

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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Agenda Item 16g

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

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POSITION PAPER ON CHLOROPROPONALS

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 15 February 2001** as follows: S.P.J Hagenstein, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 EK, The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: s.p.j.hagenstein@vvm.agro.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, as directed above, on the following specific issues:
 - Any additional information on chloropropanols that is not addressed in this position paper.
 - Proposals for revisions to this position paper.

BACKGROUND

2. The 32nd Session of the Codex Committee on Food Additives and Contaminants (CCFAC) requested the United Kingdom, with assistance provided by Canada and the United States, to prepare a Position Paper on Chloropropanols for circulation, comment and consideration at the current 33rd Session of the CCFAC (ALINORM 01/12, paras. 148-150).
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. 3-MCPD has been shown to be a precursor for 1,3-DCP formation.¹
4. 3-MCPD is a well-known 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.
5. 3-MCPD has also been found to occur in a range of other foods and ingredients, most notably in soy sauce^{5,6} (Annex I). 1,3-DCP has also been detected in acid-HVP^{2,3} and soy sauce⁶ 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, very low levels of this substance may also 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. A summary of the possible sources of chloropropanols in the diet is given in Annex I.

6. 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 developed⁷ 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).

7. The most recent assessments of the toxicology of 3-MCPD have been conducted in the UK. It has been concluded that 3-MCPD can be regarded as having no significant genotoxic potential *in vivo* and therefore acts as a non-genotoxic carcinogen.^{8,9}

8. 1,3-DCP has been found to be mutagenic in bacterial and mammalian cell systems *in vitro*, but has not been tested *in vivo*. One carcinogenicity study has been reported, with 1,3-DCP administered in drinking water to rats, this was also positive. However, much of the data are not in the public domain.¹⁰ On the basis of the limited information available, 1,3-DCP should be regarded as a genotoxic carcinogen.

9. The 57th Session of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) will consider chloropropanols in June 2001.

Codex Member States' Activities on Chloropropanols

Canada

10. Following the discovery of 3-MCPD levels up to 178 ppm in sauces Health Canada introduced an interim guideline of 1 ppm for 3-MCPD in sauces¹¹. Based on the Lowest Observable Effect Level (LOEL) of 1.1 mg/kg bw/day in a chronic rat study¹² 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. This 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 currently conducting preliminary investigations to verify the effectiveness of compliance measures taken to date.

United Kingdom

11. Two recent mutagenicity studies^{13, 14} of 3-MCPD have been considered by the UK's Committee on Mutagenicity (COM). They concluded that 3-MCPD can be regarded as having no significant genotoxic potential *in vivo*,⁸ however, it has observable carcinogenic effects in animals. The UK Committee on Carcinogenicity (COC) subsequently agreed that 3-MCPD should be viewed as a non-genotoxic carcinogen, with a no observed effect level (NOEL) in the region of 1.1 mg/kg bw/day. Application of a suitable uncertainty factor to the NOEL for tumourigenic effects would then be acceptable as an approach for risk assessment.⁹ In October 2000, in light of the new toxicological status of 3-MCPD, the UK's Food Standards Agency's Food Advisory Committee advised¹⁵ industry to continue to reduce concentrations of 3-MCPD in all foods and food ingredients to the lowest technologically achievable.

12. The UK has commissioned a research project to investigate the origin and formation of 3-MCPD in food.

13. Surveys of 3-MCPD levels in food and food ingredients have been conducted in the UK. A survey is also being conducted on 3-MCPD and 1,3-DCP levels in soy sauces and related products. The results of these are due to be published in 2001. The results of these will be available on www.foodstandards.gov.uk.

United States of America

14. 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 health from the diverse array of products that use acid-HVP. FDA's Center for Food Safety and Applied Nutrition (CFSAN), Cancer Assessment Committee and Quantitative Risk Assessment Committees have recently finished their formal evaluations of 3-MCPD and are providing these assessments to JECFA, which will assist the Codex in establishing an international specification. CFSAN is currently monitoring chloropropanol levels and evaluating its risk management options to lower levels of chloropropanols in Asian soy sauces in order to eliminate any significant human health risk from these products.

Activities by Non-Codex Member Organizations on Chloropropanols

European Community

15. Discussions began in December 1999 on a European Commission proposal to set a limit for 3-MCPD in certain foods and food ingredients. A limit of 0.02 mg/kg for 3-MCPD in acid-HVP and soy sauce was agreed by the Commission in December 2000. The regulations are likely to be adopted in early 2001, following this there will be a 12 month delay before they are implemented, i.e. in early 2002. The Scientific Committee for Food (SCF) have been informed of the new opinions on the toxicology of 3-MCPD and it is expected that they will review their current opinion in 2001 before the regulations come into force. It is therefore probable that the limits will be reviewed prior to the implementation date. A separate Commission Directive is being prepared on sampling and analysis. It is recognised that 3-MCPD can be found in other foods and food ingredients not currently covered by the proposal. However, the European Community considers that further data are required before any discussion of limits for these other products can take place. It is anticipated that surveys underway in the UK and other Member States will provide the necessary information and will be considered as part of the planned review of the proposal (currently scheduled for June 2002).

