GUIDANCE ON VIABLE PARASITES IN FISHERY PRODUCTS THAT MAY REPRESENT A RISK TO THE HEALTH OF THE CONSUMER

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Point D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 contains a requirement that certain fishery products shall undergo a treatment sufficient to kill viable parasites that may represent a health hazard to the consumer. It applies to fishery products that are meant to be consumed raw and fishery products that have not undergone, or are not meant before consumption to undergo, a treatment that kills such parasites. The larval stages of such parasites representing a health hazard to the consumer are (1) nematodes, mainly larvae of *Anisakis* species and *Pseudoterranova decipiens*, (2) larvae (plerocercoids) of *Diphyllobothrium* cestodes and (3) larvae (metacercariae) of trematodes.

1. METHODS TO KILL LARVAL STAGES OF PARASITES

Fishery products are often placed on the market as fresh fishery products which, before eaten, are heat-treated by the consumer in a way that ensures the killing of viable parasites. This is an established and accepted practice even though such fresh fishery products may contain live parasites at the moment of purchase.

The legislative text specifies the temperature and time for the treatment to be applied by food business operators to kill viable parasites. For parasites other than trematodes the freezing treatment must lower the temperature in all part of the product to either -20 °C or lower for not less than 24 hours, or to -35 °C or lower for not less than 15 hours.

For parasites other than trematodes the legislation specifies a heat treatment with a core temperature of 60° C or more for 1 minute. Reaching such a core temperature depends on the thickness and composition of the product. It has been estimated that a 3 cm thick fillet should be heated for 10 minutes to ensure that *Anisakis* spp. larvae are destroyed.

However, the larval stage (metacercaria) of trematodes (including *Opisthorchis* species and *Clonorchis* species) that occur in fresh water fish in certain geographical areas is more resistant to temperatures. Food business operators placing fresh-water fish on the market must therefore also take into account the risk that such products may contain metacercariae that may represent a health hazard if meant to be eaten without a treatment that kills such parasites.

Various reports indicate different parameters for the freezing treatment that kill various trematode metacercariae, which again have been reflected in different legislative provisions worldwide. EFSA refers in its Opinion on Parasites in Fishery Products to WHO statements that the metacercaria of *Opisthorchis spp*. and *Clonorchis spp*. are killed by freezing at -10°C for 5 days. Other temperature-time parameters for various metacercariae can *inter* alia be found in FAO Fisheries Technical Paper 444[3]. These data

include references that it shall take 3-4 days to kill the larvae of *Clonorchis sinensis* if frozen at -20°C and 32 hours to kill the larvae of *Opisthorchis felinus* at -28°C.

Regarding the heat treatment that will kill metacercariae EFSA refers in its Opinion on Parasites in Fishery Products[1] to a temperature of 70°C for 30 min for killing the *Clonorchis* and *Opisthorchis* metacercariae.

The legislation specifies that food business operators need not carry out the freezing treatment for fishery products that have been preserved as frozen fishery products for a sufficiently long period to kill the viable parasites. According to the legislation frozen fishery products must be kept at a temperature of not more than -18°C in all parts of the product. EFSA[1] recommends minimum 96 hours storage at -18°C to ensure successful killing of *Anisakis simplex*. For cestode larvae, the *Diphyllobothrium* larvae are inactivated if the fish is kept at -18ºC for at least one day. Though larvae of trematodes are somewhat more resistant it can be concluded that the period frozen fishery products are normally kept at -18 °C during cold storage, transport and the distribution chain shall kill all parasites that may represent a health hazard to the consumer.

Other methods than freezing or heat treatment, as for example dry salting for a certain period, may also kill parasites present in fishery products. If such other methods are used by food business operators to kill parasites that may represent a health hazard to the consumer the treatment must be performed in line with a risk assessment documenting its efficiency.

Further data on methods to kill larval stages of parasites of public health concern can be found in various documents. These include the Opinion of EFSA on parasites in fishery products[1], the Opinion of EFSA on Fish parasites of the Baltic Sea[2], the FAO Fisheries Technical Paper 444[3] and Opinion 2007-SA-0379[4] from the French risk assessment body, Afssa.

2. WILD CATCHES OF FISHERY PRODUCTS

Point D.3(c) of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 provides for the competent authority of a Member State to authorise that the freezing treatment need not be carried out when epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites.

EFSA[1] has concluded 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. Consequently, an evaluation of new documentation that wild caught fish, whether from salt water or fresh water, is free from parasites should be based on an appropriate risk assessment.

An assessment of whether fishery products from a fishing ground is likely to present a health hazard should take into account the prevalence, abundance, as well as species and geographical distributions of the parasites and their hosts together with results from monitoring systems and trends in parasite presence and abundance.

It should also be noted that a Member State has to respect its obligation to notify any such national measure in accordance with Directive 98/34/EC.

