

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2016/22

of 7 January 2016

on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits, repealing Recommendation 2010/133/EU

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) 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 ⁽¹⁾. The Panel 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.
- (2) Maximum contents of hydrocyanic acid in stone fruit spirits and stone fruit marc spirits have been laid down in Regulation (EC) No 110/2008 of the European Parliament and of the Council ⁽²⁾. This Regulation stipulates that the maximum hydrocyanic acid content in stone fruit spirits and stone fruit marc spirits shall be 7 grams per hectolitre of 100 % vol. alcohol (70 mg/l).
- (3) Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁽³⁾ establishes a maximum level of hydrocyanic acid of 35 mg/kg in alcoholic beverages. This maximum level applies without prejudice to Regulation (EC) No 110/2008.
- (4) Commission Recommendation 2010/133/EU ⁽⁴⁾ provided for a Code of Practice on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits and recommended the Member States to take the necessary measures to ensure that this Code is implemented by all concerned food business operators. Furthermore it had to be ensured that all the appropriate measures were taken to achieve levels of ethyl carbamate in stone fruit spirits and stone fruit marc spirits as low as possible with the aim to achieve the level of 1 mg/l as a target. It was furthermore recommended to monitor the levels of ethyl carbamate in stone fruit spirits and stone fruit marc spirits during the years 2010, 2011 and 2012 in order to assess the effects of the Code of Practice.

⁽¹⁾ 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/en/scdocs/doc/Contam_ej551_ethyl_carbamate_en_rev.1.3.pdf

⁽²⁾ Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

⁽³⁾ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

⁽⁴⁾ Commission Recommendation 2010/133/EU of 2 March 2010 on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits and on the monitoring of ethyl carbamate levels in these beverages (OJ L 52, 3.3.2010, p. 53).

- (5) These monitoring results were reported in the EFSA technical report 'Evaluation of monitoring data on levels of ethyl carbamate in the years 2010-2012 ⁽¹⁾', adopted on 28 March 2014. The report provides an overview of ethyl carbamate levels in 'Spirits made from stone fruits' and 'Spirits made from fruits other than stone fruits' across the three sampling years 2010-2012. Overall, in the 2010-2012 ethyl carbamate dataset more than 80 % of the analytical results in 'Spirits made from stone fruits' and more than 95 % of the analytical results in 'Spirits made from fruits other than stone fruits' were below the target value of 1 mg/l. The mean occurrence in the same food groups was also below the target (roughly two-thirds of the target for 'Spirits made from stone fruits' and one-third of the target for 'Spirits made from fruits other than stone fruits').
- (6) It is appropriate to maintain the Code of Practice, with the target level for ethyl carbamate of 1 mg/l but to update the Code with experiences gained and to align it on certain aspects with the Codex Code of Practice on ethyl carbamate contamination in stone fruit distillates, adopted in 2011 (CAC/RCP 70-2011),

HAS ADOPTED THIS RECOMMENDATION:

It is recommended that the Member States:

- (1) take the necessary measures to ensure that the 'Code of Practice on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits' as described in the Annex to this Recommendation, is implemented by all operators involved in the production, packaging, transport, holding and storage of stone fruit spirits and stone fruit marc spirits;
- (2) ensure that all the appropriate measures are taken to achieve levels of ethyl carbamate in stone fruit spirits and stone fruit marc spirits as low as possible with the aim to achieve the level of 1 mg/l as a target.

Recommendation 2010/133/EU is repealed.

Done at Brussels, 7 January 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

⁽¹⁾ European Food Safety Authority, 2014; Evaluation of monitoring data on levels of ethyl carbamate in the years 2010-2012. EFSA supporting publication 2014:EN-578. 22 pp. Available on: <http://www.efsa.europa.eu/en/supporting/doc/578e.pdf>

ANNEX

INTRODUCTION

1. Ethyl carbamate is a compound that occurs naturally in fermented foods and alcoholic beverages such as bread, yoghurt, soy 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. 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 broken 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. Under influence of light cyanide is oxidised to cyanate reacting with ethanol to form ethyl carbamate. Once the reaction has been triggered, it cannot be stopped. Certain environmental conditions such as exposure to light, high temperatures and the presence of copper ions promote the formation of ethyl carbamate in the distillate.
4. A major reduction in the concentration 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.
5. 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 ⁽¹⁾ ⁽²⁾. Based on practical experiences, it can be assumed that from 1 mg of hydrocyanic acid up to 0,4 mg ethyl carbamate can be formed in a non-equimolar relationship.
6. Part I gives details of the production process. Part II contains specific recommendations based on Good Manufacturing Practices (GMP).

