

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⁾;
 - 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 853/2004 of the European Parliament and of the Council ⁽⁵⁾;

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

⁽³⁾ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

⁽⁴⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

⁽⁵⁾ Regulation (EC) No 853/2004 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).

특정 동물 및 식품의 유럽 연합 반입 요건에 관련된 유럽의 회 및 이사회의 보충 규정 (EU) 2017/625

2019년 3월 4일자

위원회 위임 규정 (EU) 2019/625

**특정 식용 동물 및 상품화물의 유럽 연합 반입 요건에 관련된 유럽의 회 및 이사회의 보충 규정 (EU) 2017/625
(EEA 에 적용 가능한 텍스트)**

유럽 위원회는

유럽 연합의 기능에 관한 조약에 관련하여,

유럽의 회 및 이사회의 규정 (EC) 제 999/2001호, (EC) 제 396/2005호, (EC) 제 1069/2009호, (EC) 제 1107/2009호, (EU) 제 1151/2012호, (EU) 제 652/2014호, (EU) 2016/429 및 (EU) 2016/2031 과 이사회 규정 (EC) 제 1/2005호 및 (EC) 제 1099/2009 와 이사회 지침 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC 및 2008/120/EC 를 개정하고 유럽의 회 및 이사회의 규정 (EC) 제 854/2004호 및 (EC) 제 882/2004호 와 이사회 지침 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC 및 97/78/EC 와 이사회 결정 92/438/EEC (공식 통제 조치 규정) (1)) 와 특히 그 제 126(1) 항 을 폐지한, 동물 건강 및 복지, 식물 건강 및 식품 보호 제품에 관한 식품 및 사료 법령의 적용을 보장하기 위해 수행되는 공식 통제 조치 및 기타 공식 활동에 관한 유럽의 회 및 이사회의 2017년 3월 15일 자 규정 (EU) 2017/625 에 관련하여,

배경 사실:

- (1) 규정 (EU) 2017/625에서는 제 3국 또는 그 지역에서 반출된 동물 및 상품화물의 유럽 연합 반입을 위해 이행해야 할 요건의 제정과 식용 동물 및 상품화물 이 식품 및 식품 안전성 영역에 관한 유럽 연합 법률을 준수할 수 있도록 상기 동물 및 상품에 수행되는 공식 통제 조치를 포함하여 회원국 관할 관청이 수행하는 공식 통제 조치 및 기타 공식 활동에 관한 규칙을 정하고 있다.
- (2) 규정 (EU) 2017/625에서는 특정 동물 및 상품의 유럽 연합 반입에 관한 규정에서 정하는 조건을 보완하기 위해 채택할 수 있는 위임 입법의 법적 근거를 규정하고 있다. 이 추가 요건에서는 다음 사항의 준수를 검증하기 위한 보증을 규정한다.
- 이사회 지침 96/23/EC (2) 에 따라 식용 동물 및 상품의 물질 및 잔류물 그룹을 모니터링하기 위한 조치.
 - 유럽의 회 및 이사회의 규정 (EC) 제 999/2001호 (3) 에 따라 살아 있는 동물 및 동물 유래 생산물에서 전염성 해면상 뇌증 (TSE) 의 예방, 억제 및 박멸하기 위한 규칙.
 - 유럽의 회 및 이사회의 규정 (EC) 제 178/2002호 (4) 에 따라 유럽 연합 및 회원국 수준에서 일반적인 식품과 특정적인 식품 안전성을 규율하는 일반 원칙 및 요건.
 - 유럽의 회 및 이사회의 규정 (EC) 제 852/2004호 (5) 에 따라 식품 사업 운영자들이 식품의 위생에 관련하여 준수해야 할 일반 규칙.

(1) OJ L 95, 7.4.2017, p. 1.

(2) 살아 있는 동물 및 동물 생산물의 특정 물질 및 잔류물을 모니터링하는 조치에 관한 규정하고 지침 85/358/EEC 및 86/469/EEC 과 결정 89/187/EEC 및 91/664/EEC 를 폐지한 이사회 지침 96/23/EC (OJ L 125, 23.5.1996, p. 10).

(3) 특정 전염성 해면상 뇌증을 예방, 억제 및 박멸하는 규칙을 정한 유럽의 회 및 이사회의 2001년 5월 22일 자 규정 (EC) 제 999/2001호 (OJ L 147, 31.5.2001, p. 1).

(4) 식품 법률의 일반 원칙 및 요건, 유럽 식품 안전청의 설치 및 식품 안전성 문제의 절차를 규정한 유럽의 회 및 이사회의 2002년 1월 28일 자 규정 (EC) 제 178/2002호 (OJ L 31, 1.2.2002, p. 1).

(5) 식품 위생에 관한 유럽의 회 및 이사회의 2004년 4월 29일 자 규정 (EC) 제 852/2004호 (OJ L 139, 30.4.2004, p. 1).

- 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 ⁽⁷⁾;
 - 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 ⁽⁸⁾ and Commission Implementing Regulation (EU) 2019/627 ⁽⁹⁾.
- (3) Regulation (EC) No 854/2004 of the European Parliament and of the Council ⁽¹⁰⁾ 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 ⁽¹¹⁾ 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 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 ⁽¹²⁾ 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 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 ⁽¹³⁾.
 - (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 ⁽¹⁴⁾. 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.

⁽⁷⁾ 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).

⁽⁸⁾ Commission Delegated Regulation (EU) 2019/624, of 8 February 2018 concerning specific rules for the performance of official controls on the production of meat and for production and rearing areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (see page 1 of this Official Journal).

⁽⁹⁾ Commission Implementing Regulation (EU) 2019/627 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 (see page 51 of this Official Journal).

⁽¹⁰⁾ 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 39, 30.4.2004, p. 206).

⁽¹¹⁾ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

⁽¹²⁾ Commission Regulation (EU) 2017/185 of 2 February 2017 laying down transitional measures for the application of certain provisions of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and the Council (OJ L 29, 3.2.2017, p. 21).

