

codex alimentarius commission



FOOD AND AGRICULTURE
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

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DISCUSSION PAPER ON CHLOROPROPANOLS

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 4 April 2005** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature and Food Quality, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl - *preferably*), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org - *preferably*).

BACKGROUND

1. The 36th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) agreed that a working group under the direction of the United Kingdom with the assistance of Australia, Canada, China, European Community, Japan, Korea, Philippines, Russia, Thailand, United States and International Hydrolyzed Protein Council would prepare an updated Discussion Paper on Chloropropanols with proposals for maximum levels of 3-MCPD in relevant commodities including acid-hydrolysed vegetable proteins (HVPs) and foods containing acid-HVP (ALINORM 04/27/12, para. 194) for circulation, comment and consideration at the 37th Session of the CCFAC. The Committee also proposed the addition of chloropropanols to the JECFA priority list (ALINORM 04/27/12, App XXVII).

2. In addition, the Committee agreed to commence work on the establishment of a maximum level for 3-MCPD in acid-HVPs and acid-HVP containing products subject to approval as new work by the Codex Alimentarius Commission while requesting comments on proposals for maximum levels for chloropropanol in these commodities (ALINORM 04/27/12, para. 193). The 27th session of the Codex Alimentarius Commission endorsed this as new work for the CCFAC (ALINORM 04/27/41, App. VI).

3. 3-Monochloropropane-1,2-diol (3-MCPD) and 1,3-dichloro-2-propanol (1,3-DCP) belong to a group of chemicals called chloropropanols. They can be formed in foods as a result of processing/storage conditions, though the mechanism for their formation is not fully understood.

4. The 57th Session of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered chloropropanols, 3-MCPD and 1,3-DCP, in June 2001.²⁰ They assigned a provisional maximum tolerable daily intake (PMTDI) for 3-MCPD of 2 µg/kg bw. JECFA concluded that available studies clearly indicated that 1,3-DCP was genotoxic *in vitro* and the establishment of a tolerable intake was inappropriate because of the nature of toxicity. JECFA noted that the available evidence suggests that 1,3-DCP is associated with high concentrations of 3-MCPD in foods. Regulatory control of the latter would therefore obviate the need for specific controls on 1,3-DCP.

5. The UK Committee on Carcinogenicity (COC) considered 1,3-DCP and 2,3-dichloro-2-propanol (2,3-DCP) in June 2004 and concluded that 1,3-DCP should be regarded as a genotoxic carcinogen following a long-term toxicological study.¹⁷ The Committee also recommended that further investigations regarding the mechanisms of 1,3-DCP carcinogenicity *in vivo* are needed. The Committee concluded that the available evidence is consistent with the conclusion that 2,3-DCP does not possess genotoxic activity *in-vivo*. No conclusions regarding carcinogenicity of 2,3-DCP could be reached. The UK Committee on Mutagenicity (COM) also considered 2,3-DCP in May 2004 and concluded that 2,3-DCP can be regarded as having no significant genotoxic potential *in vivo*.¹⁸

6. Despite its widespread occurrence, research into the mechanisms for 3-MCPD formation has not been resolved for foods other than acid-HVP. The UK Government has commissioned a research project to investigate the factors effecting the formation of 3-MCPD in foods which is due to be reported in 2005.

OCCURENCE IN FOOD

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 the Association of Official Analytical Chemists (AOAC).¹⁵

Soy sauce and HVP

8. 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.¹ These controls have already been put in place successfully by many HVP manufacturers. Thus, it should be possible to have similar controls during soy sauce manufacture.

9. In the EU, it has been identified that there are many liquid seasoning condiments similar to soy sauce (such as fish sauce, mushroom sauce, meat seasoning sauces etc.) that can contain 3-MCPD and other chloropropanols, whether as a result of processing or from the use of processed ingredients.³¹

10. Formation of 3-MCPD in acid-HVP has been found to be related to production processes, and the concentration can be reduced markedly with suitable modifications. The source of 3-MCPD in soy sauce is being investigated. By analogy with HVP, however, 3-MCPD may arise during acid hydrolysis in the manufacture of some products. Traditionally fermented soy sauces is unlikely to contain 3-MCPD²⁰, however these can potentially be contaminated by the addition of 3-MCPD containing ingredients such as contaminated HVP.

11. 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 sauce. 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.²⁰

12. In Canada a nationwide investigation of 3-MCPD in various soy, mushroom and oyster-flavoured sauces is being conducted. In this continuing project, results for 2004 indicated significant improvement with the majority (~95%) of the sauces tested, in compliance with the Canadian maximum level of 1 ppm for 3-MCPD. 3-MCPD levels in tested products have frequently been well below 1 ppm.

