



Brussels, **XXX**  
SANTE/PLAN/364/2023 feedback  
(POOL/G5/2023/364/364-EN.docx)  
[...] (2023) **XXX** draft

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

**of XXX**

**amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards specific hygiene requirements for certain fresh meat, fishery products, dairy products and eggs**

(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

Regulation (EC) No 853/2004 of the European Parliament and of the Council<sup>1</sup> lays down specific rules on the hygiene of food of animal origin for food business operators. It empowers the Commission to adopt delegated acts amending Annexes II and III thereto.

Based on experience gained in the application of Regulation (EC) No 853/2004 and new scientific advice published by the European Food Safety Authority, it is proposed to amend Annexes II and III to that Regulation in order to:

- allow the stunning and bleeding on the farm of a limited number of ovine and caprine animals under certain conditions and amend the conditions for all ungulates;
- introduce specific requirements for dry-ageing of beef, subject to a transitional period;
- amend the transport conditions of carcasses and certain cuts of domestic ungulates and harmonise the testing of the surface temperature of such meat;
- allow the transport of farmed game slaughtered on the farm, to be transported to a game handling establishment;
- introduce alternative options to demonstrate the effectiveness of heat treatments of milk;
- allow the flavouring of eggs under certain conditions.

It is also appropriate to use this opportunity to clarify certain requirements laid down in Annexes II and III to Regulation (EC) No 853/2004 in order to avoid any ambiguity, in particular as regards:

- the identification marking of products of animal origin;
- the certification requirements at the point of entry into the Union of certain meat of ungulates;
- the operation to slightly decrease the temperature for slicing fresh or processed fishery products or to increase the temperature of frozen fishery products and the prohibition to store or transport fishery products at that temporarily technologically-required temperature.

### 2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE DELEGATED REGULATION

Certain of the proposed amendments to Annexes II and III 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 meetings of the relevant expert group, representing the competent authorities of all Member States, and are largely supported by those experts.

---

<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).

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 of 13 April 2016 between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making<sup>2</sup>.

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

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

DRAFT

---

<sup>2</sup> OJ L 123, 12.5.2016, p. 1.

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

of **XXX**

**amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards specific hygiene requirements for certain fresh meat, fishery products, dairy products and eggs**

(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>3</sup>, and in particular Article 10(1), second subparagraph, points (a), (c), (d), (e) and (f), thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. In particular, Annex II to that Regulation lays down requirements concerning several products of animal origin, and Annex III thereto lays down specific requirements. Section I of Annex II to Regulation (EC) No 853/2004 lays down requirements on the application of an identification mark to products of animal origin. Part B of Section I of Annex II to Regulation (EC) No 853/2004 refers to the European Community, instead of the European Union. Abbreviations of the identification mark which refer to the 'European Union' should therefore replace references to the 'European Community'. However, such replacement creates a substantial administrative burden. A transitional period should therefore be provided for during which the products bearing an identification mark with the abbreviation for the 'European Community' before the end of the transitional period may remain on the market.
- (2) In addition, clarification is needed on the link between the form of the identification mark required by (EC) No 853/2004, and the requirements for a special health or identification mark laid down for the control of certain animal diseases in Regulation (EU) 2016/429 of the European Parliament and of the Council<sup>4</sup>. Part B of Section I of Annex II to Regulation (EC) No 853/2004 should be amended to clarify which form should be applied in specific circumstances.
- (3) Mobile slaughterhouses are increasingly used to avoid possible animal welfare issues during transport, for example, due to long transport times of animals reared in remote areas. Mobile slaughterhouses are subject to approval like any other slaughterhouse in accordance with Article 4(2) of Regulation (EC) No 853/2004. There is, however, a need to clarify how this approval should be applied, for example, in the case of cross-

<sup>3</sup> OJ L 139, 30.4.2004, p. 55.

<sup>4</sup> Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

border activities of the mobile slaughterhouse or for the temporary interruption of a combination of different parts of the slaughterhouse. Approval of slaughterhouses is mainly based on compliance with requirements on the construction, layout and equipment of those slaughterhouses provided for in Chapter II of Sections I and II of Annex III to Regulation (EC) No 853/2004.

