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[...] (2023) **XXX** draft

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

**of XXX**

**amending and correcting Delegated Regulation (EU) 2022/2292 with regard to requirements for the entry into the Union of honey, meat, highly refined products, gelatine capsules and fishery products**

(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 (EU) 2017/625 of the European Parliament and of the Council<sup>1</sup> lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States, in particular to ensure that consignments of animals and goods from third countries comply with the requirements for their entry into the Union.

Commission Delegated Regulation (EU) 2022/2292<sup>2</sup> supplements the requirements laid down in Regulation (EU) 2017/625 as regards the identification of food-producing animals and certain goods subject to the requirements for the inclusion of the third country or region thereof or the establishment in a list and to the issuance of official certificates or the presentation of a private attestation, and the specific conditions for entry in the Union of those animals and those goods.

Honey and other apiculture products intended for human consumption are commodities that are regularly reported as being the subject of fraudulent practices. The results of a recent Union coordinated action<sup>3</sup> have shown that a significant part of honey and apiculture products imported into the Union are adulterated. The most common type of adulteration is the addition of extraneous sugars remain undetected and present on the Union market. Of the samples taken at EU Union borders during this EU that Union coordinated action, 46 % were suspected of being non-compliant. In total, 57% of exporters in third countries that were controlled were flagged as having exported honey consignments suspected of being adulterated with extraneous sugars. The results of that Union coordinated action showed that two-thirds of importers implicated imported at least one suspicious consignment.

In order to organise reinforced checks on consignments of honey and apiculture products presented at Union border control posts for their import into the Union, it is necessary that third country establishments exporting honey to the Union are listed on a list drawn up and kept up to date in accordance with Article 127(3) points (e)(ii) and (iii), of Regulation (EU) 2017/625.

Therefore, this Delegated Regulation amends Delegated Regulation (EU) 2022/2292 in order to require that honey and other apicultural products intended for human consumption imported into the Union from third countries and that are intended to be placed on the Union market be dispatched from, and obtained or prepared in,

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<sup>1</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 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

<sup>2</sup> 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).

<sup>3</sup> [https://food.ec.europa.eu/safety/eu-agri-food-fraud-network/eu-coordinated-actions/honey-2021-2022\\_en](https://food.ec.europa.eu/safety/eu-agri-food-fraud-network/eu-coordinated-actions/honey-2021-2022_en)

establishments that appear on lists drawn up and kept up to date in accordance with Article 127(3), points (e)(ii) and (iii), of Regulation (EU) 2017/625. A transitional period of twelve months will be established for third countries to establish such lists to facilitate a smooth transition while not disrupting trade.

Delegated Regulation (EU) 2022/2292 was adopted on 6 September 2022. Since then Member States and stakeholders' organisations have signalled the need to amend some provisions. These amendments intend to:

- (a) exempt fishery products from wild catch from the additional requirements laid down in Articles 6 to 12 of Delegated Regulation (EU) 2022/2292;
- (b) allow the use of raw materials from Member States for the entry of food produced in third countries;
- (c) extend the derogation from the certification requirements to certain filled gelatine capsules;
- (d) amended wording in Articles 21 and 22 as regards meat products/processed meat used in composite products.

A few substantial errors are also corrected. They concern:

- (a) the Harmonised System (HS) headings of gelatine capsules and highly refined products for which the derogation on the listing of establishments applies;
- (b) the HS headings of sprouts and seeds intended for sprouting for which certification applies;
- (c) a reference to Commission Delegated Regulation (EU) 2022/1644<sup>4</sup> in Annex II Part C (2)(a).

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

Member States' experts were consulted within the Commission Expert Groups on Food Hygiene and Control of Food of Animal Origin<sup>5</sup>, which met to discuss the concerned subjects on 14 December 2022 and 10 February 2023.

In addition, relevant stakeholders' organisations were consulted during bilateral meetings.

Third countries were informed by notification to the World Trade Organisation within the framework of the Agreement on the Application of Sanitary and Phytosanitary Measures.

Finally, before adopting this Delegated Regulation amending Delegated Regulation (EU) 2022/2292, the Commission conducted open and transparent public consultations in accordance with the procedures laid down in the Inter-institutional Agreement on Better Law-Making<sup>6</sup>.

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<sup>4</sup> Commission Delegated Regulation (EU) 2022/1644 of 7 July 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific requirements for the performance of official controls on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof (OJ L 248, 26.9.2022, p. 3).

<sup>5</sup> Reference E03522 in the Register of Commission Expert Groups and other similar entities.

<sup>6</sup> OJ L 123, 12.5.2016, p. 1.

As the Delegated Regulation is largely only providing clarifications, no impact assessment has been carried out.

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

The legal basis for the Delegated Regulation is Article 126(1) of Regulation (EU) 2017/625.

