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
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Rotterdam, The Netherlands, 11-15 March 2002

POSITION PAPER ON CHLOROPROPANOLS

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 31 January 2002** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl, 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).

COMMENTS

1. Comments are requested on the following specific issues based on the Background explanation below:

- Any additional information on chloropropanols that is not addressed in this position paper.
- Proposals for revisions to this position paper.
- The setting of limits for chloropropanols (3-MCPD and 1,3-DCP) in food.

BACKGROUND

2. The 33rd Session of the Codex Committee on Food Additives and Contaminants (CCFAC) requested the United Kingdom, with assistance provided by Canada and the United States of America, to revise the Position Paper on Chloropropanols presented at the 33rd Session (CX/FAC 01/31) for circulation, comment and consideration at the 34th Session of the CCFAC. This paper has been revised in light of comments submitted on the earlier paper and the re-evaluation of chloropropanols at the 57th JECFA meeting in June 2001 (ALINORM 01/12A, paras. 181-182).

3. 3-Monochloropropane-1,2-diol (3-MCPD) and 1,3-dichloro-2-proponal (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. 3-MCPD has been shown to be a precursor for 1,3-DCP formation.[1]

4. 3-MCPD was originally identified as a contaminant of acid-hydrolysed vegetable protein (acid-HVP),[2, 3, 4] a frequently used ingredient of savoury foods such as soups, prepared meals, savoury snacks, gravy mixes and stock cubes. 3-MCPD has also been found to occur in a range of other foods and ingredients,[5, 6] most notably in soy sauce[7, 8, 9] (Annex I). 1,3-DCP has also been detected in acid-HVP [2, 3] and soy sauce[8, 10] but its presence

in other foods and ingredients has not been investigated to the same extent. In addition to the presence of 3-MCPD in food, there is a theoretical source of very low levels of this substance in drinking water from upland areas in the UK. This is due to its presence as a contaminant of epichlorohydrin-linked cationic polymer resins in flocculants used for water purification in a small number of treatment plants. (Annex I). A summary of the possible sources of chloropropanols in the diet is given in Annex I.

5. A fully validated analytical method capable of measuring 3-MCPD in food and food ingredients at levels down to 0.01 mg/kg has been developed[11] by the UK's Central Science Laboratory. This method has been validated through an international collaborative trial and has been accepted as a first action status method by the Association of Official Analytical Chemists (AOAC).[12]

6. Following toxicological assessment in the UK which concluded that 3-MCPD can be regarded as having no significant genotoxic potential *in vivo* and therefore acts as a non-genotoxic carcinogen[13, 14] the European Commission's Scientific Committee for Food (SCF) were able to derive a Tolerable Daily Intake (TDI) of 2 µg/kg bw in May 2001.[15]

7. 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.[16] They 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. 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. The Committee noted that regulatory control of 3-MCPD would therefore obviate the need for specific controls on 1,3-DCP.

8. During 2001 a number of countries have introduced maximum levels for chloropropanols, including Malaysia (0.02 mg/kg for 3-MCPD in foods containing HVP and 1 mg/kg for 3-MCPD in acid-HVP),[17] Australia and New Zealand (0.2 mg/kg for 3-MCPD and 0.005 mg/kg for 1,3-DCP in soy and oyster sauces).[18]

CODEX MEMBER STATES' ACTIVITIES ON CHLOROPROPANOLS

Canada

9. Following the discovery of 3-MCPD at levels up to 178 ppm in sauces, Health Canada introduced an interim guideline of 1 ppm for 3-MCPD in sauces.[19] Based on the Lowest Observable Effect Level (LOEL) of 1.1 mg/kg bw/day for a non-tumorigenic endpoint in a chronic rat study[20] and an uncertainty factor of 1000, Health Canada established a provisional TDI of 1.1 µg/kg bw/day. The uncertainty factor was calculated using a 10-fold factor for human variability, a 10-fold factor for interspecies extrapolation and a 10-fold adjustment for use of a LOEL. The use of an interim guideline based on the provisional TDI is a preliminary strategy, with the ultimate objective being to reduce 3-MCPD levels to concentrations that are as low as reasonably achievable. The Canadian Food Inspection Agency is conducting ongoing investigations to verify the effectiveness of compliance measures.