⁽¹³⁾ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

⁽¹⁴⁾ <http://www.efsa.europa.eu/en/efsajournal/pub/578>

- 유럽의회및이사회의규정 (EC) 제 853/2004 호⁽⁶⁾에따라식품사업운영자가준수해야할동물성식품의위생에관한특별규칙.
- 위원회위임규정 (EU) 2019/624(7) 및위원회시행규정 (EU) 2019/627⁽⁸⁾에따라식품동물유래생산물생산에관한하여관할관청이수행하는공식통제조치및기타조치에대한특별규칙.
- (3) 유럽의회및이사회의규정 (EC) 제854/2004호(9) 에서는식품동물유래생산물의유럽연합에반입할수있는특별조건을규정했으며, 유럽의회및이사회의규정 (EC) 제882/2004호(10) 에서는유럽연합에반입할수있는일반조건을규정했다. 규정(EU) 2017/625에서는현재이두규정이적용되는영역에대한규칙을정하면서 2019년 12월 14일부터두규정을폐지및대체하는효력을발생한다.
- (4) 본규정에서정하고있는요건에서는고도의건강보호수준을확보하고특정식품동물및상품화물의유럽연합반입중단을방지하기위해규정 (EC) 제854/2004호및 (EC) 제882/2004호에규정된요건의연속성을보장해야한다. 동시에이두규정에규정된규칙의적용에서축적된경험을위험기반접근법을사용하여검토해야한다.
- (5) 규정 (EC) 제853/2004호에서는동물유래생산물을유럽연합으로수입하는식품사업운영자의요건을규정하고있다. 따라서이규정에서공식통제조치에대해추가로규정하는요건은규정 (EC) 제853/2004호에이미규정된요건과일치해야한다.
- (6) 위원회규정 (EU) 2017/185(11) 에서는특정동물유래생산물(곤충및파충류육류등)과식품유래생산물및가공된동물유래생산물을모두함유하는식품(복합제품) 수입의공중보건요건에관한규정 (EC) 제854/2004호를 2020년 12월 31일까지적용면제한다고규정하고있다. 또한고도의건강보호수준을확보하러면상기제품에적용되는유럽연합규칙의준수를검증하기위해상기제품의유럽연합반입에대한요건을경과조치가만료되기전에규정해야한다.
- (7) 식용으로생산되는곤충의수량이점점더많아지고있다. 수입되는곤충은식품및식품안전성에대한유럽연합요건을준수해야한다. 동물유래생산물화물의유럽연합반입에대해본규정에서정하고있는요건은따라서곤충에도적용된다. 곤충은또한유럽의회및이사회의규정 (EU) 2015/2283⁽¹²⁾에따라신규식품으로서의품목허가를얻어야할수도있다.
- (8) 2007년 10월 18일에유럽식품안전청은파충류육류의식용에관련된공중보건위험에관한의견서(13) 를채택했다. *Salmonella* 및 *Trichinella* 와같은많은위해요소가확인되었다. 유럽연합반입의요건에는파충류육류화물에서이위해요소로인한위험을줄이기위한유럽연합요건준수의검증이포함되어야한다.

⁽⁶⁾ 동물성식품의특별위생규칙을규정하고있는유럽의회및이사회의 2004년 4월 29일자규정 (EC) 제 853/2004호(OJ L 139, 30.4.2004, p. 55).

⁽⁷⁾ 유럽의회및이사회의규정 2017/625에따라식품생산에대한공식통제조치수행과살아있는쌍각류조개의생산및증개지역의특별규칙을규정한 2018년 2월 8일자위원회위임규정 (EU) 2019/624(본관보 1페이지참조).

⁽⁸⁾ 유럽의회및이사회의규정 2017/625에따라식품동물유래생산물의공식통제조치수행을위한통일적인실무장치를규정하고공식통제조치에관한위원회규정 (EC) 제 2074/2005호를개정한 2019년 3월 15일자위원회시행규정 (EU) 2019/627(본관보 51페이지참조).

⁽⁹⁾ 식품동물유래생산물에대한공식통제조치의조직의특별규칙을규정한유럽의회및이사회의 2004년 4월 29일자규정 (EC) 제 854/2004호(OJ L 139, 30.4.2004, p. 206).

⁽¹⁰⁾ 사료및식품법률, 동물보건및동물복지규칙의준수검증을확보하기위해수행되는공식통제조치에관한유럽의회및이사회의 2004년 4월 29일자규정 (EC) 제 882/2004호(OJ L 165, 30.4.2004, p. 1).

⁽¹¹⁾ 유럽의회및이사회의규정 (EC) 제 853/2004호및 (EC) 제 854/2004호의특정규정의적용에대한경과조치를규정한 2017년 2월 2일자위원회규정 (EU) 2017/185(OJ L 29, 3.2.2017, p. 21).

⁽¹²⁾ 유럽의회및이사회의규정 (EU) 제1169/2011호를개정하고유럽의회및이사회의규정 (EC) 제 258/97호와위원회규정 (EC) 제1852/2001호를폐지한신규식품에대한유럽의회및이사회의 2015년 11월 25일자규정 (EU) 2015/2283(OJ L 327, 11.12.2015, p. 1).

⁽¹³⁾ <http://www.efsa.europa.eu/en/efsajournal/pub/578>

- (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 ^(*) 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 ^(**).
- (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.
- (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.

^(*) 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).

^(**) Commission Implementing Regulation (EU) 2019/626 of 5 March 2019 concerning lists of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption and amending Implementing Regulation (EU) 2016/759 as regards these lists (see page 31 of this Official Journal).

- (9) 복합제품의 구성은 해당 식품의 물리·화학적 특성에 영향을 미치면서 다양한 위험을 생성한다. 이때문에 해당 요건, 특히 해당 식품을 구성하는 가공된 동물 유래 생산물의 기원, 식품 자체의 기원 또는 복합 제품 화물에 첨부되는 보증에 대한 요건을 준수한 복합 제품 화물만 유럽 연합 반입을 허가해야 한다. 사람의 건강에 낮은 위험을 제기하는 복합 제품의 경우에는 이 규정에서 국경 통제소의 점검을 면제해야 한다.
- (10) 특정 식용 동물 및 상품 화물을 유럽 연합에 반입하기 위한 요건을 규정할 때는 이상 품 및 동물을 분명히 식별하기 위해 이사회 규정 (EEC) 제 2658/87 호⁽¹⁴⁾에 따라 복합 품목 분류표를 참조해야 한다.
- (11) 특정 식용 동물 및 상품 화물은 이 동물 및 상품에 유래한 제 3 국 및 그 지역이 해당 식용 동물 및 상품의 안전성 요건 준수를 보장할 수 있고 위원회 시행 규정 (EU) 2019/626⁽¹⁵⁾에 적절하게 명시된 경우에만 위험 분석에 기초하여 유럽 연합 반입을 허용해야 한다.
- (12) 특정 식용 동물 및 상품의 경우에는 제 3 국 또는 그 지역의 식품 안전성에 대한 공통 제조 조치 유효성의 보증을 제공하기 위해 규정 (EU) 2017/625 의 제 127(3) 항의 요건 이외에도 특별 요건을 규정해야 한다. 제 3 국 및 그 지역은 해당 제 3 국 및 그 지역에서 유래한 동물 및 상품에 지침 96/23/EC, 규정 (EC) 제 999/2001 호, (EC) 제 178/2002 호, (EC) 제 852/2004 호, (EC) 제 853/2004 호, (EU) 2017/625 과 위임 규정 (EU) 2019/624 및 시행 규정 (EU) 2019/627 에 규정된 유럽 연합의 식품 안전성 요건 또는 이에 상당하다고 인정되는 요건을 준수하고 있다는 내용의 증거 및 보증을 제공한 후에만 목록에 표시해야 한다.
- (13) 특정 식용 상품의 화물은 해당 상품을 규정 (EU) 2017/625 제 127(3)(e) 호에 따라 작성 및 업데이트한 목록에 명시된 시설에서 공급, 취득 또는 조리한 경우에만 유럽 연합 반입을 허용해야 한다. 또한 유럽 연합 식품 위생 규칙 또는 적어도 이에 상당하다고 인정되는 규칙의 준수를 보장하려면 규정 (EU) 2017/625 제 127(3)(e) 호에 규정된 시설의 목록을 작성 및 업데이트 할 때 제 3 국이 규정 (EU) 2017/62 의 제 127(3)(e)(i) 호 및 (iv) 호에 규정된 보증 이외에 해당 보증을 제공해야 한다고 규정하는 것이 적절하다.
- (14) 위원회는 규정 어떤 시설이 해당 상품을 유럽 연합의 시장에서 판할 수 있는지에 대해 식품 사업 운영자 및 소비자의 투명성을 보장하기 위해 (EU) 2017/625 제 127 조에 규정된 시설의 목록을 일반 대중에게 제공해야 한다. 이 요건의 효과를 보장하기 위해 회원국은 위원회가 목록을 공표한 날 이후에는 해당 제 3 국의 관할 관청이 해당 유럽 연합 규칙에 따라 화물에 첨부해야 하는 공식 증명서를 발행하는 경우에 해당 상품 화물의 반입을 허용해야 한다.
- (15) 시설에 관한 상기 요건은 경유 목적의 상품은 식품 안전성 관점에서 위험이 낮고 유럽 연합 내 동물 및 상품 시장에서 판되지 않기 때문에 이에 부과해서는 안 된다. 또한 규정 (EC) 제 853/2004 의 부록 III 제 XVI 조에 규정된 온도 제어 저장 조건이 필요하지 않은 동물 유래 생산물의 1 차 생산 활동, 운송 작업 및 저장 또는 고도로 정제된 콘드로이틴 황산, 히알루론산, 기타 가수분해 연골 제품, 키토산, 글루코사민, 레넷, 아이싱글래스 및 아미노산 생산만 수행하는 시설의 경우에도 상기 요건을 부과해서는 안 된다.