13. A consequence of relatively high levels of 3-MCPD in soy sauces is that a considerable amount of 1,3-DCP can also be detected in such products.^{9,12,13} In the data collated in the European Community (EC) SCOOP task 3.2.9³¹ 282 soy sauce samples had been analysed for both 3-MCPD and 1,3-DCP. 60 of the 282 samples contained quantifiable levels of both 3-MCPD and 1,3-DCP, no sample contained quantifiable level of 1,3-DCP without containing a quantifiable level of 3-MCPD. Levels of 1,3-DCP were always lower than the 3-MCPD level in the same sample. At 3-MCPD levels at or below 0.02 mg/kg, 1,3-DCP was quantified in only one sample (at a level of 0.006 mg/kg). It is not possible to identify the method of manufacture of these products. In the same data set the range of ratios for levels of 3-MCPD to 1,3-DCP were large, indicating that there is no direct correlation between 3-MCPD and 1,3-DCP. In the case of soy sauce the SCOOP task 3.2.9 data, support JECFA's view that control of 3-MCPD would obviate the need for specific controls on 1,3-DCP.³¹ Data from a United States survey of chloropropanols in soy sauces and related products,³⁶ 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.

Foods and food ingredients other than Soy sauce and HVP

14. Chloropropanols have been detected in foods other than soy sauce and foods with HVP as an ingredient. 3-MCPD has been detected in foods including cereal products, soups, meat products and dairy produce these included baked goods, bread and cooked/cured meat/fish.^{2,6,7,31} A European Community Scientific Co-operation (SCOOP) task to collect and collate data on the levels of 3-MCPD and related substances in foodstuffs was issued in 2004.³¹ The Task collated data on the levels of 3-MCPD and other chloropropanols in a range of foods. A database of all available information on the levels of 3-MCPD and related substances in foodstuffs in the European Union was compiled as part of the task.

15. A survey conducted in Australia and New Zealand detected generally low levels of both 3-MCPD and 1,3-DCP (up to 0.083 mg/kg and up to 0.11 mg/kg, respectively), in some samples of minced beef, sausages, ham, battered fish, beef steak and lamb chops. In some cases, 1,3-DCP was detected in the absence of 3-MCPD, indicating that 1,3-DCP may be formed independently of 3-MCPD.² An investigation of cooked and uncooked UK retail meat products was conducted following this finding. 1,3-DCP was not detected in any of the samples. Low levels of 3-MCPD were detected in five of the cooked samples.³³

16. In a preliminary study, the United States analysed bread, crackers, meats and canned tuna for chloropropanols. The majority of results were below the laboratory quantitation limit (LQL); one of the bread and one of the cracker samples were above the LQL for 3-MCPD (0.014 mg/kg), and one of the tuna samples was above the LQL for 1,3-DCP (0.019 mg/kg).

17. These new findings indicate that for foods other than soy sauce JECFA's view that control of 3-MCPD would obviate the need for specific controls on 1,3-DCP may not hold true.³¹

DIETARY EXPOSURE TO CHLOROPROPANOLS

18. JECFA have recommended a provisional maximum tolerable daily intake (PMTDI) for 3-MCPD of 2 µg/kg bw. JECFA concluded that available studies clearly indicated that 1,3-DCP was genotoxic *in vitro* and the establishment of a tolerable intake was inappropriate because of the nature of toxicity. In 2001 JECFA estimated the dietary intake from 3-MCPD and concluded that the intake of 3-MCPD would be due predominantly to the consumption of contaminated soy sauces.²⁰ As described above other foods have subsequently been identified as containing chloropropanols and thus potentially contributing to intake. The European Commission's Scientific Committee for Food (SCF) similarly derive a Tolerable Daily Intake (TDI) of 2 µg/kg bw for 3-MCPD in May 2001.¹⁹

Australia & New Zealand

19. Food Standards Australia New Zealand (FSANZ) estimated the dietary exposure to 3-MCPD and 1,3-DCP from a wide range of foods.² In the first scenario, exposure estimates were determined using the mean concentrations for 3-MCPD and 1,3-DCP found in soy and oyster sauces from the 2001 Australian survey data. In the second scenario, exposure estimates were determined using the newly established maximum levels for 3-MCPD (0.2 mg/kg) and 1,3-DCP (0.005 mg/kg) in the Food Standards Code. Total estimated dietary exposure to 3-MCPD was well below the PMTDI established by JECFA in both scenarios at both mean and 95th percentile exposure levels.