United Kingdom

10. The results of surveys of 3-MCPD levels in food[6] and food ingredients[5] conducted in the UK have shown that 3-MCPD is present in a wide range of foods including baked goods, bread, cooked/cured meat/fish and malt ingredients. Surveys of 3-MCPD[9] and 1,3-DCP[10] levels in soy sauces and related products published in February 2001 showed that 31 % of the 100 retail products sampled contained quantifiable levels of 3-MCPD (ie equal to or above 0.01 mg/kg), with the highest level being 93.1 mg/kg. 17% of the same 100 samples contained quantifiable levels of 1,3-DCP, the highest level being 0.345 mg/kg. No direct correlation between the levels of 3-MCPD and 1,3-DCP was observed other than that all samples with quantifiable levels of 1,3-DCP contained levels of 3-MCPD greater than 0.02 mg/kg and that the 3-MCPD level was always greater than the 1,3-DCP level.

11. Research on chloropropanols is continuing in the UK with a programme of work including surveys of 3-MCPD in the diet, soy sauces and research to investigate the factors affecting the formation of 3-MCPD in food.

United States of America

12. Based on technological feasibility and a preliminary quantitative cancer risk assessment by the Food and Drug Administration (FDA), specifications of 1 ppm 3-MCPD and 50 ppb 1,3-DCP in acid-hydrolyzed vegetable proteins (on a dry basis) were established by the Food Chemicals Codex (FCC) in December of 1997. Following discussions with FDA, the US industry has voluntarily complied with these FCC specifications which appear to provide a significant margin of safety to protect the public from the diverse array of products that use acid-HVP. By limiting the amount of 3-MCPD permitted in acid-HVP, manufacturers can reasonably control the formation of 1,3-DCP.

13. A US FDA survey of soy sauce and related products found that 59 percent of samples contained quantifiable levels of 3-MCPD as high as 876 mg/kg and 31 percent contained quantifiable levels of 1,3-DCP as high as 9.8 mg/kg. The FDA continues to monitor chloropropanol levels and evaluate its risk management options to lower chloropropanols in soy sauces in order to eliminate any significant health risk from these products.

14. The FDA, in its formal quantitative risk assessment of 3-MCPD completed in 2000, concluded that 3-MCPD was genotoxic and carcinogenic, this assessment was provided to the 57th JECFA. The FDA arrived at its findings prior to the UK's release of the results of its genotoxicity studies, it's assessment of the mutagenicity of 3-MCPD and the conclusion reached by the 57th JECFA in June 2001 that 3-MCPD was not genotoxic *in vivo*.

ACTIVITIES BY NON-CODEX MEMBER ORGANIZATIONS ON CHLOROPROPANOLS

European Community

15. The European Commission's Scientific Committee on Food (SCF) assessed new toxicological data in May 2001 and reassessed their opinion to set a Tolerable Daily Intake (TDI) of 3-MCPD at 2 µg/kg bw.[15]

16. Discussions began in December 1999 on a European Commission proposal to set a limit for 3-MCPD in certain foods and food ingredients. In October 2001 following the SCF's new opinion on the toxicology of 3-MCPD the Standing Committee set a maximum level for 3-MCPD in HVP and soy sauce of 0.02 mg/kg for the liquid product containing 40% dry matter, corresponding to a maximum level of 0.05 mg/kg in the dry matter.[21] The regulations will apply from 5 April 2002. A separate Commission Directive has been prepared on sampling and analysis methods.[22]

17. It is recognised that 3-MCPD can be found in other foods and food ingredients not currently covered by this regulation. However, the European Community considers that further data are required before any discussion of limits for these other products can take place. A European Community Scientific Co-operation (SCOOP) task to collect and collate data on the levels of 3-MCPD and related substances in foodstuffs is underway. This is being jointly co-ordinated by Sweden and the UK. A review of information on 3-MCPD and related chloropropanols in foodstuffs shall be completed by 1 April 2003 in the light of the report from this task. The maximum levels for 3-MCPD in soy sauce and HVP will then be reassessed and the possible need for maximum levels in other foodstuffs will be considered.

18. High levels of 3-MCPD are continuing to be found in samples of soy sauce and related products sold within the European Community, with some Member States ordering the removal of some highly contaminated products from the market (Annex I).

SETTING LIMITS IN FOOD

19. The 57th Session of the JECFA discussed the impact of regulatory limits for 3-MCPD in foods. A limited amount of data was available and so the impact of setting limits in foods other than soy sauce could not be reliably ascertained.