I. DESCRIPTION OF THE PRODUCTION PROCESS

7. The production process for 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'.
8. During distillation, the heads boil off first. They can usually be recognised by their solvent or lacquer aromas. This fraction is generally unsuitable for consumption and should be discarded.
9. 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 found, is always collected.

⁽¹⁾ Christoph, N., Bauer-Christoph C., *Maßnahmen zur Reduzierung des Ethylcarbamatgehaltes bei der Herstellung von Steinobstbränden (I)*, Kleinbrennerei 1998; 11: 9-13.

⁽²⁾ Christoph, N., Bauer-Christoph C., *Maßnahmen zur Reduzierung des Ethylcarbamatgehaltes bei der Herstellung von Steinobstbränden (II)*, Kleinbrennerei 1999; 1: 5-13.

10. 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.

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

Raw materials and preparation of fruit mash

11. The raw materials and preparation of the fruit mash should be suitable to avoid the release of hydrocyanic acid, a precursor of ethyl carbamate.
12. The stone fruits should be of high quality, not mechanically damaged and not microbiologically spoiled, as damaged and spoiled fruit may contain more free cyanide.
13. The fruit should preferably be de-stoned.
14. If the fruits are not de-stoned, they should be mashed gently to avoid crushing the stones. If possible, stones should be removed from the mash.

Fermentation

15. Selected yeast strains for alcohol production should be added to the mashed fruits, according to the instructions for users.
16. Mashed fermented fruits should be handled with high standards of hygiene, and exposure to light should be minimised. The fermented fruit mash containing stones 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

17. Distillation equipment and the distillation process should be suitable, to ensure that hydrocyanic acid is not transferred into the distillate.
18. The distillation equipment should include automatic rinsing devices and copper catalytic converters. The automatic rinsing devices will keep the stills cleaned while the copper catalytic converters will bind hydrocyanic acid before it passes into the distillate.
19. Automatic rinsing devices are not necessary in the case of discontinuous distillation. The distillation equipment should be cleaned by systematic and thorough cleaning procedures.
20. In certain cases, 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. These preparations contain copper (I) ions binding hydrocyanic acid. Copper (II) ions are without effect and should not be used.
21. While copper ions can inhibit formation of ethyl carbamate precursors in the mash and in the still, they can promote formation of ethyl carbamate in the distillate. Therefore, use of a stainless steel condenser at the end of the distillation device rather than a copper condenser will limit presence of copper in the distillate and reduce the rate of ethyl carbamate formation.

Distillation process

22. Stones settled in the fermented mash should not be pumped into the distillation device.
23. Distillation should be carried out in such a way that alcohol is boiled off slowly (e.g. by using steam instead of a direct flame as the heating source).
24. The first fractions of the distillate, called 'heads', should be separated carefully.
25. 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.

26. The separated tails, possibly containing ethyl carbamate, should be collected and if they are used for re-distilling, they should be re-distilled separately. However, for reduction of ethyl carbamate concentration it is preferable to discard the tail.

Checks on the distillate, re-distillation and storage

Hydrocyanic acid:

27. 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.
28. If the concentration of hydrocyanic acid in the distillate exceeds a level of 1 mg/l, re-distillation with catalytic converters or copper agents (cf. points 18 and 20) is recommended, where appropriate.
29. Distillates with hydrocyanic acid levels close to 1 mg/l should ideally also be re-distilled or, where this is not possible, be stored in lightproof bottles or covering boxes with storage times as short as possible and not at higher temperatures in order to avoid ethyl carbamate formation during storage.

Ethyl carbamate:

30. 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, higher levels of cyanide, storage at light or at high temperatures). The level of ethyl carbamate can only be tested by a specialist laboratory.
 31. If the distillate shows an ethyl carbamate concentration exceeding the target level of 1 mg/l, the distillate should be re-distilled, where appropriate.
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