



2025/637

29.4.2025

COMMISSION DELEGATED REGULATION (EU) 2025/637

of 29 January 2025

amending Delegated Regulation (EU) 2022/2292 as regards the requirements for the entry into the Union of certain dairy products, certain food additives derived from animals, collagen casings, minced meat, meat preparations, mechanically separated meat and composite products containing gelatine capsules

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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) ⁽¹⁾, and in particular Article 126(1) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States for the verification of compliance with Union legislation in the area of, amongst others, food and food safety referred to in Article 1(2), point (a), thereof. Article 126 of that Regulation empowers the Commission to adopt delegated acts establishing conditions for the entry into the Union of animals and goods, and it provides that those conditions are to identify the animals and goods by referring to their codes from the Combined Nomenclature.
- (2) Commission Delegated Regulation (EU) 2022/2292 ⁽²⁾ supplements Regulation (EU) 2017/625 as regards the requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption in order to ensure that they comply with the applicable requirements established by the rules referred to in Article 1(2), point (a), of Regulation (EU) 2017/625 or with requirements recognised to be at least equivalent thereto.
- (3) Article 6(1), point (a), of Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽³⁾ requires food business operators importing products of animal origin from third countries to ensure that importation takes place only if the third country appears on a list of third countries from which imports of those products are permitted, drawn up in accordance with Article 11 of Regulation (EC) No 854/2004 of the European Parliament and of the Council ⁽⁴⁾, which has been replaced by Articles 126 and 127 of Regulation (EU) 2017/625. It follows from that provision of Regulation (EC) No 853/2004 that imports of products of animal origin from third

⁽¹⁾ OJ L 95, 7.4.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/625/2022-01-28>.

⁽²⁾ Commission Delegated Regulation (EU) 2022/2292 of 6 September 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption (OJ L 304, 24.11.2022, p. 1, ELI: http://data.europa.eu/eli/reg_del/2022/2292/oj).

⁽³⁾ 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, ELI: <http://data.europa.eu/eli/reg/2004/853/oj>).

⁽⁴⁾ 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, ELI: <http://data.europa.eu/eli/reg/2004/854/oj>).

countries not appearing on those lists are not permitted. Article 3, point (b), of Delegated Regulation (EU) 2022/2292 specifies the Combined Nomenclature codes or Harmonised System headings (CN/HS codes) of products of animal origin which may enter into the Union only from a third country or region thereof included in a list for those products of animal origin. In order to ensure consistency between Article 6(1), point (a), of Regulation (EC) No 853/2004 and Article 3, point (b), of Delegated Regulation (EU) 2022/2292, the CN/HS codes of some products of animal origin, which were not yet included in Article 3, namely certain dairy products, certain food additives derived from animals and collagen casings, should be included in that Article.

- (4) Annex III to Regulation (EC) No 853/2004 lays down specific requirements for products presenting a health risk, and in particular for raw milk, colostrum, dairy products and colostrum-based products (Section IX) and for collagen (Section XV). Article 6(1), point (b), of Regulation (EC) No 853/2004 requires food business operators importing products of animal origin from third countries to ensure that importation takes place only if the establishment from which the product was dispatched, and in which it was obtained or prepared, appears on a list of establishments from which imports of that product are permitted, when applicable. Article 13(1), point (a), of Delegated Regulation (EU) 2022/2292 provides that consignments of products of animal origin, the CN/HS codes of which are listed in that Article and for which requirements are laid down in Annex III to Regulation (EC) No 853/2004, may enter into the Union only where they are dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and kept up-to-date in accordance with Article 127(3) of Regulation (EU) 2017/625. In order to ensure compliance with the specific requirements laid down in Annex III to Regulation (EC) No 853/2004 and for reasons of consistency, the CN/HS codes of certain dairy products and collagen casings, which were not yet included in Article 13(1), point (a), of Delegated Regulation (EU) 2022/2292, should be included in that Article.
- (5) Article 15 of Delegated Regulation (EU) 2022/2292 lays down that consignments of, among others, minced meat, meat preparations and mechanically separated meat and meat products may only enter into the Union if they have been manufactured from raw materials obtained in slaughterhouses, game-handling establishments or cutting plants, appearing on a list of establishments drawn up and kept up to date in accordance with Article 127(3), point (e), of Regulation (EU) 2017/625. For the purposes of such listing of establishments, the competent authorities of third countries provide guarantees that those establishments are subject to conditions that comply with requirements that are equivalent to those referred to in Article 1(2), point (a), of Regulation (EU) 2017/625. Some of those raw materials, for example, for the production of meat products intended for the entry into the Union, may also be obtained from establishments producing minced meat, meat preparations or mechanically separated meat. Such establishments should thus also appear on the list of establishments from which raw materials must be obtained. Article 15 of Delegated Regulation (EU) 2022/2292 should therefore be amended accordingly.
- (6) Annex III to Regulation (EC) No 853/2004 lays down specific requirements for products presenting a health risk, and in particular for raw milk, colostrum, dairy products and colostrum-based products (Section IX) and for collagen (Section XV). Article 6(1), point (d), of Regulation (EC) No 853/2004 requires food business operators importing products of animal origin from third countries to ensure that importation takes place only if they are accompanied by a certificate when applicable. Article 21(1) of Delegated Regulation (EU) 2022/2292 specifies the CN/HS codes of products of animal origin which may enter into the Union only when accompanied by an official certificate. In order to ensure compliance with the specific requirements laid down in Annex III to Regulation (EC) No 853/2004 and for reasons of consistency, the CN/HS codes of certain dairy products and collagen casings, which were not yet included in Article 21(1) of Delegated Regulation (EU) 2022/2292, should be included in that Article.