20. As part of the European SCOOP task the UK is compiling a database of all available information on the levels of 3-MCPD and related substances in foodstuffs in the European Union. Both Member States and industry have provided data for this task. Once data collection is complete it is anticipated that modelling systems will be utilised to identify appropriate control levels for 3-MCPD in foods. Detailed dietary consumption data are available from the UK and Sweden and these will be used initially. It is planned that the Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme, (GEMS/Food) European regional diets[23] will also be used. This process could usefully be expanded to other world regions using the relevant GEMS diets providing that occurrence data could also be obtained.

21. This could also be used as a test for the Principles for Exposure Assessment of Contaminants and Toxins in Foods being developed by this Committee (ALINORM 01/12A, para. 122).

SUMMARY

22. The 57th Session of the JECFA considered 3-MCPD and 1,3-DCP in June 2001. They recommended a provisional maximum tolerable daily intake (PMTDI) for 3-MCPD of 2 μg/kg bw and concluded that the establishment of a tolerable intake for 1,3-DCP was inappropriate because of the nature of toxicity.

23. Chloropropanol contamination is a food safety issue that has international implications, and therefore a harmonised approach to control chloropropanol levels in foods is required to protect consumers. In light of this and the evaluation of the 57th Session of the JECFA that the regulatory control of 3-MCPD would therefore obviate the need for specific controls on 1,3-DCP the CCFAC are asked to consider the setting of limits for chloropropanols in food at the 35th Session of the CCFAC. In order to prepare for this the 34th Session of the CCFAC are asked in particular to consider:

- the setting of maximum levels for chloropropanols in foodstuffs;
- the chloropropanols for which maximum levels should be set;
- foods and food ingredients in which these levels should be set;
- the timetable for implementation of any such limits.

24. To assist in this process information is required on:

- levels of chloropropanols in foods and food ingredients;
- dietary exposure to chloropropanols;
- the origin and formation of chloropropanols;
- production methods which can be utilised to avoid chloropropanol contamination.

ANNEX I: SOURCES OF CHLOROPROPANOLS IN THE DIET

(a) Acid-HVP

25. The procedure used to manufacture the savoury food ingredient acid-HVP can result in the formation of 3-MCPD and 1,3-DCP. Most acid-HVP is produced using hydrochloric acid. 3-MCPD is formed as a result of the high temperature chlorination of lipids present in the protein starting materials, 1,3-DCP can then be formed from the 3-MCPD precursor.[1] Surveys carried out by the UK Government in 1990 and 1992 showed that 3-MCPD levels of up to 100 mg/kg were quite common in acid-HVP at that time.[2, 3] Since 1992, levels of 3-MCPD in acid-HVP used in the UK have declined markedly, as was shown by the results of a 1999 survey of acid-HVP in which 3-MCPD was undetectable (less than 0.01 mg/kg) or was found at low levels in over 75% of the 50 samples analysed.[4] 1,3-DCP was found in only one sample in the 1990 survey, with none being detected in any of the 34 samples analysed in the 1992 survey.[2, 3] No further analysis of 1,3-DCP in acid-HVP has been published. The US FDA has surveyed 51 samples of soy sauces and related products and found that 59 percent contained quantifiable levels of 3-MCPD as high as 876 mg/kg at a limit of quantification of 25 µg/kg using the UK's validated method.[11] In addition to products imported from Thailand, China, Hong Kong, and Taiwan, as noted by the UK, products imported from the Philippines also were among those containing the highest levels.

(b) Food Ingredients other than Acid-HVP

26. A survey of 3-MCPD in 63 samples of food ingredients available in the UK was reported in 2001.[5] 3-MCPD was quantified in 22 % of the samples using a validated method of analysis with a limit of quantification of 0.01 mg/kg. 3-MCPD was not found in any of the samples of yeast extracts, caramels or gelatines. 3-MCPD was quantified in 1 of 6 samples of breadcrumbs, 1 of 3 samples of enzyme HVPs, 1 of 5 samples of meat extracts, 2 of 7 samples of modified starches and in 9 of 24 samples of malts and malt-based ingredients. The highest level was 0.49 mg/kg for a modified starch (maize yellow dextrin). These controls have already been put in place successfully by European and US acid-HVP manufacturers.

