

COMMISSION DELEGATED REGULATION (EU) 2022/2258**of 9 September 2022****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****(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), second subparagraph, points (d), (e) and (g), thereof,Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽²⁾, and in particular Article 18(7), point (g), thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators.
- (2) Regulation (EC) No 853/2004 allows the slaughter on the farm of poultry subject to certain requirements, including the requirement that the slaughtered animals are to be accompanied by a certificate in accordance with the model set out in Commission Implementing Regulation (EU) 2020/2235 ⁽³⁾. However, Annex III to Regulation (EC) No 853/2004 refers to the wrong certificate, and that reference should therefore be corrected.
- (3) Regulation (EU) 2017/625, as amended by Regulation (EU) 2021/1756 ⁽⁴⁾, extends the possibility to derogate from the requirement to classify the production and relaying areas to all echinoderms which are not filter feeders, and not only to Holothuroidea. Consequently, Chapters IX and X of Section VII to Annex III to Regulation (EC) No 853/2004 should be amended to take account of that possibility.

⁽¹⁾ OJ L 139, 30.4.2004, p. 55.

⁽²⁾ OJ L 95, 7.4.2017, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) No 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) No 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

⁽⁴⁾ Regulation (EU) 2021/1756 of the European Parliament and of the Council of 6 October 2021 amending Regulation (EU) 2017/625 as regards official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials and Regulation (EC) No 853/2004 as regards the direct supply of meat from poultry and lagomorphs (OJ L 357, 8.10.2021, p. 27).

- (4) In addition, Annex III to Regulation (EC) No 853/2004 lays down temperature requirements and transport conditions for fishery products. It provides, inter alia, that fishery products are to be transported at the temperature of melting ice, if chilled, or at $-18\text{ }^{\circ}\text{C}$, if frozen. New transport techniques entailing lowering the fish temperature to between the initial freezing point of the fish and about $1\text{ }^{\circ}\text{C}$ to $2\text{ }^{\circ}\text{C}$ lower and allowing the transport in boxes without ice are now available, as is superchilling. These new techniques should be provided for in Regulation (EC) No 853/2004 and their use permitted taking into account the Scientific Opinion of the European Food Safety Authority (EFSA) of 28 January 2021 on the use of the so-called 'superchilling' technique for the transport of fresh fishery products ⁽⁵⁾.
- (5) In accordance with Part A of Chapter III of Section VIII to Annex III to Regulation (EC) No 853/2004, fresh fishery products are to be stored under ice in appropriate facilities and re-icing is to be carried out as often as necessary. Moreover, whole and gutted fresh fishery products may be transported and stored in cooled water until they arrive at the first establishment on land carrying out any activity other than transport or sorting.
- (6) Food business operators operating in the fishery products sector requested that Annex III to Regulation (EC) No 853/2004 be amended to allow the transport of whole and gutted fresh fishery products in cooled water after their arrival at the first establishment on land. This transport should be carried out in 'tubs', namely boxes of three-layered polyethylene, filled with water and ice.
- (7) On 19 March 2020, EFSA adopted a Scientific Opinion on the use of tubs for transporting and storing fresh fishery products ⁽⁶⁾. In that Opinion, EFSA concluded that there are no substantial differences for public health between the storage and transport of fresh fishery products in accordance with the requirements laid down in Part A of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 and the use of tubs, and gave some recommendations for their use. Annex III to Regulation (EC) No 853/2004 should therefore be amended in order to allow the use of tubs for the transport of whole and gutted fresh fishery products in water and ice after their arrival at the first establishment on land carrying out any activity other than transport or sorting.
- (8) Chapter VIII of Section VIII of Annex III to Regulation (EC) No 853/2004 lays down detailed rules for the transport of fishery products. In particular, fresh fishery products are to be maintained during their transport at a temperature approaching that of melting ice and frozen fishery products must be maintained during transport at temperature of not more than $-18\text{ }^{\circ}\text{C}$ in all parts of the product, possibly with short upward fluctuations of not more than $3\text{ }^{\circ}\text{C}$.
- (9) On 10 December 2020, EFSA adopted a Scientific Opinion on the use of the so-called 'superchilling' technique for the transport of fresh fishery products ⁽⁷⁾. In that Opinion, EFSA made a comparison between the temperature of superchilled fresh fishery products in boxes without ice, and products subject to the currently authorised practice in boxes with ice. EFSA concluded that, under appropriate conditions, there are no differences from a public health point of view between the traditional transport temperatures and the superchilling techniques. As regards analytical methods capable of detecting whether a previously frozen fish is commercially presented as superchilled, EFSA identified five methods that could be considered as fit for purposes. The use of the technique of superchilling should therefore be allowed under certain conditions for the transport of fresh fishery products referred to in point 1 of Chapter VIII of Section VIII of Annex III to Regulation (EC) No 853/2004.

⁽⁵⁾ EFSA Journal 2021;19(1):6378.

⁽⁶⁾ EFSA Journal 2020;18(4):6091.

⁽⁷⁾ EFSA Journal 2021;19(1):6378.