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**amending and correcting Delegated Regulation (EU) 2022/2292 with regard to requirements for the entry into the Union of honey, meat, highly refined products, gelatine capsules and fishery products**

(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)<sup>7</sup>, 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, in particular to ensure that consignments of animals and goods from third countries or regions thereof intended for human consumption enter the Union, they comply with relevant requirements established by the rules referred to in Article 1(2), with the exception of points (d), (e), (g) and (h) of Article 1(2) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto.
- (2) Commission Delegated Regulation (EU) 2022/2292<sup>8</sup> 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. Honey and apiculture products should be defined to ensure the correct understanding to which products the new requirements on honey and apiculture products laid down in this Delegated Regulation apply.
- (3) For fishery products from wild catch, evidence of compliance with the additional requirements laid down in Article 4 of Delegated Regulation (EU) 2022/2292 provide

<sup>7</sup> OJ L 95, 7.4.2017, p. 1.

<sup>8</sup> 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).

sufficient guarantees of compliance with Union legislation on food and feed safety. It is therefore appropriate to exempt fishery products from wild catch from the additional requirements laid down in Articles 6 to 12 of that Delegated Regulation as long as fishery products from wild catch intended for entry into the Union comply with requirements of Regulation (EU) 2023/xxxx<sup>9</sup>. Furthermore, official controls of fishery products from wild catch have to be performed by third countries as regards residues and contaminants in accordance with article 70 of Implementing Regulation (EU) 2019/627<sup>10</sup>. It is therefore appropriate to exempt fishery products from wild catch from the additional requirements laid down in Articles 6 to 12 of Delegated Regulation (EU) 2022/2292.

- (4) The results of a recent Union coordinated action have shown that a significant part of honey and apiculture products imported into the Union are adulterated and remain present on the Union market.
- (5) In order to ensure that honey and other apicultural products intended for human consumption from third countries intended to be placed on the Union market comply with the rules on food, food safety, integrity and wholesomeness at any stage of production, processing and distribution of food, including rules aimed at ensuring fair practices in trade and protecting consumer interests and information referred to in Article 1(2), point (a), of Regulation (EU) 2017/625, it is necessary to reinforce controls as from their entry into the Union.
- (6) Such coordinated performance by competent authorities of intensified official controls on products of animal origin entering the Union for placing on the market may be triggered where the establishment of origin is precisely identified through a list drawn up in accordance with Article 127(3), points (e)(ii) and (iii), of Regulation (EU) 2017/625. There is no such list of third countries' establishments producing honey or other apicultural products and it is therefore necessary to establish such list.
- (7) In accordance with Article 15 of Delegated Regulation (EU) 2022/2292, consignments of fresh meat, minced meat, meat preparations, mechanically separated meat, certain meat products, gelatine and collagen are only to enter the Union if they have been manufactured from raw materials obtained in slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products in third countries approved and listed in accordance with Article 13 of Delegated Regulation (EU) 2022/2292. Such products of animal origin should also be allowed for entry into the Union if derived from raw materials obtained in Member States/ since such raw materials also comply with requirements laid down in Union legislation. Therefore, Article 15 of Delegated Regulation (EU) 2022/2292 should be amended accordingly.
- (8) In accordance with Article 21 of Delegated Regulation (EU) 2022/2292, consignments of certain products intended for human consumption are only to enter the Union if accompanied by an official certificate. It should be clarified that this requirement also applies to food producing animals. In addition, animals and goods intended for human consumption only for transit through the Union are excluded from the scope of Delegated Regulation (EU) 2022/2292. Article 21(1) of that Regulation should not make an exception for certification.

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<sup>9</sup> Commission Regulation (EU) No 2023/xxxx of xx April 2023 on maximum levels for certain contaminants in food (OJ Lxxx, xx.04.2023, p. ).

<sup>10</sup>

- (9) The requirements on composite products laid down in Articles 21 and 22 of Delegated Regulation (EU) 2022/2292 refer to processed meat. Since ‘processed meat’ is not defined in Union legislation and in order to be consistent with other requirements related to composite products laid down in that Delegated Regulation, it is appropriate to replace the words ‘processed meat’ by ‘meat products’ in Articles 20 and 22 of Delegated Regulation (EU) 2022/2292.
- (10) Article 21 of Delegated Regulation (EU) 2022/2292 establishes a derogation from the official certification requirements for shelf-stable composite products containing gelatine and collagen. Article 21, point (f), of that Delegated Regulation should be amended to clarify that that derogation does not apply when the gelatine and collagen is derived from ruminant bones.
- (11) Article 21 of Delegated Regulation (EU) 2022/2292 also establishes a derogation for gelatine capsules from the official certification requirements in the case where gelatine capsules are not derived from ruminant bones. It should be clarified that that derogation applies not only to the entry into the Union of empty capsules but also to gelatine capsules filled with products of animal origin or when entering the Union as composite products. Therefore, Article 21 of Delegated Regulation (EU) 2022/2292 should be amended accordingly.
- (12) In accordance with Article 14 of Delegated Regulation (EU) 2022/2292, establishments producing highly refined products of animal origin or gelatine capsules are not required to appear on the lists referred to in Article 13 of that Delegated Regulation. Since Article 14 creates substantial confusion on the requirements for entry into the Union of these products and for reasons of consistency with Article 13, gelatine capsules and highly refined products identified by CN codes and HS headings not referred to in Article 13 of Delegated Regulation (EU) 2022/2292, should not be referred to in Article 14 of that Delegated Regulation. Points (d) and (e) of Article 14 should therefore be corrected.
- (13) In Article 21, errors occurred in the list of the Harmonised System subheadings for sprouts and seeds intended for the production of sprouts, laid down in Part Two of Annex I to Council Regulation (EEC) No 2658/87<sup>11</sup>. These errors are substantial as they identify the sprouts and the seeds intended for sprouts to which the conditions for entry into the Union apply. These subheadings in point 1(c) of Article 21 should therefore be corrected.
- (14) An editorial error in the original English version was made in the number of the Commission Delegated Regulation (EU) 2022/1644 referred to in Annex II part C (2)(a). Since this is a substantial error it is appropriate to correct it.
- (15) Sufficient time should be given to third countries to comply with the new requirement on the listing of establishments authorised to export honey and other apiculture products to the Union concerned by the amendments being made to Article 13 of Delegated Regulation (EU) 2022/2292 by this Regulation. A transitional period should therefore be introduced for this requirement.
- (16) Delegated Regulation (EU) 2022/2292 should be amended and corrected accordingly,