- (4) Article 43(6) of Commission Implementing Regulation (EU) 2019/627<sup>5</sup> allows, in exceptional circumstances, that live animals may be moved to another slaughterhouse. Regulation (EC) No 853/2004 does not provide for this possibility. For consistency of Union legislation, Regulation (EC) No 853/2004 should be aligned in this respect with Implementing Regulation (EU) 2019/627. Chapter IV of Section I of Annex III to Regulation (EC) No 853/2004 should therefore be amended accordingly.
- (5) Regulation (EC) 853/2004 allows the stunning and bleeding of a limited number of certain ungulates on the farm subject to specific requirements including that the animals cannot be transported to the slaughterhouse to avoid any risk to the handler and to prevent any injuries to the animals during transport. This requirement limits this possibility for stunning and bleeding on the farm largely to extensively reared animals and excludes most animals regularly handled by farmers and therefore easily transported without risk. Based on the experience gained by food business operators and competent authorities and taking into account the increasing demand to prevent any animal welfare issue during transport, it is appropriate to extend that possibility to stun and bleed ungulates on the farm in accordance with specific requirements to ovine and caprine animals and other ungulates reared under any condition of housing.
- (6) On 19 January 2023, the European Food Safety Authority published a Scientific Opinion on Microbiological Hazards of Aged Meat<sup>6</sup> ('the EFSA Opinion'). The EFSA Opinion indicates that aged meat does not create a higher public health risk than fresh meat if certain requirements are complied with. Taking into account the increasing consumption of aged meat, it is appropriate to lay down specific requirements recommended in the EFSA Opinion in Regulation (EC) No 853/2004, in particular as regards dry-aged meat from bovine animals.
- (7) Regulation (EC) No 853/2004 provides for alternative transport conditions for carcasses, half carcasses, quarters or half carcasses cut into three wholesale cuts of ovine, caprine animals, bovine and porcine animals in Chapter VII of Section I of Annex III to Regulation (EC) No 853/2004. These transport conditions are based on the control of the surface temperature of the meat instead of its core temperature and need to comply with specific requirements.
- (8) Based on the experience gained by food business operators and competent authorities, it is appropriate to amend those specific requirements laid down in Chapter VII of Section I of Annex III to Regulation (EC) No 853/2004 in particular to allow the collection of the meat from a cold store and a limited number of slaughterhouses, to allow the transport in the same compartment with more kinds of meat complying with final temperature requirements of such meat, and to provide additional temperature

---

<sup>5</sup> Commission Implementing Regulation of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

<sup>6</sup> EFSA Journal 2023;21(1):7745.

and time conditions for transport of carcasses, half carcasses, quarters or half carcasses cut into three wholesale cuts of ovine, caprine animals and bovine animals during a maximum transport time on 30 hours.

