Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 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 certain animals and goods intended for human consumption (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2019/625

of 4 March 2019

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 certain animals and goods intended for human consumption

(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, including for the establishment of requirements to be fulfilled for the entry into the Union of consignments of animals and goods from third countries or regions thereof and official controls performed on such consignments that are intended for human consumption in order to ensure that they comply with Union legislation in the area of food and food safety.

(2) Regulation (EU) 2017/625 provides a legal basis for delegated acts to be adopted in order to supplement the conditions laid down in that Regulation for the entry into Union of certain animals and goods. These additional requirements include guarantees concerning the verification of compliance with:

— the measures to monitor substances and groups of residues in animals and goods intended for human consumption in accordance with Council Directive 96/23/EC[(2)];

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— the rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in live animals and products of animal origin in accordance with Regulation (EC) No 999/2001 of the European Parliament and of the Council[(3)];

— the general principles and requirements governing food in general and food safety in particular at Union and national level in accordance with Regulation (EC) No 178/2002 of the European Parliament and of the Council[(4)];

— the general rules for food business operators on the hygiene of foodstuffs in accordance with Regulation (EC) No 852/2004 of the European Parliament and of the Council[(5)];

— the specific rules on the hygiene of food of animal origin for food business operators in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council[(6)];

— the specific rules on official controls and for action taken by the competent authorities in relation to production of products of animal origin intended for human consumption in accordance with Commission Delegated Regulation (EU) 2019/624[(7)] and Commission Implementing Regulation (EU) 2019/627[(8)].

(3) Regulation (EC) No 854/2004 of the European Parliament and of the Council[(9)] laid down specific conditions for the entry into the Union of products of animal origin intended for human consumption, while Regulation (EC) No 882/2004 of the European Parliament and of the Council[(10)] laid down the general conditions for the entry into the Union of food. Regulation (EU) 2017/625 lays down rules in areas currently covered by those two Regulations and it repeals them and replaces them with effect from 14 December 2019.

(4) The requirements laid down in this Regulation should ensure a continuation of the requirements laid down in Regulations (EC) No 854/2004 and (EC) No 882/2004 to ensure a high level of protection of health and in order to a avoid a disruption of the entry into the Union of consignments of certain animals and goods intended for human consumption. At the same time the experience gained in the application of the rules laid down in those two Regulations should be taken into account using a risk-based approach.

(5) Regulation (EC) No 853/2004 lays down requirements for food business operators importing products of animal origin into the Union. Accordingly, the additional requirements laid down in this Regulation for official controls should be consistent with those already laid down in Regulation (EC) No 853/2004.

(6) Commission Regulation (EU) 2017/185[(11)] provides for derogations from Regulation (EC) No 854/2004 concerning public health requirements for imports of certain products of animal origin (such as insects and reptile meat) and food containing both products of plant origin and processed products of animal origin (composite products) until 31 December 2020. In order to ensure a high level of protection of health, requirements for the entry into the Union of such products should also be laid down

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before the expiry of the transitional measures in order to verify compliance with Union rules covering these products.

(7) Insects are increasingly produced for human consumption. It should be ensured that imported insects comply with Union requirements for food and food safety. The additional requirements laid down in this Regulation for the entry into the Union of consignments of products of animal origin should therefore also apply to insects. Insects may also be subject to authorisation as novel food in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council[(12)].

(8) On 18 October 2007, the European Food Safety Authority adopted an Opinion on the public health risks involved in the human consumption of reptile meat[(13)]. A number of hazards such as *Salmonella* and *Trichinella* were identified. Requirements for the entry into the Union should include verification of compliance with Union requirements to reduce the risk from these hazards in consignments of reptile meat.

(9) The composition of composite products affects the physico-chemical characteristics of such foods, leading to different risks. For this reason, only consignments of composite products which comply with applicable requirements, notably on the origin of the processed products of animal origin that compose such foods, the origin of the food itself, or the guarantees that accompany the consignments of composite products, should be authorised for entry into the Union. For composite products that pose a low risk to human health, this Regulation should provide for derogations from checks at the border control posts.

(10) When laying down requirements for the entry into the Union of consignments of certain animals and good intended for human consumption, reference should be made to the Combined Nomenclature codes in accordance with Council Regulation (EEC) No 2658/87[(14)] to clearly identify these goods and animals.

(11) Consignments of certain animals and goods intended for human consumption should only be allowed to enter the Union, based on a risk analysis, when the third countries or regions thereof from which these animals and goods originate, can ensure compliance with the requirements on the safety of these animals and goods intended for human consumption and are duly listed in Commission Implementing Regulation (EU) 2019/626[(15)].

