codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 4 **CX/CF 10/4/4**
November 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

4th Session
Izmir, Turkey, 26 – 30 April 2010

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF ETHYL CARBAMATE CONTAMINATION IN STONE FRUIT SPIRITS AND STONE FRUIT MARC SPIRITS (N11-2009)

Codex Members and Observers wishing to submit comments at Step 3 on the above matter, including possible implications for their economic interests, should do so in conformity with the *Uniform Procedure for the Elaboration of Codex Standards and Related Texts* (Codex Alimentarius Commission Procedural Manual) before **15 February 2010**. Comments should be directed:

to:	with a copy to:
Ms Tanja Åkesson Codex Contact Point Ministry of Agriculture, Nature and Food Quality P.O. Box 20401 2500 EK The Hague The Netherlands Tel.: +31 70 378.4045 Fax.: +31 70 378.6141 E-mail: t.z.j.akesson@minlnv.nl - ***preferably*** -	Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy Fax: +39 (06) 5705 4593 E-mail: codex@fao.org - ***preferably*** -

BACKGROUND

1. The 3rd Session of the Codex Committee on Contaminants in Foods agreed to start new work on a Code of Practice for the Prevention and Reduction of Ethyl Carbamate in Stone Fruit Distillates subject to approval by the 32nd Session of the Codex Alimentarius Commission. The Committee further agreed that the Delegation of Germany would prepare a proposed draft Code of Practice for comments at Step 3 and consideration by the next session of the Committee[1]. The Commission approved this proposal as new work for the Committee[2]. The proposed draft Code of Practice is presented for comments at Step 3 in the Annex to this document.

1 ALINORM 09/32/41, paras. 113-116.
2 ALINORM 09/32/REP, para. 113 and App. VI.

ANNEX

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF ETHYL CARBAMATE CONTAMINATION IN STONE FRUIT SPIRITS AND STONE FRUIT MARC SPIRITS

INTRODUCTION

1. Ethyl carbamate is a compound that occurs naturally in fermented foods and alcoholic beverages such as bread, yoghurt, sauce, wine, beer, and particularly in stone fruit spirits and stone fruit marc spirits, mainly those made from cherries, plums, mirabelles and apricots.

2. Ethyl carbamate can be formed from various substances inherent in food and beverages, including hydrogen cyanide (or hydrocyanic acid), urea, citrulline, and other N-carbamyl compounds. Cyanate is probably the ultimate precursor in most cases, reacting with ethanol to form ethyl carbamate.

3. Ethyl carbamate is genotoxic and a multisite carcinogen in animals and is probably carcinogenic to humans. In 2007 the International Agency for Research on Cancer (IARC) reassessed the carcinogenicity of alcoholic drinks and up-graded ethyl carbamate from Group 2B ("possibly carcinogenic to humans") to Group 2A ("probably carcinogenic to humans)[3].

4. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 64th meeting in February 2005, considered ethyl carbamate[4]. JECFA concluded that the intake of ethyl carbamate from foods, excluding alcoholic beverages, was much lower than the amounts shown to cause cancer in laboratory animals and was therefore of low concern. However, compared to this, alcoholic beverages added a much larger amount to the total intake of ethyl carbamate, and this was a concern. JECFA therefore recommended that mitigation measures to reduce concentrations of ethyl carbamate in some alcoholic beverages should be continued.

5. Based on a broader number of samples the Scientific Panel on Contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted on 20 September 2007 a scientific opinion on ethyl carbamate and hydrocyanic acid in food and beverages[5] and concluded that ethyl carbamate in alcoholic beverages indicates a health concern, particularly with respect to stone fruit brandies, and recommended taking mitigation measures to reduce the levels of ethyl carbamate in these beverages. As hydrocyanic acid is an important precursor of ethyl carbamate formation in stone fruit spirits and stone fruit marc spirits, the Panel concluded that such measures should include focus on hydrocyanic acid and other precursors of ethyl carbamate, to prevent the formation of ethyl carbamate during the shelf-life of these products.