⁽¹⁴⁾ 관세 및 통계적 품목 분류표 그리드 공동 관세에 관한 1987년 7월 23일자 사회 규정 (EEC) 제 2658/87 호(OJ L 256, 7.9.1987, p. 1).

⁽¹⁵⁾ 특정 식용 동물 및 상품에 유럽 연합에 반입할 수 있도록 허가된 제 3 국 및 그 지역의 목록을 규정하고 상기 목록에 관한 시행 규정 (EU) 2016/759 를 개정한 2019년 3월 5일자 위원회 시행 규정 (EU) 2019/626(본관보의 31페이지 참조).

- (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 853/2004. 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 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⁾.

⁽¹⁶⁾ Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 853/2004 of the European Parliament and of the Council (OJ L 68, 12.3.2013, p. 24).

⁽¹⁷⁾ Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC (OJ L 312, 30.11.2007, p. 49).

⁽¹⁸⁾ Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted (OJ L 320, 18.11.2006, p. 53).

⁽¹⁹⁾ Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

⁽²⁰⁾ Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk, dairy products, colostrum and colostrum-based products intended for human consumption (OJ L 175, 10.7.2010, p. 1).

⁽²¹⁾ Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

- (16) 위원회규정 (EU) 제 210/2013(¹⁶)에서는싹을생산하는시설에게규정 (EC) 제 852/2004 호제 6 조에따라관할관청의승인을받도록요구하고있다. 유럽연합식품위생규칙또는적어도이에상당하다고인정되는규칙의준수를보장하기위해이규정에따라작성및업데이트된목록에명시된시설에서싹을생산한경우에만유럽연합반입을허용해야한다.
- (17) 유럽연합식품위생규칙또는적어도이에상당하다고인정되는규칙의준수를보장하기위해생고기, 다짐육, 조리육, 육류생산물, 기계적으로분리된육류와젤라틴및콜라겐을생산하기위한원료를제조하는시설의제품은해당시설이규정 (EU) 2017/625 의제 127(3)(e)호에따라작성및업데이트되고위원회가공표한목록에명시된경우에만유럽연합반입을허용해야한다. 또한상기제품을제조하는데사용한원료도 (EU) 2017/625 의제 127(3)(e)호에따라작성및업데이트되고위원회가공표한목록에명시된시설(도축장, 사냥물취급시설, 절단공장, 어류생산물취급시설)에서생산한것이어야한다.
- (18) 살아있는쌍각류조개, 극피동물, 피낭동물및해양복족류의화물은규정 (EC) 제 853/2004 호및시행규정 (EU) 2019/627 또는적어도이에상당하다고인정되는규칙의준수를보장하기위해규정 (EU) 2017/625 의제 127(3)(e)호에따라작성및업데이트된목록에명시되고위원회가공표한제 3 국또는그지역의생산구역에서생산된경우에만유럽연합반입을허용해야한다. 이목록의공표는어떤생산구역에서살아있는쌍각류조개, 극피동물, 피낭동물및해양복족류를유럽연합에반입할수있는지에대해식품사업운영자및소비자의투명성을확보해야한다.
- (19) 어류생산물화물은유럽연합요건, 특히규정 (EC) 제 853/2004 호및시행규정 (EU) 2019/627 에규정된어류생산물의특별요건또는적어도이에상당하다고인정되는규칙의준수를보장하기위해규정 (EU) 2017/625 의제 127(3)(e)호에따라작성및업데이트된목록에명시되고위원회가공표한목록에명시된육상시설과제 3 국깃발을계양한리퍼선, 공선또는냉동선에서공급, 취득또는조리된경우에만유럽연합반입을허용해야한다.
- (20) 규정 (EC) 제 853/2004 호에규정된동물유래생산물의유럽연합반입조건은복합제품에는적용되지않는다. 그러나이규정에서는복합제품을수입하는식품사업운영자에게해당식품에포함된가공된동물유래생산물에관한여상기규정에명시된요건을충족하도록요구하고있다.
- (21) 복합제품에관련된위험은성분의유형및저장조건에따라다르다. 따라서복합제품화물에관련된요건은위험을제기하는해당복합제품을위원회결정 2007/777/EC(¹⁷), 위원회결정 2006/766/EC(¹⁸), 위원회규정 (EC) 제798/2008호(¹⁹), 위원회규정 (EU) 제605/2010호(²⁰) 및위원회결정 2011/163/EU(²¹)에따라유럽연합에수출할수있도록허가된국가로부터수출할수있도록규정해야한다.

(¹⁶) 유럽의회및이사회규정 (EC) 제852/2004에따라싹을생산하는시설의승인을규정한 2013년 3월 11일자위원회규정 (EU) 제 210/2013(OJ L 68, 12.3.2013, p. 24).

(¹⁷) 특정식용육류생산물과처리된위, 방광및내장을제3국에서수입하기위한동물및공중보건조건과모델증명서를규정하고결정 2005/432/EC를폐지한 2007년 11월 29일자위원회결정 2007/777/EC(OJ L 312, 30.11.2007, p. 49).

(¹⁸) 살아있는쌍각류조개, 극피동물, 피낭동물, 해양복족류및어류생산물의수입을허가할수있는제3국및영토의목록을작성한 2006년 11월 6일자위원회결정 2006/766/EC(OJ L 320, 18.11.2006, p. 53).

