products, with the highest level reported being 1779 mg/kg. Data reported in the SCOOP task were collected from several European Member States. Each Member State also provided dietary exposure assessments, taking into account national consumption patterns, resulting in a range of estimated intakes. Dietary intakes were calculated as population estimates (the product of population consumption and occurrence levels. This type of estimate takes into account consumption of food across all the population and therefore takes into account those consumers that do not eat the foods in question) and as consumer estimates (where intake is calculated for only those members of the population that consume the foods in question). SCOOP task 3.2.9 reported population dietary exposure assessments in the range 0.5 – 1.4 µg/kg bw/day for high-level adult consumers (95th percentile) and 0.5 – 1.7 µg/kg bw/day for high-level children consumers (95th percentile), all of which are below the PMTDI. Consumer dietary exposure estimates from individual food groups were also less than the PMTDI, with the highest estimate being 1.1 µg/kg bw/day, for soy sauce and related products. Although intake of 3-MCPD amongst consumers was greatest from soy sauce for all countries, other foods such as bread, pasta, noodles and flavoured sauces or food to which sauces can be added, were found to contribute significantly to overall 3-MCPD intake

62. Food Standards Australia New Zealand (FSANZ) has also performed dietary exposure estimates.[76] Occurrence data taken from surveys conducted between 2001 and 2002 were fed into a deterministic model to estimate consumer dietary exposures from the whole diet. For a mean 3-MCPD level of 14.9 mg/kg in soy and oyster sauce, consumer dietary exposures for consumers specifically exposed to 3-MCPD from soy and oyster sauces were estimated as 7.0 and 8.1 µg/kg bw/day for high-level (95th percentile) consuming adults and children, respectively. These exposure levels are well in excess of the PMTDI. FSANZ also performed an exposure assessment with the level of 3-MCPD in soy and oyster sauces set at 0.2 mg/kg (the current FSANZ limit for 3-MCPD in liquid condiments containing acid-HVP); dietary exposure to 3-MCPD was shown to be significantly reduced, with consumer estimates for those specifically exposed to 3-MCPD through consumption of soy and oyster sauces having intakes of up to 5 % of the PMTDI (for high-level consuming adults) and consumer estimates of up to 7 % of the PMTDI (for high-level consuming children) from consumption of all foods.

63. During 2004 – 2005, Thailand conducted a deterministic estimate of dietary exposure combining consumption data from 1945 people with occurrence data.[77] The exposure estimate was only for consumption of soy sauce and related products. High-level (95th percentile) consumers were estimated to have intakes of 0.043 µg/kg bw/day. A second exposure assessment was made with the level of 3-MCPD in soy sauce and related products set at 1.0 mg/kg; the resulting high-level intake was found to be 0.32 µg/kg bw/day, equivalent to 16 % of the PMTDI.

64. The International Hydrolyzed Protein Council (IHPC) submitted a dietary exposure assessment to inform discussions at the 37th Session of CCFAC.[78] The IHPC assessment is based on the 2001 JECFA assessment.[29] Using Japanese consumption data for soy sauce, IHPC estimated that for 3-MCPD levels of 0.4 mg/kg in soy sauce and acid-HVP, Japanese consumers could be expected to have intakes of 26 µg/day for high-level consumers (estimated 90th percentile). This intake is equivalent to 0.4 µg/kg bw/day for a 60 kg adult, which represents 20 % of the PMTDI. It must be noted that this estimate only accounts for consumption of soy sauce and savoury foods made from acid-HVP. There will, of course, be additional intake of 3-MCPD from other dietary sources.

65. The Association Internationale des Industries de Bouillons et Potages (AIIBP) and the Federation des Associations de L'industrie des Bouillons et Potages de la CEE (FAIBP) also provided dietary exposure assessments to inform discussions at the 37th Session of CCFAC.[79] A rudimentary dietary exposure assessment was presented, using several stringent assumptions. Consumption data were estimated by assuming that 10 % of the European population consumes the volume of acid-HVP produced in Europe. This assumption led to estimation of a daily intake of acid-HVP of 2.17 g/day. Intakes of 3-MCPD were then estimated for different maximum levels of 3-MCPD in acid-HVP. For a maximum level of 1.0 mg/kg, adult consumers were estimated to be exposed to 0.031 µg/kg bw/day (for a 70 kg adult), while children were estimated to be exposed to 0.054 µg/kg bw/day (for a 40 kg child). Both of these estimates are well below the PMTDI. Again, it should be noted that this estimate does not take into account other dietary sources of 3-MCPD[79].

66. The Food and Veterinary Administration of Singapore conducted an exposure assessment to 3-MCPD using occurrence data collected during a national monitoring programme running from January 2000 until April 2002.[74] Consumption data for soy and oyster sauces were obtained from the Singapore National Nutrition Survey (1998). High-level adult consumers (95th percentile) were found to have intakes of 0.15 µg/kg bw/day (equivalent to 7.4 % of the PMTDI) for a mean 3-MCPD concentration in soy and oyster sauce of 0.45 mg/kg. A dietary exposure estimate was also calculated for a maximum 3-MCPD level in soy and oyster sauce of 0.02 mg/kg (the current Singapore National limit for 3-MCPD in soy sauce). The resulting high-level adult consumer intake was estimated at 0.66 µg/kg bw/day, equivalent to 0.3 % of the PMTDI[74]. Again, it should be noted that these estimates do not take into account other dietary sources of 3-MCPD.

