

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 14 (e)

CX/FAC 06/38/32-Add. 1
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(English only)

**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: European Community, Japan and AIBP/FAIBP

EUROPEAN COMMUNITY:

The European Community (EC) refers and reiterates its comments as mentioned in CX/FAC 06/38/32.

The EC notes that a draft Code of Practice for the Reduction of Chloropropanols in acid hydrolysed vegetable protein (HVP) and products that contain acid-HVPs is currently under discussion at CCFAC.

The EC 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. 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.

Taking into account the comments made by other member countries on this issue in CCFAC, the EC is in favour of finding a common solution which meets to a large extent the concerns and comments made by the different member countries.

Therefore, the EC is in a position **to accept a level of 0.1 mg/kg for 3-MCPD in liquid condiments containing HVPS**. For reasons outlined in the document CX/FAC 06/38/32, the exception clause “excluding naturally fermented soy sauce” should be deleted.

For **any level higher than 0.1 mg/kg for 3-MCPD in liquid condiments containing HVPS** which is put forward for consideration at CCFAC, **the EC is of the opinion** that it is **necessary to demonstrate that such a higher level is the lowest level reasonably achievable by applying good practices**.

Furthermore the EC fully agrees with the recommendations mentioned in the discussion paper on ACID-HVP containing products and other products containing chloropropanols (CX/FAC 06/38/33, § 61-62).

JAPAN:

1. 3-MCPD concentration in acid-HVPs and products manufactured with those, which are produced/not produced in accordance with code of practice for reducing chloropropanol levels

Table 1 and Fig. 1 in the annex show the analytical results of 3-MCPD in acid-HVPs obtained from “well-controlled production processes” (acid-HVP-C) while Table 2 and Fig. 2 show those from other production processes (acid-HVP-NC). In the “well-controlled production processes”, the pH, temperature, heating time of acid hydrolysis and subsequent alkaline treatment are controlled in accordance with one of the methods presented in the proposed draft code of practice for the reduction of chloropropanols in acid-HVPs and products that contain acid-HVPs(CX/FAC 06/38/31).

Analyzing the 3-MCPD concentration in acid-HVP-C and acid-HVP-NC by the U-test of Mann-Whitney and Z-test confirmed that these samples do not belong to the same population ($P < 0.05$). Samples of acid-HVP-C gave significantly lower 3-MCPD concentrations with median, mean and SD at 0.049, 0.047 and 0.026 mg/kg respectively. On the other hand, samples of acid-HVP-NC, although the number of samples is too small at 9, gave significantly higher 3-MCPD concentration with median, mean and SD at 2.7, 8.4 and 14 mg/kg.

Table 3 and Fig.3 in the annex show the analytical results of 3-MCPD in soy sauce manufactured with acid-HVPs which were either purchased from outside suppliers (soy sauce-O) or produced in the same factory as soy sauce (soy sauce-I).

Analyzing the 3-MCPD concentration in soy sauce-O and soy sauce-I by the U-test of Mann-Whitney and Z-test confirmed that these samples do not belong to the same population ($P < 0.05$). Samples (n=110) of soy sauce-O gave significantly lower 3-MCPD concentrations with median, mean and SD at 0.016, 0.017 and 0.008 mg/kg respectively. On the other hand, the analytical results of 3-MCPD in soy sauce-I, although the number of sample is limited at ten, indicate that those of soy sauce with internally produced acid-HVP contain significantly higher 3-MCPD.

The analytical results of 3-MCPD in acid-HVP-C (median, 0.049 mg/kg; mean, 0.047 mg/kg; SD, 0.026 mg/kg) and that in soy sauce-O (median, 0.016; mean, 0.017 mg/kg; SD, 0.008 mg/kg; n=110) indicate clearly that the maximum levels at 0.02 mg/kg is not achievable. From this fact, we believe that we should consider a maximum level(s) by applying the ALARA principle to data on 3-MCPD in acid-HVPs and in soy sauce manufactured with acid-HVPs.

2. Information on traditionally fermented soy sauce

Table 4 and Fig. 4 in the annex show the analytical results of 3-MCPD in traditionally fermented soy sauce.

Traditionally fermented soy sauce is produced without using acid-HVPs. As expected, the analytical results of traditionally fermented soy sauce show that 3-MCPD is either not quantifiable or contained at very low level (maximum, 0.008 mg/kg). An investigation into potential cause of 3-MCPD above the limit of quantitation (0.004 mg/kg) in certain products indicated a possibility of contamination of 3-MCPD from the use of the same tanks and hoses in the factory for producing both traditionally fermented soy sauce and soy sauce with acid-HVPs as an ingredient. The situation can be improved by enforcing good manufacturing practice in the factory and confirming no or very little 3-MCPD by analysis.

