

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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WORLD
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Agenda Item 14 (e)

CX/FAC 06/38/32
February 2006

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

Thirty-eighth Session

The Hague, the Netherlands, 24 – 28 April 2006

**PROPOSED DRAFT MAXIMUM LEVEL FOR 3-MCPD IN LIQUID CONDIMENTS
CONTAINING HVPS**

Comments at Step 3 (in response to CL 2005/22-FAC)

The following comments have been received from: Brazil, Canada, European Community, Mexico, USA, AIIBP/FAIBP, and IHPC

BRAZIL:

Brazil supports the proposed maximum level for 3-MCPD in liquid condiments containing acid-HVP at Step 3. Since naturally fermented soy sauce did not contain detectable levels of 3-MCPD it may not be necessary to mention the exclusion once the contaminant is naturally excluded.

CANADA:

Canada supports the proposed ML of 0.4 mg/kg for 3-MCPD in “liquid condiments containing acid-hydrolysed vegetable protein (excluding naturally-fermented soy sauce).”

The exclusion, however, begs the question as to what ML, if any, should be applied to naturally-fermented soy sauce. As presently worded, there is no ML for the latter commodity.

EUROPEAN COMMUNITY:

1. The European Community supports the need to set maximum levels for 3-MCPD in hydrolysed vegetable protein (HVP), in soy sauces and in other sauces that involve acid-hydrolysis in the production processes or where products from acid-hydrolysis might be present in the sauce.
2. The proposed category of ‘liquid condiments containing acid-HVP’ covers the products of concern, although the exception clause ‘excluding naturally fermented soya sauce’ should be deleted. If fermented sauces do not contain acid-HVP then they are already excluded by ‘liquid condiments containing acid-HVP’. Control authorities have occasionally found 3-MCPD in soy sauces labelled as brewed which otherwise would not be expected to involve acid-hydrolysis. Therefore if the definition were left open to include liquid condiments containing acid-HVP these products would be covered. Avoiding a specific exclusion would also help prevent the possibility that mislabelling might be used as a way to avoid scrutiny of products, which could otherwise damage the image of brewed sauces.

3. The European Community has operated a maximum level of 0.02 mg/kg for 3-MCPD in HVP and soy sauce since April 2002. This level was set using the principle of ALARA (as low as reasonably achievable) when 3-MCPD was originally considered to be a genotoxic carcinogen. Subsequent risk assessments have concluded that 3-MCPD is carcinogenic, but not genotoxic. In view of the apparent lower risk the maximum level was reviewed. However, enforcement activities showed that 3-MCPD levels above this value tend to be very much higher and appear to be a result of bad practice. No information has come forward to show that following good practice a level greater than 0.02 mg/kg is necessary.

4. The recent collection of data and estimates of dietary intake by the EU Member States* confirm that 0.02 mg/kg would protect consumers and help ensure that soy sauces do not contribute significantly towards the Tolerable Daily Intake (TDI) of 2 µg/kg body weight, derived by the Scientific Committee on Food in 2001**. Moreover, at 0.02 mg/kg 3-MCPD, the levels of associated chloropropanols, such as 1,3 DCP, are generally very low and would not require separate maximum levels.

5. The European Community awaits the revised discussion paper on 3-MCPD and other chloropropanols before finalising its position on the proposed maximum level for 3-MCPD.

6. The European Community believes that a maximum level for 3-MCPD in liquid condiments containing acid-HVP should take into account dietary exposure to all potential sources of chloropropanols.

*http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/scoop_3-2-9_final_report_chloropropanols_en.pdf

**http://europa.eu.int/comm/food/fs/sc/scf/out91_en.pdf

MEXICO:

Mexico supports the maximum level of 0.4 mg/kg for 3-MCPD (3-monochloropropane-1-2-diol) in liquid condiments containing acid-HVP.

