



Council of the
European Union

Brussels, 14 September 2022
(OR. en)

12385/22
ADD 1

AGRILEG 126
DENLEG 68
VETER 68
DELECT 166

COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 9 September 2022

To: General Secretariat of the Council

No. Cion doc.: C(2022) 4999 final ANNEX

Subject: ANNEX to the COMMISSION DELEGATED REGULATION (EU) .../... amending and correcting Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin as regards fishery products, eggs and certain highly refined products, and amending Commission Delegated Regulation (EU) 2019/624 as regards certain bivalve molluscs

Delegations will find attached document C(2022) 4999 final ANNEX.

Encl.: C(2022) 4999 final ANNEX



Brussels, 9.9.2022
C(2022) 4999 final

ANNEX

ANNEX

to the

COMMISSION DELEGATED REGULATION (EU) .../...

amending and correcting Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin as regards fishery products, eggs and certain highly refined products, and amending Commission Delegated Regulation (EU) 2019/624 as regards certain bivalve molluscs

ANNEX

Annex III to Regulation (EC) No 853/2004 is amended and corrected as follows:

(1) in Section II, in Chapter VI, point 7 is replaced by the following:

‘7. In addition to the food chain information to be submitted in accordance with Section III of Annex II to this Regulation, the animal health certificate set out in Chapter 2 of Annex IV to Implementing Regulation (EU) 2020/2235 must accompany the slaughtered animal to the slaughterhouse or cutting plant, or be sent in advance in any format.’;

(2) Section VII is amended as follows:

(a) Chapter IX is replaced by the following:

‘CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE, MARINE GASTROPODS AND ECHINODERMS WHICH ARE NOT FILTER FEEDERS HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae, marine gastropods and echinoderms which are not filter feeders, outside classified production areas or handling such pectinidae, and/or such marine gastropods and/or echinoderms must comply with the following requirements:

1. Pectinidae, marine gastropods and echinoderms which are not filter feeders, must not be placed on the market unless they are harvested and handled in accordance with Part B of Chapter II and meet the standards laid down in Chapter V, as demonstrated by a system of own checks by the food business operators operating a fish auction, a dispatch centre or a processing establishment;
2. In addition to point 1, where data from official monitoring programmes enable the competent authority to classify fishing grounds – where appropriate, in cooperation with food business operators – the provisions of Part A of Chapter II apply by analogy to pectinidae;
3. Pectinidae, marine gastropods and echinoderms which are not filter feeders, must not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae and/or such marine gastropods, and/or echinoderms food business operators operating such establishments must inform the competent authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV;
4. Food business operators handling pectinidae, marine gastropods and echinoderms which are not filter feeders, must comply with the following requirements:
 - (a) with the documentary requirements of Chapter I, points 3 to 7, where applicable. In this case, the registration document must clearly indicate the location of the area, indicating the system used to describe the

coordinates, where the live pectinidae and/or live marine gastropods and/or live echinoderms were harvested; or

- (b) with the requirements of Chapter VI, point 2, concerning the closing of all packages of live pectinidae, live marine gastropods and live echinoderms dispatched for retail sale and Chapter VII concerning identification marking and labelling.’;
- (b) in Chapter X, in the model of registration document of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, the explanatory notes are amended as follows:
 - (i) the contents of box I.3 is replaced by the following:

‘Supplier

Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of origin. In the case of production areas, please indicate the area as authorised by the competent authorities (CAs). In the case of live pectinidae, marine gastropods or echinoderms, indicate the location of the harvesting area.

Where applicable, indicate the registration or approval number of the establishment. Indicate the activity (gatherer, purification centre, dispatch centre, auction hall or intermediary activities).

Where the batch of live bivalve molluscs is sent from a purification centre/dispatch centre, or, in case of pectinidae, marine gastropods and echinoderms which are not filter feeders harvested outside classified production areas, from a fish auction, indicate the approval number and the address of the purification centre/dispatch centre or fish auction.’;

- (ii) the contents of box I.7 is replaced by the following:

‘From purification centre/dispatch centre or fish auction

Where the batch of live bivalve molluscs is sent from a purification centre/dispatch centre, or, in case of pectinidae, marine gastropods and echinoderms which are not filter feeders harvested outside classified production areas, from an auction hall, indicate the approval number and the address of the purification centre/dispatch centre or auction hall.

If sent from a purification centre, the duration of the purification and the dates on which the batch entered and left the purification centre. Delete as appropriate.’;

- (3) Section VIII is amended as follows:

- (a) in the introductory part, point 1 is replaced by the following:

‘1. This Section shall not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods if they are still alive when placed on the market. With the exception of Chapters I and II, it shall apply to such animals when they are not placed on the market live, in which case they must have been obtained in accordance with Section VII.