Annex

(1) Acid-HVPs (from well-controlled production processes)

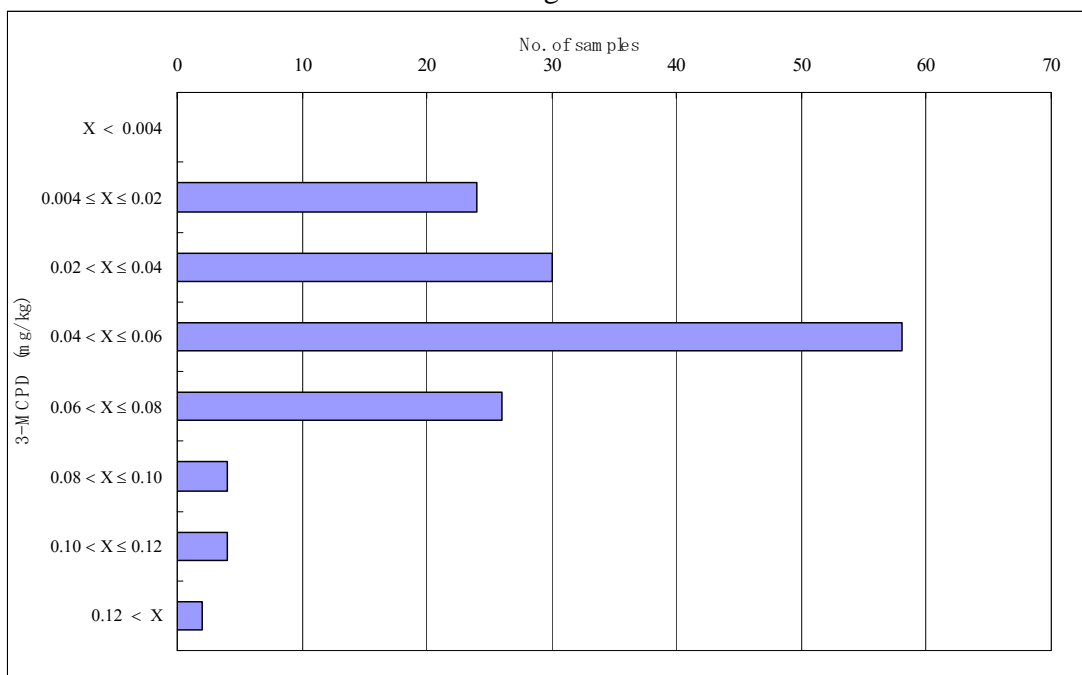
Table.1

Total number of samples	Minimum concentration (µg/kg)	Maximum concentration (µg/kg)	Median (µg/kg)	Average (µg/kg)
148	0.004	0.14	0.049	0.047

Concentration (µg/kg)	No. of samples	Ratio (%)	Cumulative No. of samples	Ratio (%)
X < 0.004	0	0%	0	0%
0.004 ≤ X ≤ 0.02	24	16%	24	16%
0.02 < X ≤ 0.04	30	20%	54	36%
0.04 < X ≤ 0.06	58	39%	112	76%
0.06 < X ≤ 0.08	26	18%	138	93%
0.08 < X ≤ 0.10	4	3%	142	96%
0.10 < X ≤ 0.12	4	3%	146	99%
0.12 < X	2	1%	148	100%

X = concentration

Fig.1



n=148

2) Acid-HVPs from other production processes)

