

Commission Regulation (EU) No 1276/2011 of 8 December 2011 amending
Annex III to Regulation (EC) No 853/2004 of the European Parliament
and of the Council as regards the treatment to kill viable parasites in
fishery products for human consumption (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1276/2011

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amending Annex III to Regulation (EC) No 853/2004 of the
European Parliament and of the Council as regards the treatment
to kill viable parasites in fishery products for human consumption

(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 853/2004 of the European Parliament and of the Council
of 29 April 2004 laying down specific hygiene rules for food of animal origin⁽¹⁾, and in particular
Article 10(1) thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. It provides, inter alia, that food business operators are to place products of animal origin on the market in the European Union, only if they have been prepared and handled exclusively in establishments that meet the relevant requirements of Annex III to that Regulation.
- (2) Part D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 provides that food business operators must ensure that certain fishery products, including those to be consumed raw or almost raw, undergo a freezing treatment to kill viable parasites that may represent a risk to the health of the consumer.
- (3) In April 2010, the European Food Safety Authority adopted a scientific opinion on risk assessment of parasites in fishery products⁽²⁾ (the EFSA Opinion). That Opinion includes information regarding the cases where fishery products may present a health hazard with regard to the presence of viable parasites. The EFSA Opinion also analyses the effects of various treatments for killing such parasites in fishery products.
- (4) Though the EFSA Opinion indicates that all wild caught seawater and freshwater fish must be considered at risk of containing viable parasites of human health hazard if these products are to be eaten raw or almost raw, in the case that epidemiological data show that the fishing grounds do not represent a health hazard with regard to the presence of parasites, the competent authority may adopt national measures which authorise an exemption from the required freezing treatment on fishery products derived from wild catches. These national measures should be notified to the Commission.

- (5) The EFSA Opinion concludes that where farmed Atlantic salmon is reared in floating cages or onshore tanks, and fed compound feedstuffs, which are unlikely to contain live parasites, the risk of infection with larval anisakids is negligible unless changes in farming practices occur. Though the Opinion concludes that sufficient monitoring data are not available for any other farmed fish EFSA has set up criteria for considering when fishery products from aquaculture do not present a health hazard with regard to the presence of parasites.
- (6) Therefore, if the same rearing procedures based on these criteria are followed, farmed fishery products other than Atlantic salmon may be considered to present a negligible risk for parasites that may be a risk to the health of the consumer. Consequently, such farmed fishery products may also be exempted from the freezing requirements while the high level of health protection is still ensured.
- (7) It is therefore appropriate to amend the requirements set out in Part D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 in order to take account of certain points of the new scientific advice included in the EFSA Opinion and practical experience gained.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 853/2004 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 8 December 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex III, Section VIII, Chapter III to Regulation (EC) No 853/2004, Part D is replaced by the following:

D. REQUIREMENTS CONCERNING PARASITES

1. Food business operators placing on the market the following fishery products derived from finfish or cephalopod molluscs:
 - (a) fishery products intended to be consumed raw; or
 - (b) marinated, salted and any other treated fishery products, if the treatment is insufficient to kill the viable parasite;

must ensure that the raw material or finished product undergo a freezing treatment in order to kill viable parasites that may be a risk to the health of the consumer.
2. For parasites other than trematodes the freezing treatment must consist of lowering the temperature in all parts of the product to at least:
 - (a) – 20 °C for not less than 24 hours; or
 - (b) – 35 °C for not less than 15 hours.
3. Food business operators need not carry out the freezing treatment set out in point 1 for fishery products:
 - (a) that have undergone, or are intended to undergo before consumption a heat treatment that kills the viable parasite. In the case of parasites other than trematodes the product is heated to a core temperature of 60 °C or more for at least one minute;
 - (b) that have been preserved as frozen fishery products for a sufficiently long period to kill the viable parasites;
 - (c) from wild catches, provided that:
 - (i) there are epidemiological data available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and
 - (ii) the competent authority so authorises;
 - (d) derived from fish farming, cultured from embryos and have been fed exclusively on a diet that cannot contain viable parasites that present a health hazard, and one of the following requirements is complied with:
 - (i) have been exclusively reared in an environment that is free from viable parasites; or
 - (ii) the food business operator verifies through procedures, approved by the competent authority, that the fishery products do not represent a health hazard with regard to the presence of viable parasites.
4. (a) When placing on the market, except when supplied to the final consumer, fishery products referred to in point 1 must be accompanied by a document

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issued by the food business operator performing the freezing treatment, stating the type of freezing treatment that the products have undergone.

- (b) Before placing on the market fishery products referred to in points 3(c) and (d) which have not undergone the freezing treatment or which are not intended to undergo before consumption a treatment that kills viable parasites that present a health hazard, a food business operator must ensure that the fishery products originate from a fishing ground or fish farming which complies with the specific conditions referred to in one of those points. This provision may be met by information in the commercial document or by any other information accompanying the fishery products.

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- (1) [OJ L 139, 30.4.2004, p. 55.](#)
- (2) [EFSA Journal 2010; 8\(4\):1543.](#)