20. Dietary exposure to 3-MCPD was estimated for the smaller group of consumers specifically exposed through consumption of soy and oyster sauces. Estimated dietary exposure to 3-MCPD for these consumers at the 95th percentile, using the 2001 survey data, was up to 400 % of the PMTDI. However, when the dietary exposure was estimated using the newly established maximum level for 3-MCPD of 0.2 mg/kg in the Food Standards Code, the 95th percentile exposure was only up to 5% of the PMTDI.²

21. Total estimated dietary exposure for consumers of 1,3-DCP from a wide range of foods was also low, the major food contributors being minced meat, sausages, bread, soy and oyster sauce, ham and bacon for both scenarios. Although no tolerable daily intake has been established for 1,3-DCP, the margin between the level of exposure for high consumers and the level causing tumour formation in animal studies is extremely large (approximately 200,000 fold). Under these circumstances, the public health and safety risk for consumers is considered by FSANZ to be very low and therefore did not warrant any regulatory action.²

East Asia and Southeast Asia

22. In East Asia and Southeast Asia, Soy sauce, oyster sauce, fish sauce, and similar products are consumed as seasonings. They are manufactured by traditional fermentation processes and also by using acid-HVP.

European Community

23. An EC Scientific Co-operation (SCOOP) task 3.2.9 that collected and collated data on the levels of 3-MCPD and related substances in foodstuffs was issued in 2004.³¹ As part of this task, EC Member States used the collated information on levels of 3-MCPD in foodstuffs to conduct 3-MCPD dietary exposure estimates. Results show that there are foods other than soy sauce that may contribute significantly to the overall exposure to chloropropanols, these included bread/bakery products, sauces other than soy sauce and products containing sauces.

SETTING LIMITS IN FOOD

24. The 57th Session of the JECFA discussed the impact of regulatory limits for 3-MCPD in foods. The Committee observed that a regulatory limit on the concentration of 3-MCPD in soy sauce could markedly reduce 3-MCPD intake by soy sauce consumers and that the available evidence suggested that 1,3-DCP is associated with high concentrations of 3-MCPD.²⁰ The Committee noted that regulatory control of 3-MCPD in soy sauce would therefore obviate the need for specific controls on 1,3-DCP in these products. The data in the recent EC SCOOP task 3.2.9 support this conclusion.³¹

25. However, recent studies in Australia and New Zealand have indicated that 1,3-DCP may be formed independently of 3-MCPD in some minced meat, sausages, bread, soy and oyster sauce, ham and bacon.² The 36th Session of CCFAC requested JECFA to re-evaluate the formation of 3-MCPD and 1,3-DCP in food.

26. A number of EC Member States estimated dietary exposure to 3-MCPD using occurrence data for foods other than soy sauce and a presumed maximum level of 0.02 mg/kg for soy sauce as part of the EC SCOOP Task.³¹ These calculations showed that dietary exposure to 3-MCPD from foods other than soy sauce and soy sauce with 3-MCPD levels of 0.02 mg/kg would enable dietary exposures to 3-MCPD to be maintained below the JECFA PMTDI of 2 µg/kg bw. Controlling 3-MCPD in soy sauce with a maximum limit of 0.02 mg/kg also maintains 1,3-DCP content in those products to below the limit of quantification. The new data from Australia shows that this may not be the case for other food groups.²

27. A number of countries/regions have introduced maximum levels for chloropropanols, these are summarised in table 1.

Table 1 : Summary of Existing Maximum Levels/Specifications for Chloropropanols in food

Country/Region	Maximum Level/Specification				
	3-MCPD			1,3-DCP	
	HVP	Soy Sauce	Other Foods	HVP	Soy Sauce
Australia & New Zealand ^{22 d}	-	0.2 mg/kg ^a	0.2 mg/kg ^a - oyster sauce	-	0.005 mg/kg ^a (Limit of detection)
Canada (Interim Guideline) ²³	-	1.0 ppm ^a	1.0 ppm ^a mushroom and oyster- flavoured sauces		
European Community ²⁶	0.02 mg/kg ^b	0.02 mg/kg ^b	-	-	-
Malaysia ³⁵	1.0 mg/kg ^a	-	0.02 mg/kg- food containing acid hydrolysed proteins	-	-
US Food Chemical Codex ^{27 c}	-	-	1.0 mg/kg - acid hydrolysates of proteins, including acid-HVP	0.05 mg/kg	-
Thailand ³⁴	-	-	1 mg/kg - seasoning products obtained from protein hydrolyzation of soy bean	-	-

^a whether the level is to be applied to the product is not specified on a liquid or dried basis.

