codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-eighth Session

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DISCUSSION PAPER ON ACID HVP CONTAINING PRODUCTS AND OTHER PRODUCTS CONTAINING CHLOROPROPANOLS

BACKGROUND

1. At the 37th Session of the Codex Committee on Food Additives and Contaminants (CCFAC), the committee agreed that an electronic working group led by the United Kingdom, with the assistance of Australia, Canada, China, European Community, Germany, Japan, Philippines, Republic of Korea, Thailand, United States and International Hydrolyzed Protein Council, (IHPC), would prepare an updated Discussion Paper on acid HVP containing products and other products containing chloropropanols.[48] The paper would define the acid-HVP containing products and collect information on other products that contain 3-monochloropropane-1,2-diol (3-MCPD). The committee also agreed to request the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to conduct an exposure assessment for chloropropanols from all sources.[49]

2. A maximum level for 3-MCPD was considered at the 37th Session for adoption at Step 3. After a lengthy discussion of various maximum levels, in an attempt to reach a compromise, the Committee agreed to use as a starting point a maximum level of 0.4 mg/kg for 3-MCPD in liquid condiments containing acid-HVP (excluding naturally fermented soya sauce).[50] Due to the need to better define the products for which maximum levels should be set, the Committee agreed that the discussion paper will define the different acid-HVP containing products and collect information on other products that contain 3-MCPD.[49]

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 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 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 summarized previously by JECFA in 2001.[29]

9. 3-MCPD has been investigated in short- and long-term toxicity studies. In rats and mice the kidney was the main target organ for toxicity. Reported effects in the kidney were focal tubule necrosis, regeneration, and tubule dilatation.[19] Effects on the male rat reproductive tract and fertility have also been reported for 3-MCPD, with male rats rendered infertile at oral doses of 5 mg/kg bw/day for 14 days.[20]

10. Studies have demonstrated that 3-MCPD has mutagenic activity *in vitro*.[54,55,56,57,58,59,66] However, JECFA considered the observations in bacterial studies used extremely high doses, which would not be recommended today for standard mutagenicity testing, and that the positive findings in tests with yeast and cultured mammalian cells were also compromised by conditions such as excessive doses, seriously detracting from their validity. Negative results have been reported from a bone marrow micronucleus assay in rats and a rat liver unscheduled DNA synthesis (UDS) assay.[61,62]

11. A two year rat carcinogenicity study found treatment via the drinking water was associated with dose-related increases in the incidence of hyperplasia and benign tumours in the kidney and malignant tumours of the mammary gland in males.[35] Interstitial-cell tumours of the testis were also observed with increased incidence in treated male rats. JECFA considered that this finding represents an equivocal finding since they are common, variable in incidence, and associated with old age in Fischer 344 rats. The renal hyperplasia was not associated with chronic progressive nephritis also observed in these animals, and was considered to represent a unique, treatment-related lesion and a precursor to tubule neoplasia.

12. No epidemiological or clinical studies in humans are available.[23]

Risk assessment

13. The 57th Session of JECFA considered 3-MCPD and 1,3-dichloro-2-propanol (1,3-DCP), 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 and was considered adequate to account for the effects on male fertility and for inadequacies in the reproductive toxicity data.

1,3-DCP

Toxicology

14. The available toxicology, mutagenicity and carcinogenicity data for 1,3-DCP has been summarised previously by JECFA in 2001.[32]

15. Hepatocellular necrosis, kidney tubule degeneration and erosion of the gastrointestinal tract mucosa has been reported following treatment of rats with 1,3-DCP, at 140 and 290 mg/kg bw by intraperitoneal injection.[21] 1,3-DCP has been shown to be mutagenic in bacterial and mammalian *in vitro* mutagenicity assays, and negative in the wing spot test in *Drosophila melanogaster* (a somatic mutation and recombination test). A 104-week carcinogenicity study in Wistar rats showed a carcinogenic effect of 1,3-DCP on the liver, kidney, oral epithelium and tongue, and thyroid gland, primarily at the highest doses tested (19 and 30 mg/kg bw/day for males and females, respectively). Hepatotoxic effects were evident at doses (2.1 and 3.4 mg/kg bw/day for males and females, respectively) below those producing a significant increase in combined hepatocellular adenoma and carcinoma (6.3 and 9.6 mg/kg bw/day for males and females, respectively).