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<sup>11</sup> 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).

HAS ADOPTED THIS REGULATION:

*Article 1*  
*Amendments to Delegated Regulation (EU) 2022/2292*

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

- (1) in Article 2, the following points 34a and 34b are inserted after point 34:
  - '34a "honey" means honey as defined in Article 2 of Council Directive 2001/110/EC\*;
  - 34b "apiculture products" means apiculture products as defined in Part XXII, point 2, of Annex II to Regulation (EU) No 1308/2013 of the European Parliament and of the Council\*\*, intended for human consumption;

\* Council Directive 2001/110/EC of 20 December 2001 relating to honey (OJ L 10, 12.1.2002, p. 47).

\*\* Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).';
- (2) in Article 5(2), the fourth indent is replaced by the following:

'— fishery products from wild catch, insects, frogs, frogs' legs, snails, reptiles and reptile meat.';
- (3) in Article 13(1), the following point (c) is added:

'(c) honey and other apiculture products intended for human consumption for which the following HS headings have been laid down in Part Two of Annex I to Regulation (EEC) No 2658/8: 0409, 0410, 1212, 1521 or 1702.';
- (4) 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 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:';
- (5) Article 21 is amended as follows:
  - (a) paragraph 1 is amended as follows:
    - (i) the introductory paragraph is replaced by the following:

'Each consignment of the following animals and goods shall enter the Union for placing on the market only where the consignment is accompanied by an official certificate:';
    - (ii) point (f) is replaced by the following:

- ‘(f) composite products referred to in Article 20(2), points (a) and (b), , with the exclusion of shelf-stable composite products that do not contain colostrum-based products or meat products other than gelatine or collagen, not derived from ruminant bones, or highly refined products of animal origin.’;
- (b) paragraph 3 is replaced by the following:
- ‘3 No official certificate shall be required for the entry into the Union of gelatine capsules covered by HS headings 3913, 3926 or 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87, nor for gelatine capsules as part of the products of animal origin referred to in point 1(b) of this Article or as part of the composite products referred to in Article 20(1) of this Regulation, where those capsules are not derived from ruminant bones.’;
- (6) in Article 22(1), point (a) is replaced by the following:
- ‘(a) the consignments of the composite products referred to in Article 20(2), point (b), where the composite products do not contain colostrum-based products or meat products other than gelatine, collagen, not derived from ruminant bones, or highly refined products of animal origin; and’;

## *Article 2*

### *Corrections to Delegated Regulation (EU) 2022/2292*

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

- (1) Article 14 is amended as follows:
- (a) point (d) is replaced by the following:
- ‘(d) production of highly refined products of animal origin referred to by HS headings, 2932 or 3503, of Part Two of Annex I to Regulation (EEC) No 2658/87.’;
- (b) point (e) is deleted;
- (2) in Article 21(1), point (c) is replaced by the following:
- ‘(c) sprouts and seeds intended for the production of sprouts and referred to by the following HS subheadings: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90, 0713 10, 0713 33, 0713 34, 0713 35, 0713 39, 0713 40, 0713 50, 0713 60, 0713 90, 0910 99, 1201 10, 1201 90, 1207 50, 1207 99, 1209 10, 1209 21, 1209 91 or 1214 90 of Part Two of Annex I to Regulation (EEC) No 2658/87.’;
- (3) in Annex I, in Part II, in Section C, in point (2), (a) is replaced by the following:
- ‘(a) point A.1 of Annex II to Delegated Regulation (EU) 2022/1644 for group A substances referred to in Annex I to Delegated Regulation (EU) 2022/1644.’.

## *Article 3*

### *Transitional provision*

Consignments of honey and of other apiculture products intended for human consumption may enter the Union from establishments that are not listed in accordance with Article 13 of

Regulation Delegated Regulation (EU) 2022/2292 for a period of 12 months from the date of publication of this Regulation.

*Article 4*  
*Entry into force*

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*