- (9) Different outcomes have been signalled by competent authorities on the measurement of the surface temperature when using different methods. It is therefore appropriate to lay down a reference method based on the experience gained by food business operators and technological developments while maintaining the possibility to use alternative methods.
- (10) Section III of Annex III to Regulation (EC) No 853/2004 requires that farmed raptives and farmed ungulates slaughtered on the farm are to be transported to the slaughterhouse for further processing. Also, game-handling establishments have appropriate facilities to hygienically handle such farmed game slaughtered on the farm, they should also be authorised to receive and handle farmed raptives and farmed ungulates.
- (11) Third countries exporting to the Union farmed game, domestic bovine, porcine and equine animals slaughtered at the holding of provenance must certify compliance with the requirements set out in Section III, point 3(j), of Annex III to Regulation (EC) 853/2004, using the model health certificate set out in Chapter 3 of Annex IV to Commission Implementing Regulation (EU) 2020/2235<sup>7</sup>. To avoid any ambiguity between the legal requirement laid down in Regulation (EC) No 853/2004 and the model health certificate set out in Implementing Regulation (EU) 2020/2235, the wording of the health certificate in both these Regulations needs to be fully consistent.
- (12) In order to comply with the production requirements laid down in Chapter VII of Section VIII of Annex III to Regulation (EC) No 853/2004, the fishery product sector deploys machines that slice and can build the slices again by using automatically placed interleaving sheets. In this case, the fishery product is placed in a cold room to decrease or, in case of already frozen products, increase, the temperature to approximatively -7°C to -11°C for permitting the cutting or the slicing.
- (13) To avoid abusive practices consisting in using such production requirements for storing fishery products at a temperature not in compliance with Chapter VII, point 2, of Section VIII of Annex III to Regulation (EC) 853/2004, the decreasing, or for already frozen products, the increasing, of temperature should be done as quickly as possible and the storage of fishery products at a temperature facilitating the cutting or slicing should be limited in time.
- (14) Part I of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 lays down health requirements for raw milk and colostrum production in herds of farmed animals from which the milk and colostrum are collected with a view to placing them on the market. Point 3 of that Part I provides that raw milk from cows, buffaloes, sheep or goats that do not come from herds free or officially free of brucellosis and tuberculosis are to undergo a heat treatment such as one to show a negative reaction to the alkaline phosphatase test. However, alkaline phosphatase testing is not a suitable method to verify heat treatment of raw milk from non-bovine species or raw milk separated in different fractions before being heat-treated in modern processing plants. Alternative options based on hazard analysis and critical control points (HACCP) principles laid down in Regulation (EC) No 852/2004 of the European Parliament and

<sup>7</sup>

Please insert the reference here.

of the Council<sup>8</sup> should therefore be offered to food business operators to demonstrate the effectiveness of the heat treatment applied.

- (15) Part II of Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004 lays down the requirements for heat treatment for raw milk, colostrum, dairy or colostrum-based products. Point 1(a) of that Part II provides that pasteurised products must show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment. Owing to the unsuitability of alkaline phosphatase testing to verify heat treatment of raw milk from non-bovine species or raw milk separated in different fractions before being heat-treated, alternative options based on HACCP principles should also be offered to food business operators to demonstrate the effectiveness of the pasteurisation.
- (16) Chapter I of Section X of Annex III to Regulation (EC) No 853/2004 lays down hygiene rules for the production of eggs and in particular provides that, at the producer's premises until sale to the consumer, eggs must be kept free of extraneous odour as such an odour may be indicative of an alteration of eggs which would render them unsuitable for direct consumption by the final consumer. However, where an extraneous odour has been intentionally applied to eggs by a food business operator in order to flavour them with particular tastes, the presence of such an odour does not mean that the eggs present a risk to the consumer. The placing on the market of eggs to which an odour has been applied intentionally should therefore be permitted, provided that such practice is not intended to hide the pre-existence of any foreign odour of the eggs.
- (17) It is appropriate to provide food business operators with sufficient time to adapt to the new requirements on the dry-ageing of beef or to demonstrate to the satisfaction of the competent authorities the safety of alternative approaches. Therefore, these new requirements laid down in Chapter VII of Section I of Annex III to Regulation (EC) No 853/2004, as amended by this Regulation should apply 6 months from the date of entry into force of this Regulation.
- (18) Therefore, Regulation (EC) No 853/2004 should be amended accordingly,

HAS ADOPTED THIS REGULATION.

#### *Article 1*

Annexes II and III to Regulation (EC) No 853/2004 are amended in accordance with the Annex to this Regulation.

#### *Article 2*

The identification mark on products of animal origin may continue to include the abbreviations of 'European Community' set out in Annex II, Section I, Part B, point 8, of Regulation (EC) No 853/2004 as it stood before the amendments made by this Regulation, until 31 December 2028, and the products of animal origin with such identification marks applied before that date may remain on the market.

<sup>8</sup> Regulation (EC) No 852/2004 of the European Parliament and the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

*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*.

Point (2)(c)(i) of the Annex, shall apply from ... [*6 months from the date of entry into force of this Regulation*].

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*

DRAFT