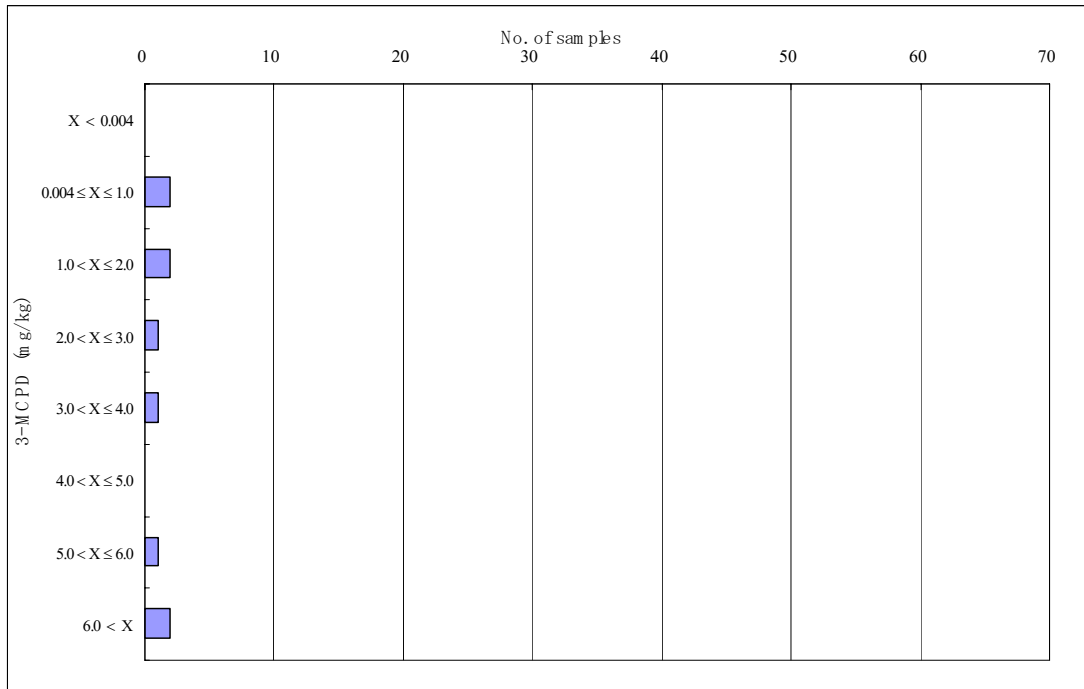
Table.2

Total number of samples	Minimum concentration (µg/kg)	Maximum concentration (µg/kg)	Median (µg/kg)	Average (µg/kg)
9	0.1	44	2.7	8.4

Concentration (µg/kg)	No. of samples	Ratio (%)	Cumulative No. of samples	Ratio (%)
X < 0.004	0	0%	0	0%
0.004 ≤ X ≤ 1.0	2	22%	2	22%
1.0 < X ≤ 2.0	2	22%	4	44%
2.0 < X ≤ 3.0	1	11%	5	56%
3.0 < X ≤ 4.0	1	11%	6	67%
4.0 < X ≤ 5.0	0	0%	6	67%
5.0 < X ≤ 6.0	1	11%	7	78%
6.0 < X	2	22%	9	100%

X = concentration

Fig.2



n=9

(3) Soy sauce (made with Acid-HVPs)

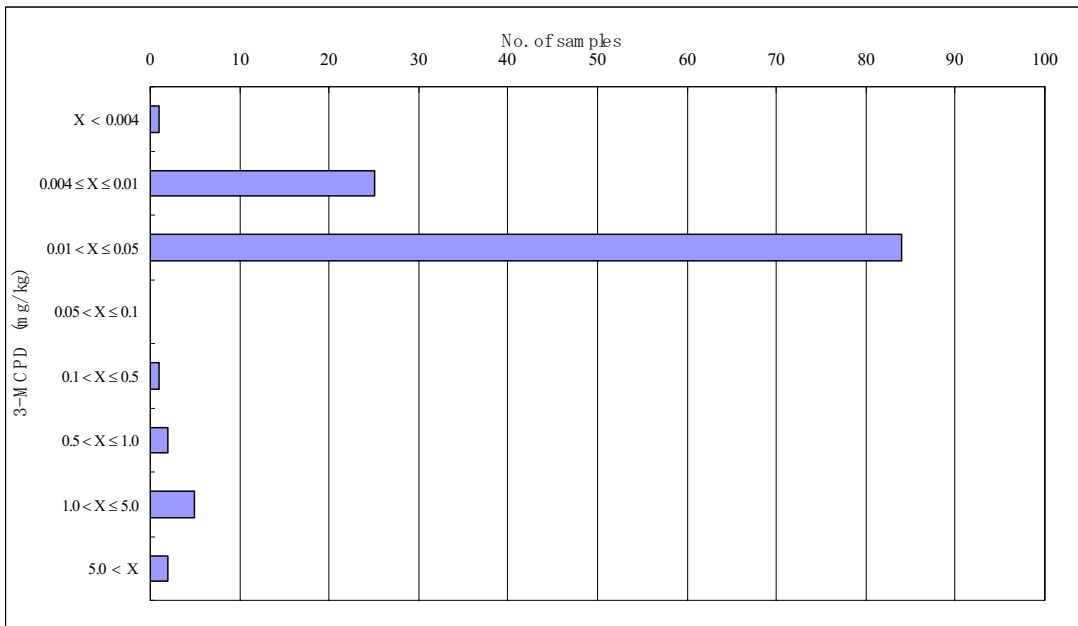
Table.3

Total number of samples	Minimum concentration (µg/kg)	Maximum concentration (µg/kg)	Median (µg/kg)	Average (µg/kg)
120	< 0.004	7.8	0.016	0.21