For the purpose of this Section, “superchilling” means a process by which the temperature of fresh fishery product is lowered to between the initial freezing point of the fish and about 1 to 2°C lower.

This Section shall apply to thawed unprocessed fishery products and fresh fishery products to which food additives have been added in accordance with the appropriate Union legislation.’;

(b) in Chapter III, point A is replaced by the following:

‘A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS

1. Whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from aquaculture establishments, until they arrive at the establishment on land carrying out any activity other than transport or sorting. When three- layered polyethylene containers filled with water and ice are used, the whole and gutted fresh fishery products may be transported after arriving at the establishment on land carrying out other activity than transport provided that the requirements of Chapter VIII, point 1(a) are met.

2. Where chilled, unpackaged products are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, they must be stored under ice in appropriate facilities or in case of whole or gutted fresh fishery products, in three- layered polyethylene containers made of insulating material filled with ice and water.

3. Re-icing must be carried out as often as necessary. When three- layered polyethylene containers filled with water and ice are used, they must be clean and undamaged. The water must have a temperature as close to 0° C as possible and cover all the fish. Ice shall cover the whole surface of the water within containers, making sure that all fish is below the ice layer.

4. Packaged fresh fishery products must be chilled to a temperature approaching that of melting ice.

5. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly immediately after these operations.

6. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices. Fillets and slices must not remain on the work tables beyond the time necessary for their preparation.

Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.

7. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water is drained away and does not remain in contact with any fishery products.’

(c) in Chapter VIII, point 1 is replaced by the following:

‘1. During transport, fishery products must be maintained at the required temperature. In particular:

- (a) fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice. When three- layered polyethylene containers filled with water and ice are used for transporting whole and gutted fresh fishery products, ice must be present during the whole storage/transport, which must be carried out at controlled temperature. The transport and storage of whole and gutted fresh fishery products in three- layered polyethylene containers filled with water and ice must not exceed 3 days.
- (b) frozen fishery products, with the exception of whole fish initially frozen in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than – 18 °C in all parts of the product, possibly with short upward fluctuations of not more than 3 °C.
- (c) if the superchilling process is used for transporting fresh fishery products, the transport in boxes without ice shall be permitted under the condition that those boxes clearly indicate that they contain superchilled fishery products. During transport, superchilled fishery products must respect temperature requirements included in a range between -0.5 and -2°C temperature in the core of the product. The transport and storage of superchilled fishery products must not exceed 5 days.’;

(4) Section X is amended as follows

(a) In Chapter I, point 3 is replaced by the following:

‘3. Eggs must be delivered to the consumer within a maximum time limit of 28 days of laying.’

(b) In Chapter I, the following point 4 is added:

‘4. For eggs produced by hens of the species *Gallus gallus*, the “date of minimum durability” as defined in Article 2(2), point (r), of Regulation (EU) No 1169/2011 shall be fixed at not more than 28 days after the laying. Where the period of laying is indicated, this date shall be determined from the first day of that period.’

(5) Section XVI is replaced by the following:

‘SECTION XVI: HIGHLY REFINED PRODUCTS

- (1) Food business operators manufacturing the following highly refined products of animal origin must ensure that the treatment of the raw materials used eliminates any animal or public health risk:
 - (a) chondroitin sulphate;
 - (b) hyaluronic acid;
 - (c) other hydrolysed cartilage products;
 - (d) chitosan;
 - (e) glucosamine;
 - (f) rennet;
 - (g) isinglass;
 - (h) amino acids that are authorised as food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council*;
 - (i) food flavourings that are authorised in accordance with Regulation (EC) No 1334/2008 of the European Parliament and of the Council**;
 - (j) fat derivatives.
- (2) The raw materials used for the manufacturing of the highly refined products referred to in point 1 must be derived from:
 - (a) animals, including feathers thereof, which have been slaughtered in a slaughterhouse and the meat of which have been found fit for human consumption following ante-mortem and post-mortem inspection, or
 - (b) fishery products complying with Section VIII, or
 - (c) rendered fats and greaves complying with Section XII, or wool, if these products are submitted to one of the following processes:
 - (1) transesterification or hydrolysis at a temperature of at least 200 °C, under corresponding appropriate pressure, for at least 20 minutes (glycerol, fatty acids and esters);
 - (2) saponification with NaOH 12M:
 - in a batch process at 95 °C for three hours; or
 - in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes; or
 - (3) hydrogenation at 160 °C at 12 bars (12 000 hPa) for 20 minutes.

Human hair may not be used as a source for the manufacture of amino acids.

* Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

** Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavorings and certain food ingredients with flavoring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).’.