16. Since the JECFA evaluation, two new *in vivo* genotoxicity studies, a rat bone marrow micronucleus test and a rat liver UDS assay, have been reported and both were negative.[22]

Risk assessment

17. 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]

18. The UK Committees on Mutagenicity (COM) and Carcinogenicity (COC) considered 1,3-DCP in 2003 and 2004, respectively, following the publication of results from *in vivo* rat bone marrow micronucleus and rat liver UDS tests. The COM concluded that 1,3-DCP is not genotoxic *in vivo* in the tested tissues. However, the COC concluded that 1,3-DCP should be regarded as a genotoxic carcinogen as it was not possible to exclude a genotoxic mechanism for the induction of tumours of rat tongue observed in the two-year carcinogenicity study.[24] The Committee also recommended that further investigation regarding the mechanisms of 1,3-DCP carcinogenicity *in vivo* is needed.

19. 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 Cooperation (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. No sample 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. The EC SCOOP findings appear not entirely consistent with those of JECFA which reviewed the available data and concluded in its report that the available evidence suggests 1,3-DCP "is associated with high concentrations of 3-chloro-1, 2-propanediol in food" and that "regulatory control of the latter would, therefore, obviate the need for specific controls on 1,3-dichloro-2-propanol".

20. Data from a United States survey of chloropropanols in soy sauces and related products[47] suggests 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.

21. 1,3-DCP was detected in the absence of 3-MCPD in a survey of retail meat products conducted in Australia and New Zealand, indicating that 1,3-DCP may be formed independently of 3-MCPD.[8] However, the UK did not find detectable quantities of 1,3-DCP in samples of retail meat products, either cooked or uncooked.

22. These findings indicate that control of 3-MCPD may not control 1,3-DCP formation and surveillance is needed to ensure that 1,3-DCP is kept at levels as low as reasonably achievable.

2,3-DCP

Toxicology

23. There are very few data on 2,3-dichloro-1-propanol. However, there are structural alerts for genotoxicity and carcinogenicity as 2,3-DCP could theoretically be metabolised to epichlorohydrin (and subsequently glycidol).

24. Limited *in vitro* mutagenicity data indicate that 2,3-DCP is genotoxic with and without metabolic activation in bacterial and mammalian cells. Recently published *in vivo* rat bone marrow micronucleus and rat liver UDS assays were negative.[22]

25. No appropriate carcinogenicity studies of 2,3-DCP are available.

Risk assessment

26. There are insufficient toxicity data available for 2,3-DCP with which to make a valid risk assessment.

27. JECFA has not considered 2,3-dichloro-1-propanol previously. However, the COM considered 2,3-DCP in May 2004 and concluded that it has no significant genotoxic potential *in vivo* in the tissues evaluated (i.e. bone marrow and liver in the rat).[25] The COC considered that no conclusions regarding carcinogenicity of 2,3-DCP could be reached.

ROUTES OF FORMATION OF 3-MCPD

1) Acid hydrolysis

28. 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)

29. 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 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]

30. 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]

31. The major factors affecting 3-MCPD formation are temperature and pH. 3-MCPD is formed at temperatures above 170°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]

32. 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) Epichlorohydrin

33. 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 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

34. 3-MCPD can be detected in breads and other cereal products. Savoury biscuits appear to account for 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]

35. 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 has the highest mean level of 3-MCPD.[31]

36. 3-MCPD has also been reported in commercial breadcrumbs for coating at 0.014 mg/kg[42].

Malt

37. 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]

Batter

38. 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

39. There is no evidence for direct 3-MCPD formation during salami manufacture. But, salami can contain high concentrations of 3-MCPD esters, a potential source of 3-MCPD.[5] However, 3-MCPD levels of up to 0.1 mg/kg have been reported for salami samples.[42] This may have originated from epichlorohydrin in the salami coating since the salami samples containing 3-MCPD were taken prior to the enforcement of Directive 2002/72/EC[3].

40. 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]

41. 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]

42. 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] The mechanism for this formation has not been identified.[44]

Cheese

43. 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.

44. 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]

45. Table 1 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.

Table 1: Products that potentially 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
7.1.1	Breads & Rolls	0.001 - 0.57	966	524
7.1.2	Crackers excluding sweet crackers	0.01 - 0.26	166	112
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)	0.01 - 0.21	98	25
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	0.005 - 0.10	109	30
8.3	Comminuted processed meat	0.007 – 1.8	158	58
21	Meat Extract	0.014 - 0.55	16	5
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	0.01 – 0.04	60	7
22.2	Malt extract	0.005 - 0.85	31	17
23	Modified Starched Dextrins	0.012 - 0.49	9	2
26	Other ingredients	0.019 - 0.025	11	2
Includes	Flavourings	0.025	2	1
16	Composite foods	0.004 - 0.11	113	36
Includes	Pizza	0.004 - 0.09	83	31

OCCURRENCE OF 3-MCPD IN ACID-HVP CONTAINING FOODS

Acid-HVP

46. 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]

47. Comments were received in response to CX/FAC/37/32 (Discussion Paper on Chloropropanols) by Japan, who provided information on acid-HVP and soy sauce production. Acid-HVPs, manufactured using well-controlled (acid-HVP-C) and other production processes (acid-HVP-NC) were analysed. The 3-MCPD concentrations for acid-HVP-C were significantly lower than for acid-HVP-NC (means of 0.047 mg/kg and 8.4 mg/kg respectively). Japan continues to investigate levels of 3-MCPD and 1,3-DCP in acid-HVP-NC in order to control levels in these substances in the finished products.

