

codex alimentarius commission



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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
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**3-MCPD ON ACID-HVPS AND ACID HVP-CONTAINING PRODUCTS
(I) PROPOSALS FOR MAXIMUM LEVELS**

(SUBMITTED IN RESPONSE TO CL 2004/9-FAC)

The following comments have been received European Community, AIIBP/FAIBP and IHPC:

EUROPEAN COMMUNITY

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. Control authorities have occasionally found 3-MCPD in soy sauces labelled as brewed which otherwise would not be expected to involve acid-hydrolysis. Therefore the maximum levels should apply to all soy sauces.

The European Community supports a maximum level for 3-MCPD of 0.02 mg/kg in HVP, in soy sauces and in other sauces produced or containing ingredients produced using acid-hydrolysis processes. The level applies to the liquid product containing 40% dry matter, corresponding to 0.05 mg/kg in the dry matter. The level needs to be adjusted proportionally according to the dry matter content of the products

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 has been shown to be widely achievable. 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 for 3-MCPD the levels of associated chloropropanols, such as 1,3 DCP, are very low and would not require separate maximum levels. Dietary intake of 3-MCPD is not only a result of acid-HVP processing and data on levels found in other foods need to be considered in the future.

*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

AIIBP/FAIBP

1. 3-MCPD

AIIBP recognises the evaluation of JECFA which indicates that the safe intake of 3-MCPD should not exceed the value of 2 µg /kg bodyweight.

Based on this AIIBP proposes to set limits for 3-MCPD in liquid HVP (40% dry matter) based on the evaluated intake of HVP's.

For the evaluation, AIIBP uses production data of HVP in Europe and stringent consumption assumptions.

The production volume of acid HVP in Europe is about constant for the last few years. The figures used in the evaluation are based on year 2000 data: 30'109'000 kg.

The intake of HVP per person uses the conservative approach that only 10% of the whole European population (380'000'000 persons) consumes HVP at all.

These assumptions lead to a daily consumption of 2.17g of HVP.

By applying the various scenarios of maximum levels of 3-MCPD in HVP's, the following results were obtained:

Intake of 3-MCPD / day		Intake of 3-MCPD (µg /kg bw/day)	
MCPD Level	3-MCPD Intake	70 kg (adult)	40 kg (child)
1.000 mg/kg	2.171 µg	0.031	0.054
0.500 mg/kg	1.085 µg	0.016	0.027
0.200 mg/kg	0.434 µg	0.006	0.011
0.100 mg/kg	0.217 µg	0.003	0.005
0.020 mg/kg	0.043 µg	0.001	0.001
0.051 ma/ka *	0.111 µg	0.002	0.003

These data clearly show that the intake of 3-MCPD through the consumption of HVP is measurable but relatively low.

Even the worst scenario with a level of 3-MCPD not exceeding 1 mg/kg and taking into account the consumption of a child of 40 kg, only 1/40th of the safe dose will be contributed by HVP.

AIIBP therefore suggest to introduce a limit of 1 mg/kg for liquid HVP (40% dry matter) for products sold to the consumer as well as for products for use as ingredient in food products.

A limit of 1 mg/kg is sufficient to fulfill all safety requirements.

2. Dichloropropanols (DCP)

AIIBP is of the opinion that the levels of DCP's can be set at 0.02 mg/kg. This opinion is

based on the fact that with proper production processes this contaminant is, if at all, always present at levels below this value which represents the current analytical limit of detection.

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-HVPs, autolyzed yeasts and yeast extracts.

IHPC submitted comments to the Thirty-sixth Session of CCFAC in March, 2004 that were made available at the meeting as CRD 12. IHPC would like to reiterate its support for the establishment by CCFAC of a safe, reasonable and achievable maximum level for 3-monochloropropane-1,2-diol (3-MCPD) in acid-hydrolyzed vegetable proteins (acid-HVPs). For the reasons discussed in the attached position paper, IHPC applauds CCFAC for making the decision to undertake new work to establish a safe maximum level for 3-MCPD in acid-HVPs. An internationally harmonized maximum level will facilitate important international trade in acid-HVPs and products made from acid-HVPs.

IHPC continues to believe that it is not necessary to establish a maximum level for 3-MCPD in soy sauces because it is the acid-HVP in soy sauces that contributes the 3-MCPD. By controlling the 3-MCPD level in acid-HVPs, the 3-MCPD level would be controlled in soy sauces and other condiments made from such acid-HVPs. If CCFAC continues to recommend establishing a maximum level for soy sauces, IHPC recommends designating the product category as “Liquid Condiments Made from Acid-HVPs.” This product category best describes the condiments that could be sources of 3-MCPD.