6. Particularly stone fruit and stone fruit marc spirits, contain ethyl carbamate in manifold higher concentrations than other fermented foods and beverages. In stone fruit distillates (stone fruit spirits and stone fruit marc spirits) ethyl carbamate can be formed from cyanogenic glycosides that are natural constituents of the stones. When mashing the fruit, the stones may be damaged and cyanogenic glycosides from the stones may come into contact with enzymes in the fruit mash. Cyanogenic glycosides are then degraded to hydrocyanic acid/cyanides. Hydrocyanic acid may also be released from intact stones during a longer storage of the fermented mash. During the distillation process hydrocyanic acid may be enriched in all fractions. Certain environmental conditions such as light exposure or copper ions promote the formation process - oxidation of cyanide to cyanate, reacting with ethanol - of ethyl carbamate, in the distillate. Once the reaction has been triggered, it cannot be stopped.

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3 IARC Monograph Vol. 96 in Press, Consumption of Alcoholic Beverages and Ethyl Carbamate (Urethane), (6-13 February 2007); http://monographs.iarc.fr/ENG/Meetings/96-ethylcarbamate.pdf

4 Evaluation of certain food contaminants (Sixty-fourth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 930, P. 31, 2006.

5 Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on ethyl carbamate and hydrocyanic acid in food and beverages, The EFSA Journal (2007) Journal number, 551, 1-44. http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/Contam_ej551_ethyl_carbamate_en_rev.1.pdf?ssbinary=true.

7. Although no strong correlation between the level of hydrocyanic acid and ethyl carbamate has been established so far, it is evident that under certain conditions high concentrations of hydrocyanic acid lead to higher levels of ethyl carbamate. A potential increase in ethyl carbamate formation has been associated with levels at or above 1 mg/l hydrocyanic acid in the final distillate[6,7].

8. It is recognised that reasonably applicable technological measures - Good Manufacturing Practices - can be taken to prevent and reduce significantly high ethyl carbamate levels in stone fruit distillates. The reduction of ethyl carbamate could be achieved using two different approaches: first, by reducing the concentration of the main precursor substances; second, by reducing the tendency of these substances to react to form cyanate. The main influencing factors are the concentration of precursors (e.g. hydrocyanic acid and cyanides) and storage conditions, such as light exposure and temperature.

9. The levels of ethyl carbamate in stone fruit spirits and stone fruit marc spirits should be monitored during a time period of three years and the results be used to assess the effects of this Code of Practice after three years of implementation. Thereafter, the possibility of setting a maximum level should be assessed.

Part I gives details of the typical production process. Part II contains specific recommendations based on Good Manufacturing Practices (GMP).

PART I. TYPICAL PRODUCTION PROCESS

10. The production process for stone fruit spirits and fruit marc spirits involves mashing and fermentation of the whole fruit, followed by distillation. The process typically follows the steps listed below:

    - crushing the whole ripe fruit;
    - fermenting the mash in stainless steel tanks or other suitable fermentation vessels;
    - transferring the fermented mash into the distillation device, often a copper pot;
    - heating the fermented mash by a suitable heating method in order to slowly boil off the alcohol;
    - cooling the alcohol vapour in an appropriate (e. g. stainless steel) column where it condenses and is collected;
    - separation of three different fractions of alcohol: ‘heads’, ‘hearts’ and ‘tails’;
    - dilution to the final alcoholic grade

11. During distillation, the heads boil off first. Components with low boiling point e.g. methanol are part of the heads. This fraction is generally unsuitable for consumption and should be discarded.

12. During the middle distillation run (the ‘hearts’), the principal alcohol in all spirits, ethyl alcohol (ethanol), is distilled. This part of the distilling run, where the content of volatiles other than ethanol is lowest and the purest fruit aromas are present, is always collected.