Soy sauce

48. 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.

49. Traditionally fermented soy sauces are unlikely to contain 3-MCPD[29], although the addition of 3-MCPD containing ingredients such as contaminated acid-HVP can give rise to the presence of 3-MCPD in products described as fermented if labelling legislation of the country concerned allows the use of such terms.

50. The EU has 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]

51. 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 both ingredients 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]

52. 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. In 33 samples the chloropropanol 3-MCPD was not detected. In a further 3 samples the level of 3-MCPD was above the detection limit but below the current maximum level in Canada, i.e., 1 mg/kg (range 0.02 to 0.63 mg/kg). At such levels of 3-MCPD the chloropropanol 1,3-DCP was not detected.

53. Nine samples were contaminated with 3-MCPD above 1 mg/kg, the values ranged from 2.97 to 812 mg/kg (mean, 194.25 mg/kg). Eight of these were also contaminated 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.

54. Table 2 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 2: Products that potentially contain 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
	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 (wheredaavailable).	0.001 - 1779	3368	1169
	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	0.014 - 8.8	139	33
	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	0.006 - 1015	1085	431
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

[a] Types of soy sauce included: 12.6.4.2, 12.6.4.4, 12.6.4.6, 12.6.4.8, 12.6.4.12, 12.6.4.13, 12.6.4.16, 12.6.4.17

DIETARY EXPOSURE TO CHLOROPROPANOLS

55. Comments were received in response to CL 2004/9-FAC, Maximum Levels for 3-MCPD (Chloropropanol) in Acid-hydrolyzed Vegetable Proteins (acid-HVPs) and Acid-HVP Containing Products. 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), provided estimates for mean 3-MCPD intake due to acid-HVP consumption. Results indicated daily intakes of less than 2µg/kg bw for 3-MCPD levels up to 1mg/kg in acid-HVP. The International Hydrolysed Protein Council (IHPC) provided intakes estimates based on high level (Japanese) consumption of soy sauce. (These estimates do not take into account dietary intake from other sources of chloropropanols, for example foods listed in tables 1 and 2). Results indicated that 3-MCPD intake from soy sauces and savoury foods comprising 1/8th of the diet made with acid-HVPs containing 0.4 mg/kg 3-MCPD would be 14µg/person/day for the mean Japanese consumer of soy sauces (2µg from savoury foods and 12µg from soy sauce), and 26µg/person/day for the 95th percentile consumer of soy sauces, (2µg from savoury foods and 24µg from soy sauce). In addition, the data presented by IHPC showed that the remaining 7/8 of the diet could contain 3-MCPD levels of 0.071 mg/kg without exceeding the PMTDI for the Japanese consumer in the 95th percentile of soy sauce consumption.

56. However, low levels of 3-MCPD in widely and regularly consumed foods, such as bread and other cereal products, can contribute considerably to the total dietary intake of 3-MCPD. Exposure to chloropropanols from these foods can be more significant than the exposure from soy sauce related products since, despite the relatively low concentration of 3-MCPD present, they are consumed in large quantities. Vulnerable groups include children, who have a high level of consumption for their body weight. Dietary intake estimates for children can be more than twice the adult estimates.[42]

A Codex standard for Soy sauce

57. The 22nd session of the Codex Committee on Processed Fruit and Vegetables (CCPFV) agreed that a proposed draft Codex standard for soy sauce (CX/PFV 04/22/8) would more appropriately be dealt with by the Codex Committee on Cereals Pulses and Legumes (CCCPL).[43]

58. The 55th Executive Committee agreed to this on the understanding that, before proceeding, the CCCPL should have a discussion on the need for a Codex Standard for Soy Sauce.[53]

59. The 56th Executive Committee recommended the discontinuation of work, with the understanding that such a decision would not prevent the Commission from revisiting this matter in the future and reconsider the amenability of the product to standardisation.[51]

60. The 28th Session of the Codex Alimentarius Commission decided to discontinue work on soy sauce.[52]

RECOMMENDATIONS

61. Request JECFA to carry out an exposure assessment for 3-MCPD based on the contributions from all food groups in the diet, with particular consideration to groups that might have higher levels of exposure to 3-MCPD.

62. Request JECFA to carry out an exposure assessment to readdress 1,3-DCP as a separate issue from 3-MCPD.

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