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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 12.4.2021 amending 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

Delegations will find attached document C(2021) 199 final.

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Brussels, 12.4.2021
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COMMISSION DELEGATED REGULATION (EU) .../...

of 12.4.2021

amending 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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council¹ lays down specific hygiene rules for different food of animal origin. 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 the implementation, technological developments and their practical consequences and changes in patterns of consumption.

The following amendments are therefore proposed by this Delegated Regulation:

- introduction of more flexibility for slaughter of bovine and equine animals at the holding of provenance for animal welfare reasons and to avoid risks for the handler (e.g. in case of free range animals), under strict conditions of hygiene and official controls. This action will support continued improvement of animal welfare standards as called for by the European Green Deal and ‘Farm to Fork’ Strategy;
- sorting out practical difficulties/inconsistencies in the handling of stomachs for rennet production, the handling of heads and feet, including temperature conditions for storage;
- aligning the role of the official veterinarian in case of emergency slaughter with the new requirements in Delegated Regulation (EU) 2019/624;
- allowing freezing of meat at retail level for the purpose of facilitating food donation, thereby preventing food waste and promoting food security , in line with the objectives laid down in the Commission’s Farm to Fork strategy;
- deleting the wording “approved veterinarian” in the section on farmed game since the definition of such veterinarian was merged with the definition of official veterinarian by Regulation (EU) 2017/625;
- introduction of specific hygiene conditions in collection centres for wild game;
- extension of hygiene requirements for farmed game, snails and frogs’ legs to new species/families placed on the market for human consumption;
- adaptation of storage conditions for greaves and animal fats to new technologies such as vacuum packaging;
- deletion of pectenotoxins from the list of marine biotoxins to be analysed in live bivalve molluscs based on an EFSA opinion;
- establishing a specific model of the registration document that must accompany movements of live bivalve molluscs after harvesting and until their placing on the market;
- aligning the rules for echinoderms fixed in Delegated Regulation (EU) 2019/624 to the limitations in derogation established by the Parliament and the Council in Regulation (EU) 2017/625;

¹ 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).

- fixing specific temperature requirements for fishery products handled on board of fishing vessels, specific hygiene requirements for reefer vessels as regards transport temperature and cold store maintenance, obligation on board vessels that containers used for fishery products are not used for other purposes.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Several of the proposed amendments were requested by competent authorities of Member States and certain private stakeholders' organisations. They have been discussed during several meetings of the relevant expert group, representing competent authorities of all Member States, and are largely supported by these experts.

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 Interinstitutional Agreement on Better Law-Making.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Amendments to Annex III of Regulation (EC) No 853/2004 should be made by a Delegated Regulation in accordance with Article 10(1) of Regulation (EC) No 853/2004.

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

of 12.4.2021

amending 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

(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 origin², and in particular Article 10(1) thereof,

Whereas:

- (1) Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council lays down specific rules on the hygiene of food of animal origin for food business operators.
- (2) Rennet is a complex of enzymes used for the production of certain cheeses. It is collected from the stomachs of young ruminants. Based on the experience gained by food business operators, the specific hygiene requirements on stomachs for the production of rennet, laid down in Point 18(a) of Chapter IV to Section I to Annex III of Regulation (EC) No 853/2004, should be amended in order to optimise the collection of rennet from young sheep and goats. In particular, it is appropriate to allow such stomachs to leave the slaughterhouse without being emptied or cleaned.
- (3) Technological developments have resulted in a demand for heads and feet of domestic ungulates to be permitted to be skinned or scalded and depilated outside the slaughterhouse in specialised approved establishments for further processing of food. As a practical consequence, heads and feet of domestic ungulates should therefore be allowed to be transported to these establishments under certain conditions that ensure food safety. Point 18(c) of Chapter IV to Section I of Annex III to Regulation (EC) No 853/2004 should therefore be amended.
- (4) In accordance with Article 4 of Commission Delegated Regulation (EU) 2019/624³, the official veterinarian may perform ante-mortem inspection outside a slaughterhouse in the case of emergency slaughter of domestic ungulates. Point 2 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004 requires a veterinarian to carry out ante mortem inspection in the case of emergency slaughter. That requirement should be amended so as to be consistent with that Article 4 of Delegated Regulation (EU) 2019/624 and refer instead to the official veterinarian.

² OJ L 139, 30.4.2004, p. 55.