USA:

This responds to CL 2005/22-FAC (May 2005) requesting comments on a proposed draft maximum level (ML) of 0.4 mg/kg for 3-monochloropropane-1,2-diol (3-MCPD) in liquid condiments containing acid-hydrolyzed vegetable protein (acid-HVP) (excluding naturally fermented soy sauce). The United States of America appreciates the opportunity to provide the following comments for consideration at the forthcoming 38th Session of the Codex Committee on Food Additives and Contaminants.

The United States supports the establishment of a ML for 3-MCPD in liquid condiments containing acid-HVP (excluding naturally fermented soy sauce). We would not object to the proposed ML of 0.4 mg/kg for 3-MCPD in liquid condiments containing acid-HVP (excluding naturally fermented soy sauce). The proposed ML of 0.4 mg/kg on a liquid basis presuming a level of 40 percent solids would be consistent with the Food Chemicals Codex specification limit of 1 mg/kg 3-MCPD (on a dry basis) for acid hydrolysates of proteins, which includes acid-HVP.

AIIBP/FAIBP:

AIIBP/FAIBP has been informed that comments to the Proposed Draft Code of Practice for the Reduction of Chloropropanols in Acid-HVPs are requested until 30 September 2005.

With regard to our letter of 29 September 2004 (revised version) we would like to announce a description of the production of acid-HVP and the steps to reduce 3-MCPD to underline our suggestion to introduce a limit of 1 mg/kg für liquid HVP (40 % dry matter).

When producing HVP, different vegetable, protein raw materials are macerated according to a given formula and are phased out to amino acids. The hydrolysis is carried out under high temperature and pressure with hydrochloric acid. This step produces among others 3-MCPD as a follow-up product of lipids - fats in protein carriers - that are exposed to a rather strong heat treatment. In order to reduce the MCPD content, the product is taken out of the acid sphere and is introduced in the alkali sphere. In the alkali sphere, the hydrolysate is strongly heated and after a defined period of time again taken into the acid sphere.

This production process has negative effects on HVP, whereas despite the MCPD content being reduced, a loss respectively a destruction of significant taste components and amino acids can occur. A simple increase of the limits would enable a much more gentle production process, destroying less amino acids and having a positive impact on the sensory qualities of HVP.

According to our above mentioned letter of 29 September 2004 and based on a study of JECFA (Joint FAO/WHO Expert Committee on Food Additives) an increase of the 3-MCPD limit to 1 mg/kg would not be harmful to consumer health. If necessary, we would like to give a more detailed description of the production and especially the MCPD reduction process to show how quality and taste of the product can be increased by limiting the 3-MCPD content to 1 mg/kg.

IHPC:

The International Hydrolyzed Protein Council (IHPC) is an international non-governmental organization with headquarters in Washington, D.C. and represents manufacturers, users, or sellers of hydrolyzed proteins throughout the world. Hydrolyzed proteins include acid-hydrolyzed vegetable proteins (acid-HVPs), autolyzed yeasts and yeast extracts.

IHPC supports the establishment by the Codex Committee on Food Additives and Contaminants (CCFAC) of a safe, reasonable, and achievable maximum level for 3-monochloropropane-1,2-diol (3-MCPD). For the reasons discussed in the attached position paper, IHPC applauds CCFAC for proposing a draft maximum level of 0.4 mg/kg for 3-MCPD in liquid condiments containing acid-HVPs (excluding naturally fermented soy sauce). Such an internationally harmonized maximum level is supported by the available scientific and analytical data and will facilitate important international trade in acid-HVPs and products made from acid-HVPs.

IHPC Supports a Maximum Level of 0.4 mg/kg for 3-MCPD in Liquid Condiments Containing Acid-HVPs (Excluding Naturally Fermented Soy Sauce)

a. Executive Summary

IHPC supports the decision taken at the 37th Session of CCFAC to propose a draft maximum level of 0.4 mg/kg for 3-MCPD in liquid condiments containing acid-hydrolyzed vegetable proteins (acid-HVPs) (excluding naturally fermented soy sauce). The establishment of this internationally harmonized maximum level for 3-MCPD will provide protection for consumers, while facilitating important international trade in liquid condiments that might contain 3-MCPD. IHPC urges CCFAC ultimately to adopt a maximum level that is safe, reasonable, and achievable in all countries and based on the safety assessment performed by JECFA.