Concentration (µg/kg)	No. of samples	Ratio (%)	Cumulative No. of samples	Ratio (%)
X < 0.004	1	1%	1	1%
0.004 ≤ X ≤ 0.01	25	21%	26	22%
0.01 < X ≤ 0.05	84	70%	110	92%
0.05 < X ≤ 0.1	0	0%	110	92%
0.1 < X ≤ 0.5	1	1%	111	93%
0.5 < X ≤ 1.0	2	2%	113	94%
1.0 < X ≤ 5.0	5	4%	118	98%
5.0 < X	2	2%	120	100%

X = concentration

Fig.3



n=120

(4) Soy sauce (from traditional fermentation)

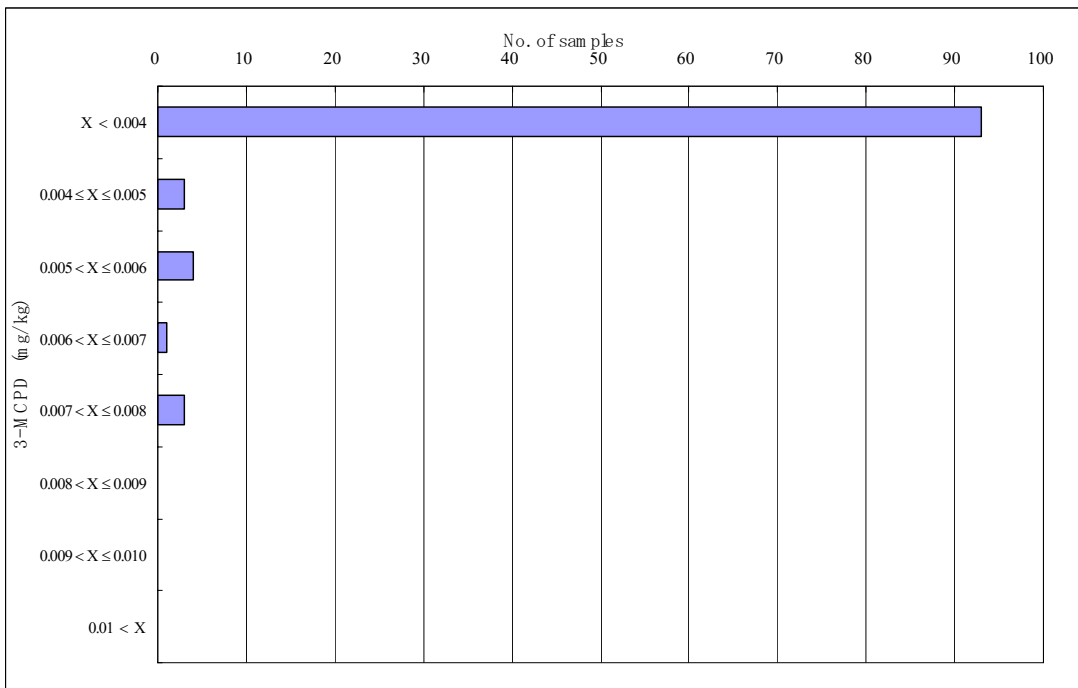
Table.4

Total number of samples	Minimum concentration (µg/kg)	Maximum concentration (µg/kg)	Median (µg/kg)	Average (µg/kg)
104	< 0.004	0.008		

Concentration (µg/kg)	No. of samples	Ratio (%)	Cumulative No. of samples	Ratio (%)
X < 0.004	93	89%	93	89%
0.004 ≤ X ≤ 0.005	3	3%	96	92%
0.005 < X ≤ 0.006	4	4%	100	96%
0.006 < X ≤ 0.007	1	1%	101	97%
0.007 < X ≤ 0.008	3	3%	104	100%
0.008 < X ≤ 0.009				
0.009 < X ≤ 0.010				
0.01 < X				

X = concentration

Fig.4



n=104

AIIBP/FAIBP:

Further to our statement of 29 September 2005 we would like to point out two items of concern for the European producers of acid hydrolysed vegetable protein (HVP):

- The description of the production process given in our letter of 29 September 2005 shows that efforts have to be made to reduce the levels of chloropropanols to the current limit of 0.02 mg/kg. Nevertheless the products manufactured according to the state of technology are tasty and well accepted by customers. HVP producers in Europe do not intend to change the production process if legal provisions change to an increased maximum level of 3-MCPD.
- The JECFA (2001) Intake Assessment justifies a maximum level of 0.4 mg/kg (liquid). Reference is made to the explanations in the IHPC statement (CX/FAC 06/38/32). The European HVP producers welcome the justification of a level of 0.4 mg/kg as being safe to consumers. This proves and underlines the highest quality and safety of HVP produced under EU legislation.

We would appreciate this additional statement being distributed to the members of the Thirty-Eight Session of the Codex Committee on Food Additives and Contaminants in The Hague.