(¹⁹) 가금류및가금류생산물을유럽공동체로수입하거나유럽공동체를경유시킬수있는제3국, 영토, 지대또는구역과수의인증요건을규정한 2008년 8월 8일자위원회규정 (EC) 제 798/2008호(OJ L 226, 23.8.2008, p. 1).

(²⁰) 식용원유, 유제품, 초유및초유기반제품의수입을위한동물및공중보건과수의인증조건을규정한 2010년 7월 2일자위원회규정 (EU) 제 605/2010호(OJ L 175, 10.7.2010, p. 1).

(²¹) 이사회지침 96/23/EC 제 29조에따라제 3국이제출하는계획의승인에관한 2011년 3월 16일자위원회결정 2011/163/EU(OJ L 70, 17.3.2011, p. 40).

- (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 regions thereof of the applicable Union requirements. In the case of transit, the use of the current dedicated transit certificates with animal health attestation should remain.
- (23) As Regulation (EU) 2017/625 applies with effect from 14 December 2019, this Regulation should also apply from that date. Transitional measures providing derogations from Regulations (EC) No 853/2004 and (EC) No 854/2004, concerning public health requirements for the imports of composite products have been laid down in Regulation (EU) 2017/185 and will be extended until 20 April 2021 in accordance with Commission Regulation (EU) 2019/759⁽¹⁷⁾. The import requirements laid down in this Regulation should therefore apply from 20 April 2021 for composite products in order to ensure a smooth transition,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation supplements Regulation (EU) 2017/625 as regards the requirements for the entry in the Union of consignments of certain animals and goods intended for human consumption from third countries or regions thereof in order to ensure that they comply with the applicable requirements established by the rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625 or with requirements recognised to be at least equivalent thereto.
2. The requirements referred to in paragraph 1 cover:
 - (a) the identification of animals and goods subject to the following requirements for entry into the Union:
 - (i) the requirement that those animals and goods shall come from a third country or region thereof listed in accordance with Article 126(2)(a) of Regulation (EU) 2017/625;
 - (ii) the requirement that those animals and goods be dispatched from, and obtained or prepared in, establishments which comply with applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto, and which appear on lists drawn-up and updated in accordance with Article 127(3)(c)(ii) and (iii) of Regulation (EU) 2017/625;
 - (iii) the requirement that each consignment of animals and goods be accompanied by an official certificate, or official attestation or any other evidence of compliance with the rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625, such as a private attestation, in accordance with Article 126(2)(c) of Regulation (EU) 2017/625;
 - (b) requirements for the entry into the Union of certain animals and goods from a third country or region thereof, listed in accordance with Article 127(2) of Regulation (EU) 2017/625;
 - (c) requirements that consignments of certain goods from third countries be dispatched from, and obtained or prepared in, establishments which comply with the applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto, and which appear on lists drawn-up and updated in accordance with Article 127(3)(c)(ii) and (iii) of Regulation (EU) 2017/625;
 - (d) requirements for the entry into the Union for placing on the market of the specific following commodities in addition to the requirements laid down in accordance with Article 126 of Regulation (EU) 2017/625:
 - (i) fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen;

⁽¹⁷⁾ Commission Regulation (EU) 2019/759 of 13 May 2019 laying down transitional measures for the application of public health requirements of imports of food containing both products of plant origin and processed products of animal origin (composite products) (OJ L 125, 14.5.2019, p. 11).

- (22) 규정 (EC) 제 178/2002 호에 규정된 식품 및 사료의 신속경보시스템에서 접수한 알람 개수에 기초할 때, 식용으로 시판되는 특정 동물 및 상품화물이 식품 안전성에 대한 유럽 연합 요건을 준수하지 않을 위험이 높아졌다. 식용으로 시판되는 상기 동물 및 상품화물은 따라서 유럽 연합에 반입되어 시판되려면 각 화물의 개별 인증을 획득해야 한다. 유럽 연합 요건의 준수 인증은 또한 식품 사업 운영자 및 제 3 국 또는 그 지역의 관할 관청에 해당 유럽 연합 요건을 상기시키는 데에도 기여할 수 있다. 경유 화물의 경우에는 현행 동물 건강 증명서의 전용 경유 증명서를 그대로 사용한다.
- (23) 규정 (EU) 2017/625 가 2019 년 12 월 14 일부터 발효되기 때문에 이 규정도 또한 상기 날짜에서부터 적용된다. 복합 제품의 수입을 위한 공중 보건 요건에 대해 규정 (EC) 제 853/2004 호 및 (EC) 제 854/2004 호의 적용 면제를 규정한 경과 조치가 규정 (EU) 2017/185 에 규정되었으며, 위원회 규정 (EU) 2019/759⁽²²⁾에 따라 2021 년 4 월 20 일까지 연장된다. 이 규정에 규정된 수입 요건은 따라서 복합 제품에 대해서는 원활한 이행을 확보하기 위해 2021 년 4 월 20 일에서부터 적용해야 한다.

이상의 사실을 감안하면서 본 규정을 채택했다.

제 1 조

대상 및 범위

1. 본 규정은 제 3 국 또는 그 지역으로부터 유럽 연합에 반입되는 특정 동물 및 상품화물이 규정 (EU) 2017/625 의 제 1(2)(a) 호에 규정된 요건 또는 적어도 이에 상당하다고 인정되는 요건을 준수할 수 있도록 상기 요건에 관한 규정 (EU) 2017/625 를 보완한다.
2. 제 1 항에 규정된 요건은 다음과 같다.
 - (a) 동물 및 상품의 식별에는 다음과 같은 유럽 연합 반입 요건이 적용된다.
 - (i) 동물 및 상품은 규정 (EU) 2017/625 제 126(2)(a) 호에 따라 명시된 제 3 국 또는 그 지역에서 반출된 것이어야 한다.
 - (ii) 상기 동물 및 상품은 규정 (EU) 2017/625 제 126(1) 항에 규정된 요건 또는 적어도 이에 상당하다고 인정되는 요건을 준수하고 규정 (EU) 2017/625 의 제 127(3)(e)(ii) 호 및 (iii) 호에 따라 작성 및 업데이트된 목록에 명시된 시설에서 공급, 취득 또는 조리되어야 한다.
 - (iii) 각 동물 및 상품화물에는 규정 (EU) 2017/625 제 126(2)(c) 호에 따라 공식 증명서 또는 공인 인증서 또는 규칙 (EU) 2017/625 제 1(2)(a) 호에 규정된 규칙을 준수했다는 사실 인증서 등의 기타 증거를 첨부해야 한다.
 - (b) 특정 동물 및 상품은 규정 (EU) 2017/625 제 127(2) 항에 따라 명시된 제 3 국 또는 그 지역으로부터 유럽 연합에 반입되어야 한다.
 - (c) 제 3 국으로부터 반입되는 특정 상품의 화물은 규정 (EU) 2017/625 제 126(1) 항에 규정된 해당 요건 또는 적어도 이에 상당하다고 인정되는 요건을 준수하고 규정 (EU) 2017/625 제 127(3)(e)(ii) 호 및 (iii) 호에 따라 작성 및 업데이트된 목록에 명시된 시설에서 공급, 취득 또는 조리되어야 한다.
 - (d) 다음과 같은 특정 상품은 규정 (EU) 2017/625 제 126 조에 규정된 요건 이외에도 유럽 연합 시장에서 시판하기 위해 반입해야 한다.
 - (i) 생고기, 다짐육, 조리육, 육류 생산물, 기계적으로 분리된 육류와 젤라틴 및 콜라겐의 생산을 위한 원료.

