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

Thirty-eighth Session

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PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF CHLOROPROPANOLS IN ACID-HYDROLYSED VEGETABLE PROTEINS (ACID-HVPs) AND PRODUCTS THAT CONTAIN ACID-HVPs

(N09-2005)

At Step 3 of the Procedure

(prepared by United Kingdom with the assistance of Australia, Canada, China, European Community, Japan, Republic of Korea, Thailand, United States and IHPC)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at on the following subject matter are invited to do so **no later than 31 March 2006** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature and Food Quality, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl - ***preferably***), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org - ***preferably***).

BACKGROUND

1. At the 37th Session of the Codex Committee on Food Additives and Contaminants (CCFAC), the United Kingdom assisted by Australia, Canada, China, European Community, Japan, Republic of Korea, Thailand, United States and International Hydrolyzed Protein Council, (IHPC), agreed to prepare a draft Code of Practice for the reduction of chloropropanols in acid-hydrolysed vegetable proteins and products that contain acid-HVPs. The paper would be circulated for comments at step 3 and further considered at its next session.

2. The range of soy-based condiments that are potentially susceptible to chloropropanol contamination is large, and includes soy sauce, dark soy sauce, light soy sauce, mushroom soy sauce, oyster sauce, reduced soy sauce, seasoning sauce, shrimp-flavoured soy sauce, thick soy sauce and teriyaki sauce. It is evident from the recent Scientific Cooperation (SCOOP) exercise[20.4] that the levels of 3-monochloropropane 1,2-diol (3-MCPD) within each of these categories vary widely. For example, for each category where more than ten samples were analysed, a significant proportion of samples did not contain detectable amounts of 3-MCPD. However, all these categories also contained some samples with 3-MCPD levels in excess of the 0.02 mg/kg maximum limit permitted in the European Community. The fact that in most samples 3-MCPD was not detected, clearly reflects the extent to which acid-HVP and soy sauce manufacturers have implemented the necessary procedures to minimise 3-MCPD formation.

3. The Code of Practice is being developed as a means of disseminating best practice to assist manufacturers, particularly in developing countries, to take action to reduce the levels of 3-MCPD in their products. Information in the Code was obtained initially from the literature and from Internet searches. The draft Code of Practice has been circulated to members of the drafting group. Although several comments have been received there are still areas where insufficient information is available, especially with regard to commercial scale production as opposed to laboratory experiments.

4. It is acknowledged that detailed descriptions of manufacturing processes used by industry are confidential but information outlining the procedures that are currently used to reduce 3-MCPD levels in HVP production are needed. The Code of Practice needs to include indicative details of the critical parameters if it is to be effective.

5. More information is requested, in particular in the following areas:

- preparation of the raw material
- control of the acid hydrolysis step
- use of a subsequent alkaline treatment and how it can be applied.

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF CHLOROPROPANOLS IN ACID-HYDROLYSED VEGETABLE PROTEINS (acid-HVPs) AND PRODUCTS THAT CONTAIN ACID-HVPs

(N09-2005)

(at Step 3 of the Elaboration Procedure)

INTRODUCTION

1. Chloropropanols are contaminants that are formed during the processing and manufacture of certain foodsand ingredients. They were originally discovered[20.1] in acid hydrolysed vegetable protein (acid-HVP) in the 1980s. Subsequent research in the 1990s revealed their presence in soy sauces manufactured using acid-HVP as an ingredient[20.2].

2. The occurrence of chloropropanols in acid-HVP arises from their formation during the hydrochloric acid mediated hydrolysis step of the manufacturing process[20.3]. During this hydrolytic stage the acid also reacts with residual lipids present in the defatted meal from oil seeds such as soyabean and other plant materials utilised, resulting in the formation of chloropropanols.

3. In addition to the direct usage of acid-HVP as an ingredient, chloropropanols may also be formed in those soy sauces, and related condiments, where the manufacturing process of the sauce itself includes hydrochloric acid treatment of soybean meal. As with acid-HVP the mode of formation also involves acidic hydrolysis of residual lipids.