^b For the liquid product containing 40% dry matter corresponding to maximum level of 0.02mg/kg in the dry matter.

^c The Food Chemicals Codex has established specifications for acid hydrolysates of proteins, which include acid-HVPs.²⁷ The Food Chemicals Codex specification for 3-MCPD is 1 mg/kg (dry basis) and that for 1,3-DCP is 0.05 mg/kg (dry basis). In the United States, voluntary compliance with the Food Chemicals Codex specification for 3-MCPD of 1 mg/kg (dry basis) has enabled United States manufacturers to formulate products with low levels of 3-MCPD.

^d Australia established maximum limits for 3-MCPD and 1,3-DCP in order to protect public health and safety of Australian consumers based on the JECFA risk assessment of chloropropanols,²⁰ and at a level that was considered achievable for manufacturers in order to keep levels to as low as reasonable achievable and to encourage industry to continue their efforts of minimisation of chloropropanols in the food supply.

28. In line with the Codex General Standard for Contaminants & Toxins in Foods ‘Maximum levels shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer’. The exposure assessments carried out by JECFA, FSANZ and some EC Member States³¹ have shown that when 3-MCPD levels in soy sauce are controlled the total dietary exposure to 3-MCPD is below JECFA’s PMTDI of 2 µg/kg bw. The studies concluded that soy sauce and related products such as liquid seasoning condiments (eg fish sauce, mushroom sauce, oyster sauce, meat seasoning sauces) are the predominant contributors to dietary exposure to 3-MCPD.

Commodities

29. The setting of maximum levels as outlined in the Codex General Standard for Contaminants & Toxins in Foods should be on the products that are traded internationally. Soy sauce meets this criterion. The method of production (including the use of HVP) is not necessarily labelled on these products and as such all such products would be required to comply with a maximum level for 3-MCPD.

30. Codex has considered the development of a standard for soy sauce. At the 22nd session of the Codex Committee on Processed Fruit and Vegetables (CCPFV) it was agreed that the 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).³²

31. The 55th Executive Committee noted the decision of the 22nd Session of the CCPFV to discontinue work on the standardization of soy sauce while recommending the Executive Committee to entrust this work to the Codex Committee on Cereals, Pulses and Legumes (CCCPL) on the understanding that, before proceeding further with the elaboration of the Standard, the CCCPL should have a full discussion on the need for a Codex Standard for Soy Sauce in the light of the Criteria for the Establishment of Work Priorities⁸.

32. The Executive Committee agreed that the Commission should consider, in the first place, whether there was need for continuing to develop a Codex Standard for Soy Sauce. If the answer to this question was affirmative, then the subsequent question on whether to entrust its elaboration to the Codex Committee on Cereals, Pulses and Legumes should be addressed. The Committee noted that possible options included discontinuation of this work within Codex as well as finalization of the draft standard as a regional standard.

33. The Executive Committee decided to consider this matter at its 56th Session of the Committee in the framework of the Critical Review Process. The recommendation of the Executive Committee would be then put forward to the 28th Session of the Codex Alimentarius Commission for final decision. In order to facilitate the discussion at the next session of the Committee, it was agreed that a Circular Letter be issued to seek the views of Codex Members and Observers on the need for the standardization of this product within Codex (ALINORM 05/28/03, para. 56).

34. The experience in Europe has been that controlling the amount of 3-MCPD in soy sauce, HVP and products containing these commodities as ingredients, by setting a maximum level for 3-MCPD in soy sauce and HVP of 0.02 mg/kg, allows the total dietary intake of 3-MCPD to be maintained below the JECFA PMTDI of 2 µg/kg bw.

35. The experience in the United States has been that a level of 0.400 mg/kg of 3-MCPD in acid HVP is effective in ensuring that the total dietary intake of 3-MCPD, from soy sauce, savory foods made with acid HVP and other sources, will be maintained below the JECFA PMTDI of 2 µg/kg bw.

RECOMMENDATIONS

36. Request JECFA to conduct a risk exposure assessment based on a range of maximum levels below and above the existing maximum levels in member countries for 3-MCPD in products made by vegetable protein hydrolysis **AND** other contributors to dietary intake of chloropropanols.

37. CCFAC should consider drafting a Code of Practice for reducing chloropropanol levels during the production of soy sauce, processed vegetable proteins using acid hydrolysis and other affected products.

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