(c) Soy sauces

27. Following the continued detection of high levels of 3-MCPD in samples of soy sauces sold in member states, authorities in European Community member states are continuing to report[a] elevated levels in some products. In the UK, a survey of 100 samples of soy sauce and related products showed that around one-third of the samples contained quantifiable levels of 3-MCPD (ie at or above 0.01 mg/kg)[5], the highest being 93.1 mg/kg. These products were imported from Thailand, China, Hong Kong and Taiwan, indicating that higher levels are not restricted to any one country of origin.

28. Soy sauce can be manufactured by a range of processes, including traditional fermentation as well as 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 very large amounts of 3-MCPD unless the processing conditions are well controlled. These controls have already been put in place successfully by many European acid-HVP manufacturers. Thus, it should be possible to bring in similar controls during soy sauce manufacture.

29. A further 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.[8, 10] In a UK survey of 100 samples of soy sauces and related products 17 % of samples contained quantifiable levels of 1,3-DCP (ie at or above 0.005 mg/kg)[10]. All samples with quantifiable levels of 1,3-DCP were found to contain levels of 3-MCPD above the EU limit of 0.02 mg/kg for 3-MCPD in soy sauce and HVP based on a 40% dry matter content. A follow-up survey of 3-MCPD and 1,3-DCP levels of soy sauce and related products is due to be conducted in the UK in 2002. Of the 51 samples surveyed by the US FDA for 3-MCPD, 34 of these samples also were analysed for 1,3-DCP.

[a] Notifications have been made within the European Community via the Rapid Alert System for Foodstuffs. This is a communications network administered by the European Commission which allows action of food safety taken by one Member State to be followed up across the Community.

Thirty-one percent were found to contain 1,3-DCP as high as 9.8 mg/kg at a limit of quantification of 25 ug/kg. The 1,3-DCP determinations were obtained by a modification of the UK method, which is currently undergoing method validation. The US is continuing to monitor chloropropanols in soy sauces and related products.

(d) Foods other than Soy Sauces

30. A survey conducted in the UK has shown that 3-MCPD is present in a wide range of foods. The foods analysed were from five main food groups thought most likely to contain 3-MCPD, including cereal products, soups, meat products and dairy produce. 30% of the 300 retail food samples analysed in this survey contained quantifiable levels of 3-MCPD, these included baked goods, bread and cooked/cured meat/fish.[6]

(e) Domestic cooking

31. A limited amount of work has been conducted to investigate the effect of cooking on the formation of 3-MCPD in food.[24] The results of this work showed that elevated levels of 3-MCPD can occur in toasted bread, some grilled cheeses and fried batters. In contrast, 3-MCPD was undetectable or present only at very low levels in cooked meat, gravy, sauces and stocks. In the UK survey of 3-MCPD[6] in food in all the cases where 3-MCPD was detected in cooked foods it was also present in the uncooked food. However, the data were insufficient to say whether cooking contributed towards the formation of 3-MCPD in food. Further research is being conducted in the UK to investigate the effect of domestic cooking on 3-MCPD formation.

(f) Formation of 3-MCPD in food

32. Despite its widespread occurrence, research into the mechanisms for 3-MCPD formation has not been published for foods other than acid-HVP. The UK Government have commissioned a research project to investigate the factors effecting the formation of 3-MCPD in foods which is due to be completed in 2004.

(g) Packaging materials

33. Information from the packaging industry and others indicates that very low levels of 3-MCPD may migrate into food and beverages from packaging materials. 3-MCPD is present in certain types of epichlorohydrin-based wet strength resins used in paper (e.g. tea bag paper, coffee filters, absorbent meat padding) and cellulose casings. Work has been carried out by the industry to develop 'third generation' resins that have significantly lower levels of 3-MCPD, and these are increasingly being used in the above applications. With the increase in the availability and use of these resins, 3-MCPD exposure from this source will continue to decrease.

(h) Water

34. There is a theoretical risk that very low levels of chloropropanols may be found in drinking water from upland areas in the UK. This is due to its presence as a contaminant of epichlorohydrin-linked cationic polymer resins in flocculants used for water purification in a small number of treatment plants. Current controls allow no more than 40 ppm of 3-MCPD in polyamine flocculants, coupled with a maximum dosing rate of 2.5 mg of flocculant per litre of water. This ensures a theoretical maximum possible concentration of 3-MCPD in drinking water of 0.1 µg/l.[25]

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