⁽²²⁾ 식물 유래 생산물 및 가공된 동물 유래 생산물 모두 함유한 식품(복합제품)을 수입하는 데 공중 보건 요건을 적용하기 위한 경과 조치를 규정한 2019년 5월 13일 자 위원회 규정 (EU) 2019/759(OJ L 125, 14.5.2019, p. 11).

- (ii) live bivalve molluscs, echinoderms, tunicates and marine gastropods;
 - (iii) fishery products;
 - (iv) composite products;
- (e) additional requirements for the official certificates, official attestations and private attestations that shall accompany certain animals and goods for entry into the Union.

3. This Regulation shall not apply to:

- (a) Animals and goods not intended for human consumption, however when the destination of the animals and goods has not been decided at entry into the Union, this Regulation applies;
- (b) Animals and goods intended for human consumption only for transit through the Union without being placed on the market.

Article 2

Definitions

For the purpose of this Regulation, the following definitions shall apply:

- (1) 'equivalent' means equivalent as defined in Article 2(1)(c) of Regulation (EC) No 853/2004;
- (2) 'placing on the market' means placing on the market as defined in point (8) of Article 3 of Regulation (EC) No 178/2002;
- (3) 'establishment' means an establishment as defined in Article 2(1)(c) of Regulation (EC) No 853/2004;
- (4) 'private attestation' means an attestation signed by the importing food business operator;
- (5) 'fresh meat' means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;
- (6) 'minced meat' means minced meat as defined in point 1.13 of Annex I to Regulation (EC) No 853/2004;
- (7) 'meat preparations' means meat preparations as defined in point 1.15 of Annex I to Regulation (EC) No 853/2004;
- (8) 'meat products' means meat products as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004;
- (9) 'mechanically separated meat' means mechanically separated meat as defined in point 1.14 of Annex I to Regulation (EC) No 853/2004;
- (10) 'gelatine' means gelatine as defined in point 7.7 of Annex I to Regulation (EC) No 853/2004;
- (11) 'collagen' means collagen as defined in point 7.8 of Annex I to Regulation (EC) No 853/2004;
- (12) 'bivalve molluscs' means bivalve molluscs as defined in point 2.1 of Annex I to Regulation (EC) No 853/2004;
- (13) 'fishery products' means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;
- (14) 'composite product' means food containing both products of plant origin and processed products of animal origin;
- (15) 'reptiles' means animals belonging to the species *Alligator mississippiensis*, *Crocodylus johnstoni*, *Crocodylus niloticus*, *Crocodylus porosus*, *Timon Leptus*, *Python reticulatus*, *Python molurus bivittatus* or *Pholidiscus sinensis*;
- (16) 'reptile meat' means the edible parts, either unprocessed or processed, derived from farmed reptiles, which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 and listed in Commission Implementing Regulation (EU) 2017/2470 ⁽¹⁾;

⁽¹⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel food (OJ L 351, 30.12.2017, p. 72).

- (ii) 살아있는쌍각류조개, 극피동물, 피낭동물및해양복족류.
 - (iii) 어류생산물.
 - (iv) 복합제품.
 - (e) 특정동물및상품의유럽연합반입을위해첨부해야할공식증명서, 공인인증서및사설인증서에대한추가요건.
3. 본규정은다음품목에는적용되지않는다.
- (a) 식용이아닌동물및상품. 그러나동물및상품의목적지가유럽연합반입당시에결정되지않은경우에는본규정을적용한다.
 - (b) 식용동물및상품이지만유럽연합의시장에서판매하지않고유럽연합을경유하는품목인경우.

제 2 조

정의

본규정의목적상, 다음정의가적용된다.

- (1) '상당한'은규정 (EC) 제852/2004호의제2(1)(e)호에규정된의미를가진다.
- (2) '시판'은규정 (EC) 제178/2002호의제3조 (8)호에규정된의미를가진다.
- (3) '시설'은규정 (EC) 제852/2004호의제2(1)(c)호에규정된의미를가진다.
- (4) '사설인증서'는수입식품사업운영자가서명한인증서를의미한다.
- (5) '생고기'는규정 (EC) 제853/2004호부록 I의제1.10호에규정된의미를가진다.
- (6) '다짐육'은규정 (EC) 제853/2004호부록 I의제1.13호에규정된의미를가진다.
- (7) '조리육'은규정 (EC) 제853/2004호부록 I의제1.15호에규정된의미를가진다.
- (8) '육류생산물'은규정 (EC) 제853/2004호부록 I의제7.1호에규정된의미를가진다.
- (9) '기계적으로분리된육류'는규정 (EC) 제853/2004호부록 I의제1.14호에규정된의미를가진다.
- (10) '젤라틴'은규정 (EC) 제853/2004호부록 I의제7.7호에규정된의미를가진다.
- (11) '콜라겐'은규정 (EC) 제853/2004호부록 I의제7.8호에규정된의미를가진다.
- (12) '쌍각류조개'는규정 (EC) 제853/2004호부록 I의제2.1호에규정된의미를가진다.
- (13) '어류생산물'은규정 (EC) 제853/2004호부록 I의제3.1호에규정된의미를가진다.
- (14) '복합제품'은식품유래생산물및가공된동물유래생산물을모두함유한식품을의미한다.
- (15) '파충류'는*Alligator mississippiensis*, *Crocodylus johnstoni*, *Crocodylus niloticus*, *Crocodylus porosus*, *Timon Lepidus*, *Python reticulatus*, *Python molurus bivittatus* 또는 *Pelodiscussinensis* 종에속하는동물을의미한다.
- (16) '파충류육류'는가공여부를불문하고해당되는경우에규정 (EU) 2015/2283에따라허가되고위원회시행규정 (EU) 2017/2470⁽²³⁾에명시된사육된파충류에서유래한식용부위를의미한다.

⁽²³⁾ 신규식품에대한유럽의회및사회의규정 (EU) 2015/2283에따라유럽연합의신규식품목록을정한 2017년 12월 20일자위원회시행규정 (EU) 2017/2470(OJ L 351, 30.12.2017, p. 72).