67. The UK Food Standards Agency has conducted a detailed exposure assessment for 3-MCPD using occurrence data taken from SCOOP task 3.2.9 and other EU countries, as well as setting 3-MCPD levels in acid-HVP and soy sauce at different levels to assess the impact of proposed maximum levels. Consumption data were taken from the UK National Diet and Nutrition Surveys for adults, young children and school children and combined with occurrence data *via* the use of a deterministic model. Consumer dietary exposures were estimated for the total diet, including thermally generated sources of 3-MCPD, processed products containing acid-HVP as well as soy sauce and other sauces. Using mean occurrence levels for 3-MCPD, consumer dietary exposure estimates of 0.4 and 0.7 µg/kg bw/day were estimated for high-level (97.5th percentile) consuming adults and toddlers (0 – 4 years old), respectively. A number of different scenarios were also investigated for different possible maximum levels of 3-MCPD: 0.02, 0.1, 0.2, 0.3 and 0.4 mg/kg. Consumer dietary exposures when the level of 3-MCPD in acid-HVP was capped at 0.02 mg/kg were estimated as 0.1 and 0.2 µg/kg bw/day for high-level consuming adults and toddlers, respectively. At a maximum level of 0.02 mg/kg, the highest contribution to dietary exposure of 3-MCPD was found to be the consumption of bread. Consumer dietary exposures when the level of 3-MCPD in acid-HVP was capped at 0.4 mg/kg were estimated as 0.4 and 0.5 µg/kg bw/day for high-level consuming adults and children, respectively; these exposures are equivalent to 65 % and 72 % of the PMTDI. At a maximum level of 0.4 mg/kg, the highest contributor to dietary exposure for adults was found to be instant noodles for adults and soy sauce for children (both of which contain acid-HVP). The UK exposure assessments show that for levels of 3-MCPD in acid-HVP and soy sauce below 0.3 mg/kg, consumption of bread and bread rolls becomes the major dietary source of 3-MCPD. In this situation, intake of 3-MCPD is attributable to high-level consumption of a commodity that generally has a low level of contamination.

68. At its 67th session, JECFA considered recent occurrence data from a variety of sources and were able to calculate a mean level of *ca*. 8 mg/kg for 3-MCPD in soy sauce and related products. JECFA noted that the distribution of levels of 3-MCPD in soy sauce contains a number of highly contaminated samples; therefore, regular consumption of a specific brand or type of product could lead to intakes of 3-MCPD exceeding the PMTDI. Exposure estimates from several countries were considered. These estimates ranged from 0.06 to 2.3 µg/kg bw/day for high-level (95th percentile) consumers. The committee concluded that, for consumption of the whole diet, an intake of 0.7 µg/kg bw/day could be taken to represent the average intake for the general population, while an intake of 2.3 µg/kg bw/day could be taken to represent high-level consumers. When these estimates are expressed as a percentage of the PMTDI, estimated intakes ranged from 3 to 85 % for high-level consuming adults and up to 115 % for high-level consuming children. The committee concluded by stating that efforts should be made to reduce the intake of 3-MCPD through the consumption of soy sauce and related products.

69. The dietary exposure estimates detailed above, and the outcomes of the recent 67th session of JECFA, clearly indicate that a maximum level for 3-MCPD in acid-HVP and soy sauce is required. However, any level that is imposed must take into account dietary intake from all sources of the diet, which is not the case for many of the exposure estimates described here. Such a maximum level must also be proportionate: the recent evaluation by JECFA, stating that 3-MCPD is not genotoxic, should be taken into account. It can be technically difficult and expensive to produce acid-HVP with low levels of 3-MCPD especially for small and medium manufacturers but since the introduction of regulatory limits for acid HVP and soy sauce, mitigation strategies adopted by industry both in Europe and internationally, have led to a reduction in the levels of 3-MCPD in some foods. Any maximum level that is set for 3-MCPD in acid-HVP and soy sauce must ensure the protection of human health whilst taking into account the economic achievability of implementing very strict control measures.

A Codex standard for Soy sauce

70. The 28th session of the Codex Alimentarius Commission, recognised that there was no consensus to continue to work on a Codex Standard for Soy Sauce. The Commission noted that the scope and definition of the product varied widely across national legislations, that there were presently no major health risks associated with this product and that safety issues could be or were already being addressed in the relevant horizontal committees[83].

71. The Commission endorsed the recommendation of the Executive Committee[88,] to discontinue work on soy sauce within Codex, with the understanding that such decision would not prevent the Commission from revisiting this matter in the future and reconsider the amenability of the product for standardization, noting that consumers' protection from fraudulent practices should be one of the factors to be taken into account when reassessing the need for standardizing this product[83].

RECOMMENDATIONS

72. Further work to be done on the formation of 3-MCPD from its esters. The toxicological significance of these esters should also be investigated.

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