4. A range of techniques may be employed in the manufacture of soy sauces. Products made exclusively by means of fermentation generally do not contain chloropropanols or if present, they only occur in trace amounts. It is those products that utilise acid-HVP as an ingredient that may contain chloropropanols. Soy sauces, and related products, that are subject to acid treatment during manufacture may contain chloropropanols .

5. 3-MCPD is generally the most widely occurring chloropropanol in food, It exists as a racemic mixture of (R) and (S) isomers[20.7]. The other chloropropanols that can occur, albeit usually in smaller amounts, are 2-monochloropropane-1,3-diol (2-MCPD), 1,3-dichloro-2-propanol (1,3-DCP) and 2,3-dichloro-2-propanol (2,3-DCP).

6. The presence of chloropropanols in food is of concern due to their toxicological properties. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered chloropropanols in June 2001 and assigned[20.8] a provisional maximum tolerable daily intake (PMTDI) for 3-MCPD of 2 μg/kg bw/day.

7. Chloropropanols have also been detected in a range of other foods that are not subject to acid hydrolysis during manufacture. These include processed fruits and vegetables, cereals and bakery products, processed meats, smoked fish and beer[20.4]. Chloropropanols have also been observed in food ingredients known not to involve acid hydrolysis of vegetable proteins during production; examples of such ingredients include meat extracts, malts, modified starches and seasonings. Recent studies[20.5] have shown that production of chloropropanols in these foods and ingredients, is promoted by high temperatures and low water content. Manufacture of these products is not covered by this Code of Practice.

8. The purpose of this Code of Practice is to describe and disseminate best practice for the manufacture of acid-HVP and soy sauces and related condiments, whose production involves acid hydrolysis with the aim of facilitating a reduction in the levels of chloropropanols.

9. The following two sections of this Code of Practice describe, with respect to chloropropanol minimisation, best practice in the manufacture of acid-HVPs and also those soy sauces that are subject to an acid treatment step during manufacture.

RECOMMENDED PRACTICES BASED ON GOOD MANUFACTURING PRACTICE (GMP)

Acid-HVPs

10. Common vegetable raw materials used in the production of acid-HVP include defatted oil seeds (soy, rapeseed and peanut), and protein from maize, wheat and rice[20.13]. These are hydrolysed with hydrochloric acid ranging from below 4M to 6M, at a temperature between 100°C and 130°C for up to 8 hours, although up to 20-30 hours have been reported. After cooling, the hydrolysate is neutralised with either sodium carbonate or sodium hydroxide to a pH of 5 to 9 at a temperature between 90 – 100°C for 90 to 180 minutes and then hydrochloric acid is added to the mixture to adjust pH between 4.8 to 5.2 . The hydrolysate is filtered to remove the insoluble carbohydrate fraction, humin, and then bleached or refined. Activated carbon treatment can be employed to remove both flavour and colour components, to the required specification. Following further filtration the acid-HVP may, depending upon the application, be fortified with additional flavouring components. Thereafter the product can be stored as a liquid at 30-40% dry matter (corresponding to 2-3% total nitrogen), or alternatively it may be vaccuumed, spray-dried, or steamed and stored as a solid (80-85% dry matter).

11. Two main approaches may be adopted to minimise the concentration of 3-MCPD in the final product. The first of these involves careful control of the acid hydrolysis step and the subsequent neutralisation to minimise 3-MCPD formation. The alternative strategy entails destroying the 3-MCPD formed during acid hydrolysis by employing a subsequent, alkaline treatment stage[20.7]. Both of these processes require close control to minimise 3-MCPD formation US and at the same time, prevent the occurrence of undesirable flavour components[20.14]. Manufacturers employ either or both of these strategies to minimise 3-MCPD and HVP in a production line.

12. Some manufacturers of acid-HVP have stated that, whilst it is technically possible to reduce 3-MCPD levels to below 0.1 mg/kg, the organoleptic qualities of such products are adversely affected[20.15,20.16]. Some producers of acid-HVP containing soy sauces stated that the flavour and taste (umami) directly reflect the quality of the acid-HVP. This is particularly true in aged acid –HVP products. 47 of the 56 commercially available acid-HVP samples reported in the SCOOP task[20.4], had 3-MCPD levels below 0.1 mg/kg. This suggests that it is in fact quite feasible to produce organoleptically acceptable acid-HVP with 3-MCPD levels below 0.1 mg/kg.

