

8 February 2013

SANCO/12888/2012rev2

Working document

Does not represent the views of the Commission

DRAFT COMMISSION REGULATION (EU) No .../..

of XXX

**amending Commission Regulation (EC) No 2073/2005
of 15 November 2005 on microbiological criteria as regards histamine in fishery
products**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the functioning of the European Union,

Having regard to Regulation (EC) No 852/2004 on the hygiene of foodstuffs¹, and in particular Article 4(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs² lays down microbiological criteria for foodstuffs. In particular, it provides for food safety criteria for histamine and sampling plans for fishery products from fish species associated with high amount of histidine.
- (2) Codex Alimentarius Commission has fixed the recommended maximum level of histamine in fish sauce to be that no sample unit shall contain more than 400 mg histamine /kg of fish sauce tested³. These conclusions are in line with the information on consumer exposure data presented by European Food Safety Authority (EFSA) in its Scientific Opinion on risk based control of biogenic amine formation in fermented foods⁴.
- (3) Fish sauce occurs in liquid form and histamine can be expected to be evenly distributed in the liquid. The sampling plan can therefore be more simple than for fishery product not occurring in liquid form.
- (4) It is therefore appropriate to establish a separate food safety criterion for fish sauce based on hydrolysed fishery products.

¹ OJ L 165, 30.4.2004, p. 1,

² OJ L 338, 22.12.2005, p.1.

³ Codex Alimentarius Standard for Fish Sauce (CODEX STAN 302 – 2011)

⁴ EFSA Journal 2011;9(10):2393

- (5) The normal sampling plan for histamine from fishery products consists of 9 samples which require much sample material. Footnote 18 to food safety criterion 1.26 for fishery products states that single samples may be taken at retail level. In such cases whole batch should not be deemed unsafe. However, if one of nine 9 samples analyzed is found to be above M the whole batch shall be deemed unsafe. Consequently, it is appropriate to amend footnote 18 and to apply it for both food safety criteria 1.26 and 1.27.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee.

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 2073/2005 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from *day/month/year*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
José Manuel BARROSO
The President

ANNEX

Chapter 1 of Annex I to Regulation (EC) No 2073/2005 is amended as follows:

(1) Row 1.27 is replaced by the following:

'1.27 Fishery products, except those in food category 1.27a, which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine' ¹⁷	Histamine	9 (18)	2	200 mg/kg	400 mg/kg	HPLC ¹⁹	Products placed on the market during their shelf-life'
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(2) The following row 1.27a is inserted:

'1.27a Fish sauce based on hydrolysed fishery products	Histamine	1		≤400 mg/kg		HPLC ¹⁹	Products placed on the market during their shelf-life'
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(3) Footnote 18 is replaced as follows:

¹⁸ Single samples may be taken at retail level. In such a case the presumption laid down in Article 14(6) of Regulation (EC) No 178/2002, according to which the whole batch should be deemed unsafe, shall not apply, unless the result is above M.'