The available scientific data support the establishment of a maximum level of 0.4 mg/kg for 3-MCPD (liquid basis) in liquid condiments containing acid-HVPs. JECFA (2001) stated that 3-MCPD from soy sauce is the prime contributor to its intake. 3-MCPD can be present at significant levels in soy sauces made from an acid-HVP that has not been manufactured by a process designed to reduce 3-MCPD levels. In making its intake assessment, JECFA assumed that all soy sauces would contain 3-MCPD. The JECFA assessment is conservative because JECFA recognized that 3-MCPD is not found in fermented soy sauces. This issue has been adequately addressed by the exclusion of naturally fermented soy sauces from the proposed maximum level.

b. CCFAC Should Establish a Maximum Level for 3-MCPD in Liquid Condiments Containing Acid-HVPs

IHPC has long supported the establishment of a science-based maximum level for 3-MCPD. Indeed, IHPC initiated the process that resulted in the December 1997 publication by the *Food Chemicals Codex* (FCC) of an Acid Hydrolysates of Protein monograph that contains a specification for 3-MCPD. The FCC specification is:

1 mg/kg 3-MCPD on a dry substance basis (dsb) equivalent to 0.4 mg/kg on a liquid basis

The proposed product category, “liquid condiments containing acid-HVPs (excluding naturally fermented soy sauce),” adequately covers the liquid products, including most soy sauces, in which 3-MCPD has the potential to be present. As mentioned previously, JECFA recognized that 3-MCPD is not found in fermented soy sauces. We reiterate our support for the proposed draft maximum level of 0.4 mg/kg for 3-MCPD on a liquid basis presuming a level of 40 percent solids, which would be consistent with the FCC specification limit of 1 mg/kg 3-MCPD (on a dry substance basis).

c. JECFA (2001) Intake Assessment Supports the Establishment of a Maximum Level of 0.4 mg/kg (Liquid) 3-MCPD in Liquid Condiments Containing Acid-HVPs

JECFA is the scientific body recognized by Codex to conduct safety evaluations for the purpose of Codex standards, guidelines, MRLs and recommendations on food safety. At its 2001 meeting, JECFA established the following intake for 3-MCPD:

provisional maximum tolerable daily intake (PMTDI) of 2 µg/kg bw [120 µg per 60 kg person per day].

JECFA estimated the dietary intake from 3-MCPD in 2001 using the data and information supplied by Australia, the United States, the United Kingdom and Japan. JECFA reported that 3-MCPD has been detected in concentrations in excess of 1 mg/kg in only two food ingredients: acid-HVPs and soy sauce. JECFA reported that a survey of savory foods found detectable levels of 3-MCPD in about 30% of the samples with a mean residual concentration in these foods of 0.012 mg/kg. JECFA assumed that up to 1/8th of the diet (180 grams on the basis of a 1500 gram diet) would contain savory foods that contained 3-MCPD (*i.e.*, foods that contain acid-HVPs as ingredients or that otherwise contain 3-MCPD). JECFA estimated the intake of 3-MCPD from these savory foods to be 2 µg/person/day, which is well below the PMTDI of 120 µg/person/day.

A survey of 90 commercially available samples of soy sauce revealed an average level of 3-MCPD of 18 mg/kg. JECFA considered the results of this survey to be representative of all soy sauces for purposes of its intake assessment and used 18 mg/kg when estimating exposure to 3-MCPD from soy sauces. Australia, Japan and the United States provided data on soy sauce consumption levels. The chart below summarizes the JECFA calculations on 3-MCPD exposure from soy sauce and also identifies the significant reduction on 3-MCPD exposure that could be achieved through the establishment of a maximum level of 0.4 mg/kg in soy sauce.