13. Actions taken to reduce 3-MCPD formation have an impact on organoleptic quality of the HVP. The challenge is for the manufacturers is to optimise the product. Parameters need to be optimised in order to balance the trade off between low 3-MCPD levels and the organoleptic quality.

14. With regard to the first strategy, the temperature and the heating time of the acid hydrolysis step must be simultaneously controlled and careful attention paid to the reaction conditions in the subsequent neutralisation step. Typically the hydrochloric acid concentration needs to be approximately 20% lower than that used in older procedures. Since the total nitrogen content of a typical raw material (defatted soybeans) varies between 7.8 and 8.0% wet weight basis, the hydrochloric acid concentration should be adjusted to achieve a hydrochloric acid/total nitrogen ratio of 1.0 to 1.3 in commercial practice for obtaining products of even quality. After the hydrolysis stage the solution should be neutralised promptly[20.17].

15. Alternatively, the 3-MCPD that is formed during the acid hydrolysis step may be removed by subsequent alkaline treatment. Laboratory-based studies[20.14] have described an investigation in which the neutralised acid hydrolysate of defatted soybean was treated with 4M sodium hydroxide, to achieve a pH of 6.5, 7.5, 8.5 or 9.5, and then heated at 100°C for one or more hours, prior to cooling and neutralisation to pH 5.5 with 4M hydrochloric acid. The resulting solutions were analysed for 3-MCPD content and intensity of off-flavour. Those samples heated at pH 8.5 for 2 hours at 100°C had levels of 3-MCPD below the 0.002 mg/kg limit of detection (dry weight), together with the lowest intensity of off-flavours. In the industrial scale manufacture, alkaline treatment should be conducted at a pH of 8 to 9 and a temperature of 90-100°C for 90 to 180 min. This may require the addition of more water, which subsequently has to be removed.

16. Using such acid hydrolysis and neutralisation procedures, the concentration of 3-MCPD in acid-HVP should be consistently below 0.14 mg/kg (wet weight basis), with typical values being of the order of 0.05 mg/kg (wet weight basis)[20.17].

Soy Sauces and Related Products

17. A number of different manufacturing processes are employed in the production of soy sauces[20.18,20.19] and the method used will impact on whether the product contains 3-MCPD.

Soy Sauces Produced by Fermentation.

18. Soy sauces that are produced solely by fermentation do not contain 3-MCPD. Steamed, defatted soybeans, soyabean meal and baked wheat grains are the main ingredients used for naturally fermented soy sauce. At the start of the process these materials are mixed and inoculated with *Aspergillus oryzae* and/or *Aspergillus sojae*. After incubation for 2 to 3 days, at 25°C to 30°C, salt water is added and the mixture fermented and aged at a temperature below 40°C for not less than 90 days. Short-term fermented soy sauce is produced in a similar manner except that the salt water fermentation/aging stage takes place at or above 40°C and the process is completed within 90 days.

Soy Sauces Whose Manufacture involves an Acid Treatment Stage

19. Alternatively, soy sauces may be manufactured using acid-HVP and other ingredients such as sugars and salt. These products may contain 3-MCPD and measures to prevent its occurrence are described above for acid-HVP. This will give concentrations of less than 0.02 mg/kg, which can be achieved in a liquid product of 40% dry matter.

20. A further manufacturing technique involves mixing fermented soy sauces with those derived from acid-HVP. Manufacture of some products involves ageing after mixing. Such products may also contain 3-MCPD and appropriate measures to minimise its, presence in the acid-HVP are described in Section 13. The mean, minimum and maximum concentrations of 3-MCPD in 45 brands of this type of soy sauce manufactured using low 3-MCPD acid-HVP are 0.015, 0.004 and 0.036 mg/kg (wet weight basis), respectively.

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