13. The ‘tails’ of the distillation include acetic acid and fusel oils, which are often identified by unpleasant vinegary and vegetal aromas. They are also discarded, but they may be re-distilled because some ethanol is invariably included with the tails.

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6 Christoph, N., Bauer-Christoph C., Maßnahmen zur Reduzierung des Ethylcarbamatgehaltes bei der Herstellung von Steinobstbränden (I), Kleinbrennerei 1998; 11: 9-13.

7 Christoph, N., Bauer-Christoph C., Maßnahmen zur Reduzierung des Ethylcarbamatgehaltes bei der Herstellung von Steinobstbränden (II), Kleinbrennerei 1999; 1: 5-13.

PART II RECOMMENDED PRACTICES BASED ON GOOD MANUFACTURING PRACTICES (GMP)

Raw materials and preparation of fruit mash

14. The raw materials and preparation of the fruit mash should be suitable to avoid the release of hydrocyanic acid.

15. The stone fruits should generally be of a high quality, not mechanically damaged and not microbiologically spoiled.

16. The fruit should preferably be de-stoned.

17. If the fruits are not de-stoned, they should be mashed gently avoiding the crushing of stones.

Fermentation

18. Selected yeast preparations for the production of spirit drinks should be added to the mashed fruits, according to the manufacture's instructions for users, for a fast and clean fermentation.

19. Mashed fermented fruits should be handled with high standards of hygiene, and exposure to light should be minimised. The finally fermented fruit mash should be stored as short as possible before distillation since hydrocyanic acid may also be released from intact stones during longer storage of the mash.

Distillation equipment

20. Distillation equipment and the distillation process should be suitable, to ensure that hydrocyanic acid is not transferred into the distillate.

21. The distillation equipment should include automatic rinsing devices and copper catalytic converters. The automatic rinsing devices will keep the copper stills cleaned while the copper catalytic converters will bind hydrocyanic acid before it passes into the distillate.

22. Automatic rinsing devices are not necessary in the case of discontinuous distillation. The distillation equipment should be cleaned by systematic and thorough cleaning procedures.

23. In certain cases, only when no copper catalytic converters or other dedicated cyanide separators are used, copper agents should be added to the fermented fruit mash before distillation. The purpose of the copper agents is to bind hydrocyanic acid. Copper agents are sold at specialised shops and should be used very carefully according to the manufacturer's instructions.

Distillation process

24. Stones settled in the fermented mash should not be pumped into the distillation device.

25. Distillation should be carried out in such a way that alcohol is boiled off slowly and in a controlled matter (e.g. by using steam instead of a direct flame as the heating source).

26. The first fractions of the distillate, called 'heads', should be separated carefully.

27. The middle fraction, called 'hearts', should then be collected and should be stored in the dark. When the alcohol content reaches 50 % vol. in the receiver, collection should be switched to the 'tails', so that any ethyl carbamate that may have been formed is separated in the tail fraction.

28. The separated tails, possibly containing ethyl carbamate, should be collected and if they are used for re-distilling, they should be re-distilled separately.

Checks on the distillate, re-distillation and storage

Hydrocyanic acid:

29. The distillates should be regularly checked for their levels of hydrocyanic acid. The determination should be carried out by appropriate tests, either by kits for rapid testing of the hydrocyanic acid levels, or, alternatively, by a specialist laboratory.

30. If the concentration of hydrocyanic acid in the distillate exceeds a level of 1 mg/l, re-distillation with catalytic converters or copper agents is recommended (see points 20, 21 and 23).

31. Distillates should be stored in lightproof bottles or covering boxes and storage time should be kept as short as possible, particularly if the distillates are close to a level of 1 mg/l hydrocyanic acid.

Ethyl carbamate

32. Testing of ethyl carbamate is recommended for distillates in which the compound may already have been formed (e.g. distillates with unknown history of production, distillates with higher levels of cyanide, or storage at light). The level of ethyl carbamate can only be tested by a specialist laboratory.