IHPC is of the opinion that data support the following maximum level:

0.4 mg/kg (liquid basis) of 3-monochloropropane-1,2-diol (3-MCPD) in acid-HVPs;

It is unnecessary to establish a maximum level for 3-MCPD in soy sauces. In the event that CCFAC believes that a maximum level is necessary, IHPC proposes 0.4 mg/kg (liquid basis) for the product category “Liquid Condiments Made from Acid-HVPs”;

IHPC’s Recommendations for a Maximum Level for 3-MCPD (Chloropropanol) in Acid-hydrolyzed Vegetable Proteins (acid-HVPs) and Acid-HVP containing Products

Executive Summary

IHPC welcomes the decision taken at the 36th Session of CCFAC to proceed with new work to establish a maximum level for 3-MCPD in acid-HVPs. The establishment of an internationally harmonized maximum level for 3-MCPD will provide protection for consumers, while facilitating important international trade in products that might contain 3-MCPD. If there is a need to establish a maximum level for dietary sources of 3-MCPD other than acid-HVP containing products, this work could be considered at a later date when sufficient information is available. However, various countries have already established different maximum levels for 3-MCPD in acid-HVP and soy sauce. These maximum levels are not based on the recommendations of JECFA and they are resulting in disharmony in trade. IHPC urges CCFAC to adopt a maximum level that is safe, reasonable and achievable in all countries and based on the safety assessment performed by JECFA.

JECFA (2001) stated that 3-MCPD from soy sauce is the prime contributor to its intake. 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. 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. By establishing a maximum level for 3-MCPD in the acid-HVPs, CCFAC will be controlling the levels in foods such as soy sauces and other liquid condiments that are made from acid-HVPs. The available scientific data provides information that can be used to establish a maximum level for 3-MCPD in acid-HVPs. These data support the establishment of the following maximum level:

0.4 mg/kg (liquid basis) of 3-MCPD in acid-HVPs;

Although IHPC considers it unnecessary, CCFAC also could establish a maximum level of 0.4 mg/kg (liquid basis) for “Liquid Condiments made from Acid-HVPs);

CCFAC Should Establish a Maximum Level for 3-MCPD in 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

In the past few years, the establishment of a maximum level for 3-MCPD has become a high priority for many regulatory bodies worldwide, and it is important that CCFAC has decided to establish a Codex maximum level in order to help bring about harmonization. Because some reports have indicated high levels of 3-MCPD in some soy sauces that are made from acid-HVPs, either final or interim maximum levels have been adopted in the European Union, Australia, New Zealand, Korea, Malaysia and the United States (through the listing in the Food Chemicals Codex monograph). The chart below demonstrates that there is tremendous variability in the maximum levels that have been established.

Comparison of Existing Maximum Levels for 3-MCPD		
Country/Region	3-MCPD (mg/kg)	
	HVP	Soy Sauce
Australia and New Zealand	--	0.2 (NS*)
Canada (Interim Guideline)	--	1.0 (NS*)
European Community	0.02 (liquid)	0.02 (liquid)
Korea	1 (NS*)	0.3 (NS*)
Malaysia**	1 (NS*)	--
United States and FCC	0.4 (liquid)	--
*Not Specified—the available information does not specify whether the maximum level is on a liquid or dried basis.		
**Malaysia also has established a maximum level of 0.02 mg/kg 3-MCPD in foods containing acid hydrolyzed proteins.		

It Is Unnecessary to Establish a Maximum Level for Soy Sauces.

IHPC does not believe it is necessary to establish a maximum level for soy sauces. Many liquid condiments, such as certain soy sauces, oyster sauces and Worcestershire sauces, are made with acid-HVPs. It is the acid-HVP in these liquid condiments that is primarily responsible for the presence of 3-MCPD. While soy sauces made with acid-HVPs can have detectable levels of 3-MCPD, JECFA recognized that fermented soy sauces do not contain 3-MCPD. If CCFAC sets a maximum level for “soy sauces,” it would be establishing a maximum level that is unnecessary for fermented soy sauces and would be overlooking other liquid condiments that could have detectable levels of 3-MCPD. The product category, “Liquid Condiments Made from Acid-HVPs,” would cover those liquid condiments where 3-MCPD has the potential to be present.

JECFA (2001) Intake Assessment Supports the Establishment of a Maximum Level of 0.4 mg/kg (liquid) 3-MCPD in 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 1/8 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. 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.”

The establishment of a maximum level of 0.4 mg/kg 3-MCPD (liquid) in acid-HVPs would result in significant decreases in the dietary exposure to 3-MCPD because soy sauces made from such acid-HVPs would have less than 0.4 mg/kg 3-MCPD (liquid). A maximum level of 0.4 mg/kg (liquid) would bring 3-MCPD levels far below the 120 µg/person/day PMTDI established by JECFA (2001).

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

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 the acid-HVPs in such foods are used at the maximum use level of 2.50 percent (liquid or 1.0 percent for dry acid-HVPs), such foods would contribute only 1.8 µg 3-MCPD per day.

$$(180 \text{ g food/day})(2.5\%)(0.4 \text{ mg 3-MCPD}/1000 \text{ g food}) = 1.8 \text{ µg 3-MCPD/day}$$

This 1.8 µg 3-MCPD/day is supported by the JECFA conclusion that savory foods would contribute 2 µg/person/day.