Comparison of JECFA Exposure Estimates of 3-MCPD From Soy Sauce with Exposures From a Maximum Level of 0.4 mg/kg 3-MCPD			
<u>Underlined Values Exceed PMTDI (120 µg/60 kg person/day)</u>			
	Reported Soy Sauce Intake (g/person/day)	JECFA Estimated Exposure (18 mg/kg 3-MCPD)	Exposure from Proposed Maximum Level (0.4 mg/kg 3-MCPD)
United States			
Mean	8 g	<u>140 µg</u>	3.2 µg
90th	16 g	<u>290 µg</u>	6.4 µg
Australia			
Mean (11 g/p/day)	11 g	<u>200 µg</u>	4.4 µg
90 th (or 95 th ?)*	35 g	<u>630 µg</u>	14 µg
Japan			
Mean	30 g	<u>540 µg</u>	12 µg
95 th (estimated at twice the mean)	60 g	<u>1100 µg</u>	24 µg
*JECFA reports 35 grams as the 95th percentile for consumption but then reports 3-MCPD exposure for the 90 th percentile.			

The PMTDI for 3-MCPD is exceeded on the basis of the mean soy sauce consumption values for each of the countries reporting when it is assumed that all soy sauce consumed would contain 18 mg/kg 3-MCPD. These data underscore the importance of setting a maximum level for 3-MCPD to protect consumers of soy sauces (and other liquid condiments containing acid-HVPs). Because the intake of 3-MCPD is dominated by the consumption of soy sauces, JECFA concluded that “a regulatory limit on the concentration of 3-chloro-1,2-propanediol in soya sauce could markedly reduce the intake by soya sauce consumers.” A maximum level of 0.4 mg/kg in all liquid condiments containing acid-HVPs would bring 3-MCPD consumption levels far below the 120 ug/person/day PMTDI established by JECFA (2001).

A maximum level of 0.4 mg/kg 3-MCPD in liquid condiments containing acid-HVPs would be consistent with the JECFA recommendation for the following reasons:

- a) JECFA assumed that up to 1/8 of the diet (180 g based on a 1500 gram diet) would contain savory foods made from acid-HVPs. If all such foods contain the maximum level of 3-MCPD, an assumption that is highly conservative and very likely to occur, such foods would contribute 72 µg 3-MCPD per day.

$$(180 \text{ g food/day})(0.4 \text{ mg 3-MCPD}/1000 \text{ g food}) = 72 \text{ µg 3-MCPD/day}$$

- b) Japan reported the highest soy sauce intake with a mean intake of 30 grams and an estimated 95th percentile intake of 60 grams (90th percentile is not available). Using the conservative assessment that soy sauces would contain 0.4 mg/kg 3-MCPD, the mean and 95th percentile exposure for the Japanese consumer would be 12 and 24 µg/person/day, respectively.
- c) 3-MCPD intake from soy sauces and savory foods made with acid-HVPs containing 0.4 mg/kg 3-MCPD would be 84 µg/person/day for the mean Japanese consumer of soy sauces (72 µg from savory foods and 12 µg from soy sauce) and 96 µg/person/day for the 95th percentile consumer of soy sauces (72 µg from savory foods and 24 µg from soy sauce). This is an extremely conservative estimate that is provided merely to illustrate that the proposed draft maximum level for 3-MCPD in liquid condiments containing acid-HVPs would result in 3-MCPD exposure that is well within the PMTDI.

d. Conclusion

IHPC urges CCFAC to establish a safe, reasonable and achievable maximum level for 3-MCPD in liquid condiments containing acid-HVPs (excluding naturally fermented soy sauce). Data reported by JECFA (2001) and provided in this comment demonstrate that sufficient scientific evidence is available to support the establishment of this maximum level. The establishment of a maximum level will protect consumers by reducing exposure to 3-MCPD in foods made from acid-HVPs, including condiments such as soy, oyster, and Worcestershire sauces. Exposure estimates detailed in the JECFA report and the information in this comment demonstrate that a maximum level of 0.4 mg/kg (liquid basis) for liquid condiments containing acid-HVPs would result in dietary intake that would not exceed the PMTDI established for 3-MCPD.