(12) In addition to the requirements in Article 127(3) of Regulation (EU) 2017/625, specific requirements should be laid down for certain animals and goods intended for human consumption in order to provide guarantees as regards the efficiencies of official controls on food safety in third countries or regions thereof. Third countries or regions thereof should only appear on lists after evidence and guarantees have been provided that the animals and goods concerned from the third countries or regions thereof comply with Union requirements for the safety of food, or with requirements recognised to be equivalent thereto, laid down in Directive 96/23/EC, Regulations (EC) No 999/2001, (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EU) 2017/625, and Delegated Regulation (EU) 2019/624 and Implementing Regulation (EU) 2019/627.

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(13) Consignments of certain goods intended for human consumption should only be allowed to enter the Union where those goods are dispatched from, and obtained or prepared in, establishments which appear on lists drawn up and kept up to date in accordance with Article 127(3)(e) of Regulation (EU) 2017/625. In addition, in order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, it is appropriate to provide that when drawing up and updating the lists of such establishments referred to in Article 127(3)(e) of Regulation (EU) 2017/625, the third country should give guarantees in addition those referred to in Article 127(3)(e)(i) and (iv) of Regulation (EU) 2017/625.

(14) The Commission should make the lists of establishments provided for in Article 127 of Regulation (EU) 2017/625 available to the public to ensure transparency for food business operators and consumers as regards which establishments such goods may enter the Union for placing on the market. With a view to ensure the effectiveness of these requirements, Member States should allow the entry of consignments of such goods provided that the official certificates which are required to accompany such consignments pursuant to the applicable Union rules are issued by the competent authorities of the third country starting with the date of publication by the Commission of the lists.

(15) Such requirements concerning establishments should not be established in relation to goods intended for transit, since they represent a low risk from a food safety perspective and there is no placing on the market of animals and goods within the Union. In addition, such requirements should not be established for establishments carrying out only primary production activities, transport operations, storage of products of animal origin not requiring temperature-controlled storage conditions or production of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids referred to in Section XVI of Annex III to Regulation (EC) No 853/2004.

(16) Commission Regulation (EU) No 210/2013[16] requires establishments producing sprouts to be approved by the competent authorities in accordance with Article 6 of Regulation (EC) No 852/2004. In order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, sprouts should only be allowed entry to the Union if they are produced in establishments, which appear on lists drawn-up and updated in accordance with this Regulation.

(17) In order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, products from establishments manufacturing fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen, should only be allowed entry into the Union if these establishments appear on lists drawn-up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission. In addition, the raw materials these products are manufactured from, should come from establishments (slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products) appearing

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on lists drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission.

(18) Consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods should only be allowed entry into the Union from production areas in third countries or regions thereof that appear on lists drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission, in order to ensure compliance with the applicable specific requirements for these products laid down in Regulation (EC) No 853/2004 and Implementing Regulation (EU) 2019/627, or with rules recognised to be at least equivalent thereto. The publication of those lists should ensure transparency for food business operators and consumers as regards from which production areas live bivalve molluscs, echinoderms, tunicates and marine gastropods may enter the Union.

(19) Consignments of fishery products should only be allowed entry into the Union when the consignments are dispatched from, obtained or prepared in an on-land establishment, reefer, factory or freezer vessels flying the flag of a third country that appears on lists drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission, in order to ensure compliance with Union requirements, in particular with the specific requirements for fishery products laid down in Regulation (EC) No 853/2004 and Implementing Regulation (EU) 2019/627, or with rules recognised to be at least equivalent thereto. The publication of such lists should ensure transparency for food business operators and consumers as regards the vessels from which fishery products may enter the Union.

(20) The conditions for entry into the Union of products of animal origin laid down in Regulation (EC) No 853/2004 do not apply to composite products. However, that Regulation requires the food business operators importing composite products to ensure that the processed products of animal origin contained in such foods satisfy the requirements laid down in that Regulation.

(21) The risk related to the composite products depends on the type of ingredients and on their storage conditions. Requirements concerning the consignments of composite products should therefore be laid down in order to ensure that those composite products presenting a risk be exported from countries which are authorised to export to the Union pursuant to Commission Decision 2007/777/EC[(17)], Commission Decision 2006/766/EC[(18)], Commission Regulation (EC) No 798/2008[(19)], Commission Regulation (EU) No 605/2010[(20)] and Commission Decision 2011/163/EU[(21)].

(22) Based on the number of notifications received in the Rapid Alert System for Food and Feed established by Regulation (EC) No 178/2002, consignments of certain animals and goods placed on the market for human consumption present an enhanced risk for non-compliance with Union requirements on food safety. Consignments of such animals and goods placed on the market for human consumption should therefore be subject to the individual certification of each consignment for entry into the Union for placing on the market. Certification of compliance with Union requirements may also contribute to reminding food business operators and the competent authorities of third countries or