16. A European Community Scientific Co-operation (SCOOP)¹⁶ task on the provision of validated analysis methods to support the SCF's recommendations on 3-MCPD in food was completed in 2000. A further SCOOP task to collect and collate data on the levels of 3-MCPD and related substances in foodstuffs was accepted as a task at the Standing Committee in June 2000. This is to be jointly co-ordinated by Sweden and the UK. This new task is now of particular importance as it is urgently needed to generate data to allow a reasonable Provisional Tolerable Daily Intake (PTDI) to be set by JECFA.

17. 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).

SUMMARY

18. The 32nd CCFAC requested that JECFA place a high priority on the review of chloropropanols. As a result, JECFA has requested member states to provide relevant information on the toxicity, epidemiology, levels and patterns of contamination, food consumption, and analytical methods generated since its previous evaluation of chloropropanols for further evaluation at its 57th meeting in June 2001.

19. The CCFAC have requested JECFA examine the available toxicological data on chloropropanols, especially the results of the new studies of 3-MCPD, with a view to establishing a TDI for this contaminant.

20. 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 the CCFAC are asked to consider what action is necessary to improve:

- knowledge of levels of chloropropanols in foods and food ingredients;

- knowledge of dietary exposure to chloropropanols;
- understanding of the origin and formation of chloropropanols;
- the toxicological data on 1,3-DCP and
- production methods.

SOURCES OF CHLOROPROPANOLS IN THE DIET**(a) acid-HVP**

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 conducted.

(b) Roasted cereals, dark malts and dark malt extracts

Information from the UK brewing and malting industries indicates that 3-MCPD levels increase as the colour of the malt darkens. Malt extracts, which are used to flavour certain foods and drinks, may also contain 3-MCPD. These industries have conducted extensive work to reduce the levels of 3-MCPD in these ingredients without adversely affecting their flavour characteristics. Due to the low levels of use of these ingredients, the concentrations of 3-MCPD in the final product are below 0.01 mg/kg.

(c) Fermented sausages

Certain types of fermented sausage such as salami have also been shown to contain 3-MCPD. This may be due to the formation of 3-MCPD within the meat (due to the interaction between fat and salt in the product, coupled with its long shelf life) and/or due to the presence of 3-MCPD in the resins used in the sausage casings. The casings industry is carrying out work at European level to determine the contribution of the casings to the 3-MCPD content of salami. Like other users of epichlorohydrin-based wet strength resins, the industry has also started to use higher grade resins that contain much lower levels of 3-MCPD.

(d) Soy sauces

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 40 samples of soy sauce and similar products showed that around two-thirds of the samples contained 3-MCPD at levels very close to or below 0.01 mg/kg.⁵ However, the remaining one third of the samples contained levels above 0.01 mg/kg, the highest being 30 mg/kg. These products were imported from China and Hong Kong, Taiwan and the Philippines, indicating that higher levels are not restricted to any one country of origin. A follow-up survey of 3-MCPD levels in 100 samples of soy sauce and related products is currently being conducted in the UK.

Several grades of soy sauce are manufactured in the Far East, including the traditional fermented product as well as lower grades that may 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.

^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.

A further consequence of direct acid hydrolysis of soya beans, or the incorporation of acid-HVP manufactured by outdated procedures is that a considerable amount of 1,3-DCP can also be detected in soy sauces which contain relatively high levels of 3-MCPD.⁶ The UK is currently conducting a survey of 1,3-DCP levels in 100 samples of soy sauces and related products.

(e) Domestic cooking and formation of 3-MCPD in food

A limited amount of work has been conducted to investigate the effect of cooking on the formation of 3-MCPD in food.¹⁷ 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. Some of these results can be explained by work on model systems, which suggests that 3-MCPD is not formed from lipids under the conditions commonly found in food processes where there is a high water activity. Further studies are needed to investigate the possible formation of 3-MCPD from lipids under conditions more typical of baking, roasting and toasting processes and also during Maillard browning reactions. This may help to explain the processes by which 3-MCPD is formed in roasted cereals and malts.

(f) Packaging materials

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.

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NB: The JFSSG Food Surveillance Information Sheets No. 181 and 187, are available on the WWW at <http://www.foodstandards.gov.uk>