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). A soy sauce will contain less than 0.4 mg/kg 3-MCPD when made from an acid-HVP with less than 0.4 mg/kg 3-MCPD. Nonetheless, 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.

3-MCPD intake from soy sauces and savory foods made with acid-HVPs containing 0.4 mg/kg 3-MCPD would be 14 µg/person/day for the mean Japanese consumer of soy sauces (2 µg from savory foods and 12 µg from soy sauce) and 26 µg/person/day for the 95th percentile consumer of soy sauces (2 µg from savory foods and 24 µg from soy sauce).

CONCLUSION: The establishment of a maximum level of 0.4 mg/kg 3-MCPD in acid-HVPs would result in 3-MCPD exposure from savory foods and soy sauce that is well within the PMTDI.

The following examples identify worst case scenarios for dietary exposure and are based on a 60-kilogram person that is consuming 60 grams of soy sauce (*i.e.*, the 95th percentile of soy sauce consumption in Japan—the highest country reporting) and a diet that contains 180 grams of savory foods. 1/ These calculations assume that the individual is consuming exclusively soy sauces made from acid-HVPs, a conservative assessment given the widespread use of fermented soy sauces in Japan.

Example 1:	3-MCPD (micrograms)
60 grams of soy sauce containing 0.4 mg/kg 3-MCPD	24
JECFA estimate of 3-MCPD for 1/8 of diet (180 grams) containing savory foods w/conc. 3-MCPD of 0.4 mg/kg at 2.5% use level.	2
Total:	26
Example 2:	
60 grams of soy sauce containing 0.4 mg/kg 3-MCPD	24
JECFA estimate of 3-MCPD for 1/8 of diet (180 grams) containing savory foods w/conc. of 3-MCPD of 0.4 mg/kg at 2.5% use level.	2
7/8 of diet (1320 g) contains acid-HVP with 0.4 mg/kg 3-MCPD at a maximum use level of 2.5 percent.	13
Total:	39
Example 3:	
60 grams of soy sauce containing 0.4 mg/kg 3-MCPD	24
JECFA estimate of 3-MCPD for 1/8 of diet (180 grams) containing savory foods w/conc. of 3-MCPD of 0.4 mg/kg at 2.5% use level.	2
1/8 of diet (180 grams) contains food (other than savory food) with 0.4 mg/kg 3-MCPD	72
Total:	98
Example 4:	
60 grams of soy sauce containing 0.4 mg/kg 3-MCPD	24
JECFA estimate of 3-MCPD for 1/8 of diet (180 grams) containing savory foods w/conc. 0.4 mg/kg 3-MCPD at 2.5% use level.	2
The remaining 7/8 of the food in the diet (1320 grams) could contain 3-MCPD at a level of 0.071 mg/kg (the conc. needed in order to reach the PMTDI of 120 ug/person/day).	94
Total:	120

These four examples demonstrate that it is almost impossible to exceed the PMTDI when a maximum level of 0.4 mg/kg (liquid) 3-MCPD is established for acid-HVPs and soy sauce.

Example 1 provides the most realistic "worst case" scenario and establishes that an individual would consume only 26 micrograms of 3-MCPD when consuming 60 grams of soy sauce and 180 grams of savory foods that are formulated with acid-HVP.

Example 2 shows that, even if all foods in that individual's diet contained acid-HVPs at a maximum use level of 2.5 percent, the total intake of 3-MCPD would only be 39 micrograms.

Examples 3 and 4 demonstrate that even if further data reveal additional foods that are sources of 3-MCPD, it would be highly improbable that the presence of the food or food ingredient in the diet would exceed the PMTDI, particularly given the JECFA conclusion that 3-MCPD "is found infrequently in foods." Under Example 3, this food could be present in up to 1/8th of the diet and have a maximum level of 0.4 mg/kg 3-MCPD, and the PMTDI would not be exceeded for an individual that is in the highest consumption group for soy sauce and in addition has a diet that is 1/8th savory foods containing a maximum level of 0.4 mg/kg 3-MCPD.

1/ The PMTDI for a 60 kg person is 120 micrograms 3-MCPD

Example 4 shows that all other non-savory foods in the diet (i.e., 7/8th of the diet) could contain up to 0.071 mg/kg 3-MCPD without exceeding the PMTDI. This demonstrates that, although additional sources of 3-MCPD may be identified, it is reasonable to conclude that these foods will not have 3-MCPD levels and/or be present in the diet at a level that would exceed the PMTDI.

Conclusion

IHPC urges CCFAC to establish a safe, reasonable and achievable maximum level for 3-MCPD in acid-HVPs. 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 acid-HVPs would bring intake levels down, and intake would not exceed the PMTDI established for 3-MCPD.