



Brussels, **XXX**  
SANTE/11310/2021 feedback  
(POOL/G4/2021/11310/11310-EN  
feedback.docx)  
[...] (2022) **XXX** draft

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

**of XXX**

**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)

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.*

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE DELEGATED ACT

Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council<sup>1</sup> lays down specific hygiene rules for different food of animal origin for food business operators. In order to maintain a high level of food safety for consumers, these rules need to be kept up-to-date taking into account the experience gained from their application, technological developments and their practical consequences, and changes in patterns of consumption.

The following amendments are therefore proposed by this Delegated Regulation to Annex III to Regulation (EC) No 853/2004:

- the introduction of the possibility, based on the Opinion of the European Food Safety Authority (EFSA) of 29 April 2020 on The use of the so-called ‘tubs’ for transporting and storing fresh fishery products<sup>2</sup>, to transport and store fishery products in cooled water not only on board vessels but also after their arrival at the first establishment on-land using tubs (namely, boxes of three-layered polyethylene) filled with water and ice;
- the introduction of the possibility, based on the Opinion of the EFSA of 28 January 2021 on The use of the so-called ‘superchilling’ technique for the transport of fresh fishery products<sup>3</sup>, to use new transport techniques, such as “superchilling”, a new technique that entails lowering the fish temperature to between the initial freezing point of the fish and about 1 to 2°C lower and allows its transport in boxes without ice;
- the introduction of certain fat derivatives and food flavouring derived from products of animal origin, subject to specific treatments as highly refined products;
- the introduction of the obligation to set, at not more of 28 days after laying, the date of minimum durability for eggs, and suppression of the obligation to deliver eggs to the consumer within a maximum period of 21 days after laying;
- the alignment of Chapter IX of Annex III to Regulation 853/2004 with the rules laid down in Regulation (EU) 2017/625 of the European Parliament and

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<sup>1</sup> 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 (OJ L 139, 30.4.2004, p. 55).

<sup>2</sup> EFSA Journal 2020;18(4):6091

<sup>3</sup> EFSA Journal 2021;19(1):6378

of the Council<sup>4</sup>, as amended by Regulation (EU) 2021/1756 of the European Parliament and of the Council<sup>5</sup>, as regards echinoderms;

- the correction of a wrong reference in Section II, in Chapter VI, point 7, to the model of animal health certificate in the case of the slaughter of poultry at the farm.

Commission Delegated Regulation (EU) 2019/624<sup>6</sup> lays down specific rules concerning the performance of the official controls on products of animal origin in accordance with Article 18(1) of Regulation (EU) 2017/625. It is also necessary to align the provisions of Article 1, point (a)(v), and Article 11 of that Delegated Regulation with the rules laid down in Regulation (EU) 2017/625, as amended by Regulation (EU) 2021/1756, as regards echinoderms.

Regulation (EC) No 853/2004 and Delegated Regulation (EU) 2019/624 should be amended by a single Delegated Regulation, as a number of the proposed amendments to be made to them are linked to the recent amendments made to Regulation (EU) 2017/625 by Regulation (EU) 2021/1756; the amendments to Regulation (EC) No 853/2004 and Delegated Regulation (EU) 2019/624 should take effect on the same date.

## **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE DELEGATED ACT**

Certain of the proposed amendments to be made to Regulation (EC) No 853/2004 were requested by the competent authorities of Member States and certain private stakeholders' organisations. They have been discussed during a meeting of the relevant expert group, representing the competent authorities of all Member States, and are largely supported by these experts.

The purpose of the proposed amendment to Delegated Regulation (EU) 2019/624 is to align this Regulation to Regulation (EU) 2017/625 as amended by Regulation (EU) 2021/1756. They have been discussed during a meeting of the relevant expert group, representing the competent authorities of all Member States, and are largely supported by these experts.

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<sup>4</sup> 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 92/43 (8/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

<sup>5</sup> 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).

<sup>6</sup> 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).

In addition, private stakeholders' organisations were consulted within the framework of the Advisory Group on the Food Chain and Animal and Plant Health.

Before adopting this Delegated Regulation, the Commission conducted public consultations in an open and transparent way in accordance with the procedures laid down in the Inter Institutional Agreement of 13 April 2016 between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making<sup>7</sup>.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The amendments to Annex III of Regulation (EC) No 853/2004 should be made by a Delegated Regulation adopted pursuant to Article 10(1), second subparagraph, points (d), (e) and (g), of Regulation (EC) No 853/2004.

The amendments to Delegated Regulation (EU) No 2019/624 should be made by a Delegated Regulation adopted pursuant to Article 18(7), point (g), of Regulation (EU) No 2017/625.

<sup>7</sup> OJ L 123, 12.5.2016, p. 1.

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of **XXX**

**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<sup>8</sup>, 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)<sup>9</sup>, 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<sup>10</sup>. However, Annex III to Regulation (EC)

<sup>8</sup> OJ L 139, 30.4.2004, p. 55.

<sup>9</sup> OJ L 95, 7.4.2017, p. 1.

<sup>10</sup> Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 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) 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).

853/2004 refers to the wrong certificate, and that reference should therefore be corrected.

- (3) In accordance with Article 18 (7), point (g) of Regulation (EU) 2017/625, all echinoderms which are not filter feeders may derogate from the requirement to classify the production and relaying areas. Consequently, Chapters IX and X of Section VII of Annex III to Regulation 853/2004 should be amended.
- (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°C, if frozen. New transport techniques entailing lowering the fish temperature to between the initial freezing point of the fish and about 1 to 2°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 of 28 January 2021 on the use of the so-called ‘superchilling’ technique for the transport of fresh fishery products.
- (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, the European Food Safety Authority (EFSA) adopted a Scientific Opinion on the use of tubs for transporting and storing fresh fishery products. 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 provided 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 cooled water after landing, until they arrive at the 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 °C in all parts of the product, possibly with short upward fluctuations of not more than 3 °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. 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 not differences from 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 .

- (10) Chapter I of Section X of Annex III to Regulation (EC) No 853/2004 lays down hygienic 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 (a best before date) 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<sup>11</sup> 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 (EU) 1334/2008 of the European Parliament and of the Council<sup>12</sup>. 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.

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<sup>11</sup> EFSA Journal 2014;12(7):3782.

<sup>12</sup> 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).

- (14) Commission Delegated Regulation (EU) 2019/624<sup>13</sup> lays down specific rules concerning the performance of the official controls referred to in Article 18(1) of Regulation (EU) 2017/625. Article 1, point (v), and Article 11 of Delegated Regulation (EU) 2019/624 concern 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*.
- (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 proposed 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 Regulation (EU) 2019/624 concerning echinoderms is of ancillary nature, as only an alignment with an amendment in the basic Regulation (EU) 2017/625; the amendments to Regulation (EC) No 853/2004 and Delegated Regulation (EU) 2019/624 should take effect on the same date,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Amendments and corrections to Regulation (EC) 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 Commission Delegated Regulation (EU) 2019/624**

Commission 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*,

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<sup>13</sup> 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).



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,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*