- (17) 'insects' means food consisting of, isolated from or produced from insects or their parts including any life stadia of insects intended for human consumption which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 and listed in Implementing Regulation (EU) 2017/2470;
- (18) 'sprouts' means sprouts as defined in point (a) of Article 2 of Commission Implementing Regulation (EU) No 208/2013^(*);
- (19) 'primary production' means primary production as defined in point (17) of Article 3 of Regulation (EC) No 178/2002;
- (20) 'slaughterhouse' means a slaughterhouse as defined in point 1.16 of Annex I to Regulation (EC) No 853/2004;
- (21) 'game-handling establishment' means a game-handling establishment as defined in point 1.18 of Annex I to Regulation (EC) No 853/2004;
- (22) 'cutting plant' means a cutting plant as defined in point 1.17 of Annex I to Regulation (EC) No 853/2004;
- (23) 'production area' means a production area as defined in point 2.5 of Annex I to Regulation (EC) No 853/2004;
- (24) 'factory vessel' means a factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;
- (25) 'freezer vessel' means a freezer vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;
- (26) 'reefer vessel' means a vessel equipped to store and transport palletized or loose cargo (bulk) goods in temperature controlled holds or chambers;
- (27) 'food business operator' means a food business operator as defined in point (3) of Article 3 of Regulation (EC) No 178/2002.

Article 3

Animals and goods which are required to come from third countries or regions thereof included in the list referred to in Article 126(2)(a) of Regulation (EU) 2017/625

Consignments of the following animals and goods intended for human consumption shall enter the Union only from a third country or region thereof included in the list for those animals and goods laid down in Articles 3 to 22 of Implementing Regulation (EU) 2019/626:

- (a) products of animal origin, including reptile meat and dead whole insects, parts of insects or processed insects, for which Combined Nomenclature codes (CN codes) have been laid down in Chapters 2 to 5, 15 and 16, and Harmonised System codes (HS codes) under headings 1702, 1806, 2102, 2103, 2105, 2106, 2202, 2301, 2822, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110 and 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87, when these products are intended for human consumption;
- (b) live insects referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87.

Article 4

Additional requirements for entry into the Union of certain animals and goods from a third country or region thereof

In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, the Commission shall only decide on the inclusion of third countries or regions thereof in the list referred to in Article 126(2)(a) of that Regulation if the following requirements are recognised by the Commission as being at least equivalent to the relevant requirements in the Union for animals and goods referred to in Article 3:

- (a) the legislation of the third country on:
- (i) the production of food of animal origin;

^(*) Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 16).

(17)

'곤충'은수명주기에상관없이식용곤충또는그일부로구성되었거나곤충또는그일부에서분리또는생산된식품으로서해당되는경우에규정 (EU) 2015/2283 에따라허가되고시행규정 (EU) 2017/2470 에명시된품목을의미한다.

(18) '싹'은위원회시행규정제 208/2013 호⁽²⁴⁾ 제 2 조 (a)호에규정된의미를가진다.

(19) '1 차생산'은규정 (EC) 제 178/2002 제 3 조 (17)호에규정된의미를가진다.

(20) '도축장'은규정 (EC) 제 853/2004 호부록 I 의제 1.16 호에규정된의미를가진다.

(21) '사냥물취급시설'은규정 (EC) 제 853/2004 호부록 I 의제 1.18 호에규정된의미를가진다.

(22) '절단공장'은규정 (EC) 제 853/2004 호부록 I 의제 1.17 호에규정된의미를가진다.

(23) '생산구역'은규정 (EC) 제 853/2004 호부록 I 의제 2.5 호에규정된의미를가진다.

(24) '공선'은규정 (EC) 제 853/2004 호부록 I 의제 3.2 호에규정된의미를가진다.

(25) '냉동선'은규정 (EC) 제 853/2004 호부록 I 의제 3.3 호에규정된의미를가진다.

(26) '리퍼션'은팔레트화화물또는루즈화물(벌크)을온도제어저장고또는저장실로저장맞운송할수있도록장치된선박을의미한다.

(27) '식품사업운영자'는규정 (EC) 제 178/2002 호제 3 조 (3)호에규정된의미를가진다.

제3 조

규정 (EU) 2017/625 제 126(2)(a)호에규정된목록에명시된제 3 국또는그지역에서반출해야하는동물및상품

다음의식용동물및상품화물은시행규정 (EU) 2019/626 제3-22조에규정된동물및상품목록에명시된제3국또는그지역에서만유럽연합으로반입해야한다.

- (a) 제품이식용인경우에복합품목분류표('CN 코드')가규정 (EEC) 제2658/87 부록 I의제2부제2-5장, 15장및 16장에규정되고 HS 품목분류표('HS 코드')가 1702, 1806, 2102, 2103, 2105, 2106, 2202, 2301, 2822, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110, 9602 등의표제하에규정된파충류육류와죽은곤충의전체또는일부또는가공된곤충을포함한동물유래생산물.
- (b) 규정 (EEC) 제2658/87 부록 I의제2부 CN 코드 0106 49 00에규정된살아있는곤충.

제4 조

특정동물및상품을제3국또는그지역으로부터유럽연합으로반입하기위한추가요건

규정 (EU) 2017/625 제127(3)항에규정된요건이외에도위원회는다음요건이제3조에규정된동물및상품에대해유럽연합이정한해당요건에적어도상당한 것으로인정하는경우에만상기규정제 126(2)(a)호에규정된목록에명시된제3국또는그지역의포함여부를결정해야한다.

- (a) 다음사항에대한해당제3국의법률.
- (i) 동물성식품의생산.

⁽²⁴⁾ 싹및싹의생산을위한종자의추적성요건에관한 2013년 3월 11일자위원회시행규정 (EU) 제 208/2013호(OJ L 68, 12.3.2013, p. 16).

- (ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;
 - (iii) the preparation and use of feed, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;
- (b) the hygiene conditions of production, manufacture, handling, storage and dispatch currently applied to products of animal origin destined for the Union;
 - (c) any experience of marketing of the products of animal origin from the third country and the results of any official controls on entry in the Union;
 - (d) when available, the results of controls carried out by the Commission in the third country related to other animals and goods for which the third country is already listed in accordance with Article 127(2) of Regulation (EU) 2017/625, in particular the results of the assessment of the competent authorities in the third country audited, and the action that the competent authorities have taken in the light of any recommendations addressed to them following such audits by the Commission;
 - (e) the existence, implementation and communication of a zoonoses control programme approved by the Commission when applicable;
 - (f) the existence, implementation and communication of a residues control programme approved by the Commission when applicable, in accordance with Directive 96/23/EC.