3. FARMED FISHERY PRODUCTS

Point D.3(d) of Chapter III of Annex III to Regulation (EC) No 853/2004 states that certain farmed fishery products can be exempted from the freezing requirement. Such fish must be cultured from embryos and fed their whole life on a diet that cannot contain viable parasites. They may either (1) exclusively have been reared in an environment that is free from parasites or (2) originate from systems where it can be verified by procedures applied that the fishery products do not represent a health hazard with regard to the presence of live parasites.

Procedures and measures to ensure the absence of parasites should be designed according to the risk for infection. Guides to good practices may be appropriate tools to assist food business operators in defining means to ensure that fishery products are not infected with parasites that may represent a health hazard.

3.1. Farming systems that by nature exclude any possibility for infection

These are systems where the design of the facilities and the farming system by nature protect against the access of any source of infection. Such systems include on-shore tank systems supplied with water that can be demonstrated to be free from parasites. Open systems as floating cages, etc. do not belong to this category.

When reared in fresh water, the water should be flowing continuously and should not come from lakes or reservoirs. When these requirements are not met, or when fish are reared in salt water, water should be filtered in a way that prevents the access of any source of infection.

For farming systems that by nature exclude any possibility for infection of the fishery product it is sufficient to document the compliance with good practices for such farming systems that ensures the absence of parasites that represent a health hazard.

3.2. Fish farming with negligible risk for infection

Such production systems must also meet the basic criteria that the fish is cultured from embryos and fed their whole life on a diet that cannot contain viable parasites. However, the systems are not totally secluded from their environment with regard to the possible presence of parasites. For example, the fish may live at least part of its life in an environment where the presence of parasites cannot be excluded.

According to the scientific opinion of EFSA[1] Atlantic salmon farmed in a specific way represents a negligible risk with regard to parasites of public health importance. Practical experience with other species than farmed Atlantic salmon have also shown that other fishery products farmed in certain ways and/or in specified areas, both in fresh water and salt water, may be free from parasites that represent a risk to the consumers.

Before food business operators apply the derogation from the freezing treatment for such production it must have been demonstrated that the procedures applied ensure that the production does not represent a health

hazard with regard to the presence of live parasites. The competent authority must approve those procedures.

In some cases it is sufficient to refer to EFSA's risk assessment for that kind of production, the procedures applied and have a generic monitoring programme at national level to ensure that the information on which the favourable risk assessment was based does not change. If the type of production cannot exclude the risk for parasites as a general rule more intensive monitoring of fishery products, at farm level or even at batch level, could be deemed necessary. Methods applied for checking for the absence of parasites should be adjusted to the type of parasites, type of fish species, etc., ranging from plain visual inspection[5] via candling (visual inspection on a light table) to artificial digestion in Pepsin/HCl.

If any parasites that may represent a health hazard should be revealed through monitoring programmes, or in any other way, these products should be excluded from the freezing exception until the production system has been checked and the farm has returned to the original situation that allowed the food business operator to make use of the exception.

4. PLACING ON THE MARKET FISHERY PRODUCTS IN ACCORDANCE WITH THE DEROGATIONS FROM THE FREEZING REQUIREMENT

Point D.4 (b) of Chapter III of Annex III to Regulation (EC) No 853/2004 states that before placing on the market fishery products referred to in Points D.3 (c) and (d), which have not been treated, or not intended before consumption to undergo 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 farm which complies with the specific conditions referred to in one of those points.

This requirement applies to all food business operators in the food production, processing and distribution chain. The provision may, inter alia, be met by information in the commercial document or by any other information accompanying the fishery products.

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[1] Opinion of the Scientific Panel on Biological hazards (BIOHAZ) on parasites in fishery products adopted on 11 March 2010. http://www.efsa.europa.eu/it/scdocs/doc/1543.pdf

[2] Opinion of the Scientific Panel on Biological hazards (BIOHAZ) on assessment of epidemiological data in relation to the health risks resulting from the presence of parasites in wild caught fish from fishing grounds in the Baltic Sea adopted on 7 July 2011. http://www.efsa.europa.eu/en/efsajournal/pub/2320.htm

[3] FAO Fisheries Technical Paper 444, Assessment and management of seafood safety and quality: Chapter 5.1.4 Parasites. http://www.fao.org/docrep/006/y4743e/y4743e0c.htm

[4] Opinion of the French Food Safety Agency (Afssa) on a risk assessment request concerning the presence of anisakidae in fishery products and the extension of the exemption from the freezing sanitary obligation of fishery products whose feeding is under control and for certain species of wild fish. (Afssa – Request no. 2007-SA-0379). http://www.anses.fr/Documents/MIC2007sa0379EN.pdf

[5] Chapter 1 of Section 1 of Annex II to Regulation (EC) No 2074/2005