- (10) Chapter I of Section X of Annex III to Regulation (EC) No 853/2004 lays down hygiene rules for the production of eggs. The main pathogen posing a major risk of egg-borne diseases in the Union is *Salmonella Enteritidis*, and its growth in eggs is positively influenced by the temperature during the storage and transportation of eggs. As in many Member States there are no requirements regarding time and temperature conditions during the storage and transportation of eggs, it is important that 'a date of minimum durability', as defined in Article 2(2), point (r), of Regulation (EU) No 1169/2011 of the European Parliament and of the Council⁽⁸⁾ for eggs be laid down in Regulation (EC) No 853/2004, to provide a uniform basis for final consumers to make informed choices and the safest use of their food. The EFSA Opinion of 10 July 2014 on the public health risks of table eggs due to deterioration and development of pathogens⁽⁹⁾ concludes that the date of minimum durability for eggs produced by hens of the species *Gallus gallus* should be set at a maximum 28 days, as any increase in the shelf-life of these eggs over 28 days results in an increase of the relative risk of illness. The current requirement laid down in Chapter I of Section X of Annex III to Regulation (EC) No 853/2004 that eggs are to be delivered to the consumer within a maximum period of 21 days after laying is a marketing standard with limited influence on the safety of eggs while contributing to food waste at retail level. An increase of this period from 21 days to 28 days would significantly reduce this food waste, notably for eggs produced by hens of the species *Gallus gallus* as these eggs would be removed from sale at the same time as their date of minimum durability would expire.
- (11) Section XVI of Annex III to Regulation (EC) No 853/2004 lays down specific requirements for the production of certain highly refined products intended for human consumption when a treatment of the raw material eliminates any public or animal health risk. Certain fat derivatives, such as cholesterol and Vitamin D3 derived from lanolin are also subject to specific treatments, eliminating such risks and should therefore be considered as highly refined products.
- (12) Flavourings are used in food in accordance with Regulation (EC) No 1334/2008 of the European Parliament and of the Council⁽¹⁰⁾. Their manufacturing process includes a complex physical, enzymatic or microbiological process that eliminates, on the basis of the scientific evidence available, any public or animal health risk. Flavourings derived from products of animal origin should therefore be considered as highly refined products.
- (13) Annex III to Regulation (EC) No 853/2004 should therefore be amended accordingly.
- (14) Commission Delegated Regulation (EU) 2019/624⁽¹¹⁾ lays down specific rules concerning the performance of the official controls referred to in Article 18(1) of Regulation (EU) 2017/625. More particularly, Article 1, point (v), and Article 11 of that Delegated Regulation concern rules for derogations from Article 18(6) of Regulation (EU) 2017/625 regarding the classification of production and relaying areas in relation to *Pectinidae*, marine gastropods and *Holothuroidea*. Article 18 of Regulation (EU) 2017/625, as amended by Regulation (EU) 2021/1756, extends the possibility for derogations from the requirement to classify the production and relaying areas to all echinoderms which are not filter feeders, and not only to *Holothuroidea*. Accordingly, Delegated Regulation (EU) 2019/624 should be amended so that the classification of production and relaying areas is not required in relation to the harvesting of echinoderms which are not filter feeders.
-
- ⁽⁸⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).
- ⁽⁹⁾ EFSA Journal 2014;12(7):3782.
- ⁽¹⁰⁾ 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).
- ⁽¹¹⁾ Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

- (15) Regulation (EC) No 853/2004 and Delegated Regulation (EU) 2019/624 should be amended by a single Delegated Regulation, as a number of the amendments to be made to them are linked to the recent amendments made to Regulation (EU) 2017/625 by Regulation (EU) 2021/1756. In addition, the amendment to be made to Delegated Regulation (EU) 2019/624 concerning echinoderms is of ancillary nature, as it is only an alignment with an amendment made to Regulation (EU) 2017/625 by Regulation (EU) 2021/1756. Furthermore, for the sake of consistency of Union rules, the amendments to be made to Regulation (EC) No 853/2004 and Delegated Regulation (EU) 2019/624 should take effect on the same date.
- (16) Regulation (EC) No 853/2004 and Delegated Regulation (EU) 2019/624 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments and corrections to Regulation (EC) No 853/2004

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

Article 2

Amendments to Delegated Regulation (EU) 2019/624

Delegated Regulation (EU) 2019/624 is amended as follows:

- (1) In Article 1, point (a)(v) is replaced by the following:

‘(v) derogations from Article 18(6) of Regulation (EU) 2017/625 regarding the classification of production and relaying areas in relation to *Pectinidae*, marine gastropods and echinoderms;’

- (2) Article 11 is replaced by the following:

‘*Article 11*

Official controls on *Pectinidae*, marine gastropods and echinoderms, which are not filter feeders, which are harvested from production areas which are not classified in accordance with Article 18(6) of Regulation (EU) 2017/625

By way of derogation from Article 18(6) of Regulation (EU) 2017/625, the classification of production and relaying areas shall not be required in relation to the harvesting of *Pectinidae*, marine gastropods and echinoderms, which are not filter feeders, when the competent authorities carry out official controls on such animals in fish auctions, dispatch centres and processing establishments.

Such official controls shall verify compliance with:

- (a) the health standards for live bivalve molluscs laid down in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004;
- (b) the specific requirements for *Pectinidae*, marine gastropods and echinoderms which are not filter feeders, that are harvested outside the classified production areas, laid down in Chapter IX of that Section.’

Article 3

This Regulation shall enter into force on the twentieth day following that of 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, 9 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

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 $-18\text{ }^{\circ}\text{C}$ in all parts of the product, possibly with short upward fluctuations of not more than $3\text{ }^{\circ}\text{C}$.
- (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 $-2\text{ }^{\circ}\text{C}$ 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).