Article 5

Requirements for entry into the Union of certain goods from a third country in relation to establishments

1. Consignments of the following goods shall only enter the Union where those consignments 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)(c)(ii) and (iii) of Regulation (EU) 2017/625:
 - (a) products of animal origin for which requirements are laid down in Annex III to Regulation (EC) No 853/2004, and for which CN codes have been laid down in Chapters 2 to 5, 15 and 16, and HS codes under headings 2102, 2103, 2105, 2106, 2202, 2301, 2822, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103 and 4110 of Part Two of Annex I to Regulation (EEC) No 2658/87;
 - (b) sprouts referred to by the following HS codes: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90 or 1214 90 of Part Two of Annex I to Regulation (EEC) No 2658/87.
2. Establishments referred to in paragraph 1 of this Article may be placed on the lists referred to in Article 127(3)(c) of Regulation (EU) 2017/625 only if, in addition to the guarantees laid down in Article 127(3)(c)(ii) and (iv) of Regulation (EU) 2017/625, the third country gives the following guarantees:
 - (a) such establishments, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, comply with applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, in particular those of Regulation (EC) No 853/2004, or with requirements recognised to be at least equivalent thereto;
 - (b) the establishment, where appropriate, only handles raw materials of animal origin that come from third countries with an approved residues monitoring plan for that product category in accordance with Directive 96/23/EC or from Member States;
 - (c) it has real powers to stop the establishments from exporting to the Union in the event that the establishments fail to meet the relevant Union requirements or requirements recognised to be at least equivalent thereto.
3. The Commission shall provide the Member States with any new and updated lists that it receives from the competent authorities of the third country in accordance with Article 127(3)(c)(iii) of Regulation (EU) 2017/625 and shall publish such lists on its website.
4. Member States shall allow the entry into the Union of the consignments referred to in paragraph 1 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 referred to in paragraph 1.

- (ii) 수의약품금지또는허가, 유통, 시판, 투여및검사에관한규칙등을포함한수의약품의사용.
- (iii) 첨가제사용절차를포함한사료의제조및사용, 약물배합사료의제조및사용, 사료를제조하는데사용되는원료및최종제품의위생품질.
- (b) 유럽연합에반입되는동물유래생산물에현재적용되고있는생산, 제조, 취급, 저장및공급의위생조건.
- (c) 제3국으로부터반출된동물유래생산물의마케팅경험과유럽연합반입에대한공식통제조치에의결과.
- (d) 수집가능한경우에위원회가해당제3국이규정 (EU) 2017/625 제127(2)항에따라이미명시된기타동물및상품에관련된제3국에서수행한통제조치에의결과, 특히감사대상제3국관할관청의평가결과와해당관할관청이위원회의감사후에통지된권고사항에기초하여수행한조치.
- (e) 해당되는경우에위원회가승인한동축공동전염병의존재, 실시및통지.
- (f) 해당되는경우에지침 96/23/EC에따라위원회가승인한잔류물통제프로그램의존재, 실시및통지.

제5 조

특정상품을제3국에서부터유럽연합으로반입하는경우에시설에관련된요건

- 다음상품의화물은규정 (EU) 2017/625 제127(3)(e)(ii)호및 (iii)호에따라작성및업데이트하는목록에명시된시설에서공급, 취득또는조리한경우에만유럽연합에반입할수있다.
 - 해당요건이규정 (EC) 제853/2004호부록 III에규정되고 CN 코드규정 (EEC) 제2658/87 부록 I의제2부제2-5장, 15장및 16장에규정되며 HS 코드가 2102, 2103, 2105, 2106, 2202, 2301, 2822, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110 등의표제하에규정된동물유래생산물.
 - 규정 (EEC) 제2658/87호부록 I의제2부 0704 90, 0706 90, 0708 10, 0708 20, 0708 90 또는 1214 90의 HS 코드에규정된씩.
- 본조제1항에규정된시설은해당제3국이규정 (EU) 2017/625의제127(3)(e)(ii)호및 (iv)호에규정된보증이외에다음과같은보증을제공하는경우에만규정 (EU) 2017/625 제127(3)(e)호에규정된목록에명시할수있다.
 - 해당시설이해당동물유래생산물의제조에사용되는동물유래원료를취급하는시설과함께규정 (EU) 2017/625 제126(1)항에규정된해당요건, 특히규정 (EC) 제853/2004호의요건또는적어도이에상당하다고인정되는요건을준수하고있다.
 - 해당시설이해당되는경우에지침 96/23/EC에따라해당생산물범주의잔류물모니터링계획이승인된제3국또는회원국에서반출된동물유래원료만취급하고있다.
 - 해당시설이해당유럽연합요건또는적어도이에상당하다고인정되는요건을준수하지못하는경우에유럽연합으로의반입을금지할수있는실질적인권한을가지고있다.
- 위원회는규정 (EU) 2017/625의제127(3)(e)(iii)호제3국의관할관청으로부터접수하는모든신규및업데이트목록을회원국에게제공하고그웹사이트에 게시해야한다.
- 회원국은위원회가제1항에규정된목록을공표한날이후로해당제3국의관할관청이제1항에규정된화물이해당유럽연합규칙에따라해당화물에첨부해야하는공식증명서를발행하는경우에해당화물의유럽연합반입을허용해야한다.

Article 6

Establishments not subject to the requirements of Article 5(1)

The requirements laid down in Article 5 shall not apply to establishments that only carry out the following activities:

- (a) primary production;
- (b) transport operations;
- (c) storage of products of animal origin not requiring temperature-controlled storage conditions;
- (d) 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 and referred to by the CN codes under the heading of 2833, ex 3913, 2930, ex 2932, 3507 or 3503 of Part Two of Annex I to Regulation (EEC) No 2658/87.

Article 7

Requirements for consignments of fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen

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)(e) of Regulation (EU) 2017/625:

- (a) fresh meat;
- (b) minced meat;
- (c) meat preparations;
- (d) meat products and mechanically separated meat;
- (e) raw materials intended for the production of gelatine and collagen referred to respectively in point 4(a) of Chapter I of Section XIV and in point 4(a) of Chapter I of section XV of Annex III to Regulation (EC) No 853/2004.

Article 8

Requirements for consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods

1. Notwithstanding Article 6, consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods for which CN codes have been laid down in heading 0307 of Part Two of Annex I to Regulation (EEC) No 2658/87 shall enter the Union only from production areas in third countries that appear on lists drawn up by the competent authorities of the third country in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and published by the Commission.

2. The following products may enter the Union from production areas which have not been classified by the competent authorities in the third country in accordance with Article 18(6) of Regulation (EU) 2017/625:

- (a) Pectinidae, except where data from official monitoring programmes as established by Article 57 of Implementing Regulation (EU) 2019/627 enable the competent authorities to classify fishing grounds as set out in point (2) of Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004;
- (b) marine gastropods that are not filter feeders and *Holothuroidea* that are not filter feeders.

제 6 조

제 5(1)항의요건이적용되지않는시설

제5조에 규정된 요건은 다음 활동만 수행하는 시설에는 적용되지 않는다.

- (a) 온도 제어 저장 조건이 필요하지 않은 동물 유래 생산물의 1차 생산.
- (b) 운송 작업.
- (c) 저장.
- (d) 규정 (EC) 제 853/2004호 부록 III의 제 XVI조와 규정 (EEC) 제 2658/87호 부록 I의 제 2부 2833, ex 3913, 2930, ex 2932, 3507 또는 3503 등의 표제 하에 CN 코드에 규정된 고도로 정제된 콘드로이틴 황산, 히알루론산, 기타 가수분해 연골 제품, 키토산, 글루코사민, 레넷, 아이싱글래스 및 아미노산의 생산.