³ 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)

- (5) Improving animal welfare is one of the actions proposed in the Commission's Farm to Fork Strategy⁴ for a fair, healthy and environmentally-friendly food system, as part of the European Green Deal. There is, in particular, a change in patterns of meat consumption with an increasing demand by the European Parliament, farmers and consumers that slaughter of certain domestic ungulates on the holding of provenance be authorised in order to avoid possible animal welfare concerns during collection and transport thereof.
- (6) Apart from emergency slaughter, domestic ungulates are required to be slaughtered in a slaughterhouse approved in accordance with Article 4(2) of Regulation (EC) No 853/2004 to ensure compliance with the hygiene requirements laid down in Chapters II and IV of Section I of Annex III to that Regulation. The competent authorities of Member States can approve mobile slaughterhouses in accordance with that Article. These mobile facilities may be placed in all appropriate locations, including farms, where groups of healthy animals can be slaughtered. In other circumstances, the transport of certain animals may create a risk for the handler or for the welfare of the animals. Slaughter and bleeding should therefore be permitted at the holding of provenance for a limited number of domestic bovine and porcine animals and domestic solipeds. Such practice should be subject to strict conditions to maintain a high level of food safety of the meat derived from such animal.
- (7) Domestic bovine and porcine animals and domestic solipeds slaughtered on the holding of provenance, should be accompanied by an official certificate, attesting that the hygiene requirements for slaughter have been complied with. Such an official certificate is provided for in Commission Implementing Regulation (EU) 2020/2235⁵.
- (8) On 27 September 2018, the European Food Safety Authority (EFSA) adopted a second scientific opinion on hazard analysis approaches for certain small retail establishments and food donations⁶. That Opinion recommends freezing at retail level as an additional tool for guaranteeing the safe redistribution of food to those in need. The facilitation of safe food donation practices, both prevents food waste and contributes to food security, in line with the objectives laid down in the Commission's Farm to Fork strategy and its overall aim to establish a fair, healthy and environmentally-friendly food system as part of the European Green Deal. The freezing of food can be an important means of ensuring its safe redistribution by food banks and other charities. The freezing of meat is currently not allowed in the case of retail to retail activity since meat intended for freezing is required to be frozen without undue delay after slaughter or cutting in accordance with point 4 of Chapter VII of Section I of Annex III to Regulation (EC) No 853/2004, as regards domestic ungulates and point 5 of Chapter V of Section II of that Annex as regards poultry and lagomorphs. The freezing of meat should therefore be allowed in the case of retail to retail activity under certain conditions to ensure the safe distribution for food donations.

⁴ https://ec.europa.eu/food/sites/food/files/safety/docs/f2f_action-plan_2020_strategy-info_en.pdf

⁵ 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)

⁶ EFSA Journal 2018; 16(11):5432

- (9) Regulation (EC) No 854/2004 of the European Parliament and of the Council⁷ defined ‘approved veterinarian’. Regulation (EU) 2017/625 of the European Parliament and of the Council⁸ repealed Regulation (EC) 854/2004, and defined ‘official veterinarian’. As the definition of ‘official veterinarian’ in Regulation (EU) 2017/625 encompasses ‘approved veterinarian’, the references to ‘approved veterinarian’ in Annex III to Regulation (EC) No 853/2004 should be amended to refer instead to ‘official veterinarian’.
- (10) The specific hygiene requirements for the production and placing on the market of meat from even-toed farmed game mammals laid down in Section III of Annex III to Regulation (EC) No 853/2004 only apply to meat from *Cervidae* or *Suidae*. Similar requirements should also apply to meat from other even-toed farmed game mammals such as lambs to avoid a possible food safety risk from changes in consumption patterns due to an increased consumption of such meat.
- (11) The bodies and viscera of hunted wild game may be transported to and stored in a collection centre before transport to a game-handling establishment. Specific hygiene rules on the handling and storage of these bodies and viscera in such collection centres should be introduced to ensure the food safety of that meat by amending the hygiene requirements for wild game laid down in Section IV of Annex III to Regulation (EC) No 853/2004.
- (12) Wild game is required to be transported as soon as possible to a game handling establishment after examination by a trained person in accordance with point 3 of Chapter II of Section IV of Annex III to Regulation (EC) No 853/2004 as regards large wild game and point 3 of Chapter III of that Section as regards small wild game in order to allow chilling to take place within a reasonable time after killing. That requirement should also apply to wild game where no examination took place.
- (13) Point 3 of Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004, provides that whenever a food business operator moves a batch of live bivalve molluscs between establishments, the batch is required to be accompanied by a registration document. In order to harmonise the information required by point 4 of Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004, a common model of the registration document for the movement of live bivalve molluscs between establishments should be established. Moreover it is a common practice that batches of bivalve molluscs may also be sent to intermediate operators, therefore the registration document should also include this possibility.
- (14) In accordance with point 1 of Part A of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004, live bivalve molluscs are to be washed with clean water, free of mud and accumulated debris before purification commences. However,

⁷ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206)

⁸ 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) (OJ L 95, 7.4.2017, p. 1).

in order to save water, washing of clean bivalve molluscs should not be mandatory. The point 1 of Part A of Chapter IV of Section VII should be modified accordingly.