- (7) Article 21(3) of Delegated Regulation (EU) 2022/2292 provides that no official certificate is required for the entry into the Union of gelatine capsules covered by CN/HS codes 3913, 3926 or 9602 of Part Two of Annex I to Council Regulation (EEC) No 2658/87 ⁽⁵⁾, where those capsules are not derived from ruminant bones. Article 22(1), point (a)(i), of that Delegated Regulation provides that certain composite products containing only gelatine capsules not derived from ruminant bones as processed products of animal origin are to be accompanied by a private attestation. For reasons of consistency of Union legislation, no private attestation should be required for the entry into the Union of composite products that do not contain any processed product of animal origin other than gelatine capsules not derived from ruminant bones. Article 22 of Delegated Regulation (EU) 2022/2292 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2022/2292 is amended as follows:

- (1) in Article 3, point (b) (ii) is replaced by the following:

‘(ii) Harmonised System headings (“HS headings”) 0901, 1301, 1702, 1806, 2105, 2106, 2301, 3001, 3002, 3203, 3204, 3302, 3501, 3502, 3503, 3504, 3507, 3823, 3824, 3913, 3926, 4101, 4102, 4103 or 9602 and CN codes 2202 99 and 3917 10 10;’

- (2) in Article 13(1), point (a)(ii) is replaced by the following:

‘(ii) the HS headings 1702, 1806, 2105, 2106, 2301, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 4101, 4102 or 4103, and CN codes 2202 99 and 3917 10 10;’

- (3) in Article 15, the introductory paragraph is replaced by the following:

‘Consignments of the following products of animal origin shall only enter the Union if they have been manufactured from raw materials obtained in slaughterhouses, game-handling establishments, cutting plants, establishments producing minced meat, meat preparations and mechanically separated meat, and establishments handling fishery products, appearing on lists of establishments drawn up and kept up to date in accordance with Article 127(3), point (e), of Regulation (EU) 2017/625 or obtained in Member States;’

- (4) in Article 21(1), point (b)(ii) is replaced by the following:

‘(ii) the HS headings 0901, 1702, 1806, 2105, 2106, 2301, 3001, 3002, 3302, 3501, 3502, 3503, 3504, 3507, 3913, 3926, 4101, 4102, 4103 or 9602, and CN codes 2202 99 and 3917 10 10;’

- (5) in Article 22, paragraph 2 is replaced by the following:

‘2. By way of derogation from paragraph 1 of this Article,

(a) for the composite products exempted from official controls at border control posts in accordance with Article 48, point (h), of Regulation (EU) 2017/625, the private attestation shall accompany the composite products at the time of their placing on the market, except for the products referred to in Article 20(4) of this Regulation, for which a private attestation shall not be required;

(b) a private attestation shall not be required for the entry into the Union of composite products which contain as the only processed product of animal origin gelatine capsules not derived from ruminant bones.’

⁽⁵⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1, ELI: <http://data.europa.eu/eli/reg/1987/2658/oj>).

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*.

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

Done at Brussels, 29 January 2025.

For the Commission
The President
Ursula VON DER LEYEN