- (15) Live bivalve molluscs placed on the market may not contain marine biotoxins that exceed the limits set out in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004. The EFSA has concluded in its Opinion on Marine biotoxins in shellfish – Pectenotoxin group⁹ that there are no reports of adverse effects in humans associated with Pectenotoxins (PTX) group toxins. In addition, PTX in shellfish are always accompanied by toxins from the Okadaic acid group. It is therefore appropriate to delete the reference to PTX from point 2(c) of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004.
- (16) Article 11 of Delegated Regulation 2019/624 provides that the classification of production and relaying areas is not required in relation to the harvesting of holothuroidea when the competent authorities carry out official controls on such animals in fish auctions, dispatch centres and processing establishments. Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 should be amended in order to allow the harvesting of Holothuroidea outside classified production and relaying areas.
- (17) Vessels should be designed and constructed so as not to cause contamination of fishery products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. Also holds, tanks or containers used for storing, cooling or freezing fishery products should not be used for other purposes than the storage of fishery products. Freezer vessels and reefer vessels should be equipped with freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to achieve a core temperature of not more than -18 °C. Storage holds should not be used for freezing products.. The same requirements for freezing and storage equipment should also apply to cold stores on land. Part I of Chapter I and part B of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 should therefore be amended accordingly.
- (18) Following recent frauds concerning tuna initially frozen in brine at -9°C and destined for the canning industry but diverted to be consumed as fresh fishery products, it is appropriate to clarify in point 7 of Part II of Chapter I of Section VIII of Annex III to Regulation (EC) No 853/2004 that whole fishery products initially frozen in brine at -9°C and destined for the canning industry even if further frozen at a temperature of -18°C must not have a different destination than the canning industry.
- (19) Livers and roes of fishery products intended for human consumption are to be preserved under ice, at a temperature approaching that of melting ice, or are to be frozen. It is appropriate to allow that livers and roes be also refrigerated under different conditions than under ice, at a temperature approaching that of melting ice. Accordingly, point 6 of Part II of Chapter I of Section VIII of Annex III to Regulation (EC) No 853/2004 should be amended in order to allow that livers and roes of fishery products intended for human consumption may also be refrigerated not only under ice but under different conditions of refrigeration.
- (20) It is appropriate that in containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice, the melting water should not remain in contact with any fishery products. It is important, for hygiene reasons, to clarify that

⁹ <https://doi.org/10.2903/j.efsa.2009.1109>

melt water not only should not remain in contact with fishery products but should be drained away. Accordingly, point 4 of part A of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 should be amended in order to clarify that melted water not only should not remain in contact with fishery products but should be drained away.

- (21) Specific hygiene rules on frogs' legs laid down in Section XI of Annex III to Regulation (EC) No 853/2004 only apply to frogs' legs of the species *Rana* (family Ranidae) in accordance with the definition of frogs' legs laid down in point 6.1 of Annex I to that Regulation. Specific hygiene rules for snails in that Section only apply to terrestrial gastropods of the species *Helix pomatia* Linné, *Helix aspersa* Muller, *Helix lucorum* and species of the family Achatinidae in accordance with the definition of snails laid down in point 6.2 of Annex I to Regulation (EC) No 853/2004. Due to changes in eating habits, frogs' legs and snails of other species are also produced and placed on the market for human consumption. The specific hygiene rules should therefore be extended to cover those species to ensure the safety of food derived from these species.
- (22) Section XII of Annex III to Regulation (EC) No 853/2004 lays down specific temperature requirements for the storage of greaves intended for human consumption. Technological developments have allowed certain packaging techniques, such as vacuum-packaging for which the specific temperature requirements are not needed to ensure the safety of food derived from greaves. Those temperature conditions should therefore be deleted while the food business operator should ensure the safety of food derived from the greaves by good hygiene practices and procedures based on Hazard Analysis and Critical Control Point (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council¹⁰.
- (23) Annex III to Regulation (EC) No 853/2004 should therefore be amended accordingly,
- HAS ADOPTED THIS REGULATION:

Article 1

Annex III of 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 twentieth day following that of its publication in the *Official Journal of the European Union*.

¹⁰ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

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

Done at Brussels, 12.4.2021

For the Commission
The President
Ursula VON DER LEYEN