제 7 조

생고기, 다짐육, 조리육, 육류 생산물, 기계적으로 분리된 육류와 젤라틴 및 콜라겐의 생산을 위한 원료 화물에 대한 요건

다음의 동물 유래 생산물 화물은 규정 (EU) 2017/625 의 제 127(3)(e)호에 따라 작성 및 업데이트되는 시설 목록에 명시된 도축장, 사냥물 취급 시설, 절단 공장, 어류 생산물 취급 시설에서 취득한 원료로 제조한 경우에만 유럽 연합에 반입해야 한다.

- (a) 생고기.
- (b) 다짐육.
- (c) 조리육.
- (d) 육류 생산물과 기계적으로 분리된 육류.
- (e) 규정 (EC) 제 853/2004호 부록 III의 제 XIV조제 I장제 4(a)호와 제 XV조제 I장제 4(a)호에 각각 규정된 젤라틴 및 콜라겐의 생산을 위한 원료.

제 8 조

생쌍각류 조개, 극피 동물, 피낭 동물 및 해양 복족류 화물의 요건

1. 제 6조에도 불구하고 CN 코드가 규정 (EEC) 제 2658/87호 부록 I의 제 2부 0307 표제 하에 규정된 생쌍각류 조개, 극피 동물, 피낭 동물 및 해양 복족류는 해당 제 3국의 관할 관청이 규정 (EU) 2017/625의 제 127(3)(e)호에 따라 작성 및 업데이트하고 위원회 가 공표한 목록에 명시된 해당 제 3국의 생산 구역에서 반출된 경우에만 유럽 연합에 반입해야 한다.
2. 다음 생산물은 해당 제 3국의 관할 관청이 분류하지 않은 생산 구역으로부터 규정 (EU) 2017/625의 제 18(6)항에 따라 유럽 연합에 반입할 수 있다.
 - (a) Pectinidae. 다만 시행 규정 (EU) 2019/627 제 57조에서 정하는 공식 모니터링 프로그램의 데이터에 따라 해당 관할 관청이 규정 (EC) 제 853/2004호 부록 III 제 VII조제 IX장의 제 (2)호에 규정된 어장을 분류할 수 있는 경우에는 제외한다.
 - (b) 여과 섭식자가 아닌 해양 복족류와 여과 섭식자가 아닌 *Holothuroidea*.

*Article 9***Listing of production areas**

1. Before the lists referred to in Article 8(1) are drawn up by the competent authorities of the third country, particular account shall be taken of the guarantees that the competent authorities of the third country can give concerning compliance with the requirements of Article 52 of Implementing Regulation (EU) 2019/627 on the classification and control of production areas.

The Commission shall carry out an on-the-spot control visit before such lists are drawn up.

2. Once lists referred to in Article 8(1) are drawn up, and when the competent authorities of the third country offer sufficient guarantees on the management and controls of production areas under their responsibility, the on-the-spot Commission control visit need not to be carried out prior to the addition of a new production area to an existing list established in accordance with Article 5.

*Article 10***Special requirements for fishery products**

Consignments of fishery products for which CN codes have been laid down in headings 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 1504, 1516, 1603, 1604, 1605 or 2106 of Part Two of Annex I to Regulation (EEC) No 2658/87, shall enter the Union for placing on the market only if they have been obtained or prepared, at any stage of their production, in an on-land establishment, a factory or freezer vessel or stored in a cold-store or a reefer vessel that appears on a list drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and published by the Commission.

Article 11

1. A vessel may be included on the lists of establishments referred to in Article 127(3)(e)(ii) of Regulation (EU) 2017/625 provided that the competent authorities of the third country the flag of which the vessel is flying and the competent authorities of another third country to which the competent authorities of the third country the flag of which the vessel is flying have delegated responsibility for the inspection of the vessel concerned, provide the Commission with a joint communication stating that all four of the following requirements are met:

- (a) both third countries appear on the list of third countries or regions thereof, drawn up in accordance with Article 127(3) of Regulation (EU) 2017/625, from which entry into the Union of fishery products is permitted;
- (b) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in the third country to which the third country the flag of which the vessel is flying has delegated responsibility for the inspection of the vessels concerned;
- (c) the delegated competent authorities have inspected the vessel and have declared that it complies with the applicable Union requirements;
- (d) the delegated competent authorities have declared that they will regularly inspect the vessel to ensure that it continues to comply with the applicable Union requirements.

2. A vessel may be included on the lists of establishments referred to in Article 127(3) of Regulation (EU) 2017/625 on the basis of a joint communication from the competent authorities of the third country the flag of which the vessel is flying and from the competent authorities of a Member State, to which the competent authorities of the third country the flag of which the vessel is flying have delegated responsibility for the inspection of the vessel concerned, if all three of the following requirements are met:

- (a) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in that Member State;
- (b) the competent authorities of that Member State have inspected the vessel and have declared that it complies with the applicable Union requirements;
- (c) the competent authorities of that Member State have declared that they will regularly inspect the vessel to ensure that it continues to comply with the applicable Union requirements.

제9 조

생산구역목록

1. 제3국관할관청이제8(1)항에규정된목록을작성하기전에는해당제3국의관할관청이생산구역의분류및통제에관한시행규정 (EU) 2019/627 제52조요건의준수에대해제공할수있는보증을특별히고려해야한다.

위원회는상기목록을작성하기전에현장통제방문을수행해야한다.

- 2.

제8(1)항에규정된목록을작성한후에그리고해당제3국의관할관청이관장하는생산구역의관리및통제에대해충분한보증을제공하는경우에위원회는새로운생산구역을제5조에따라정한기준목록에추가할때까지는현장통제방문을수행할필요가없다.

제10 조

어류생산물에대한특별요건

CN 코드가규정 (EEC) 제 2658/87 호부록 I 제 2 부 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 1504, 1516, 1603, 1604, 1605 또는 2106 등의표제하에규정된어류생산물의화물은어떤생산단계에서든규정 (EU) 2017/625 의제 127(3)(e)호에따라작성및데이트하고위원회가공표한목록에명시된육상시설, 공선또는냉동선에서취득또는조리되거나냉각저장선또는리퍼선에서저장된경우에만유럽연합시장에반입할수있다.

Article 11

- 1.

선박은깃발을게양한제3국의관할관청과깃발을게양한제3국의관할관청이해당선박을검사할수있는책임을위임한다큰 제3국의관할관청이다음과같은네가지요건을모두충족했다는내용의공동통신문을위원회에제출한경우에는규정 (EU) 2017/625의제 127(3)(e)(ii)호시설목록에포함시킬수있다.

- (a) 두제3국이모두규정 (EU) 2017/625의제 127(3)항에따라작성되고어류생산물의유럽연합반입이허용되는제3국또는그지역의목록에명시되어있다.

- (b) 유럽연합시장이목적지인해당선박의모든어류생산물이깃발을게양한제3국이해당선박의검사책임을위임한제3국에직접반입되었다.

- (c) 위임된관할관청이해당선박을검사한후에해당유럽연합요건을준수했음을선언했다.

- (d) 위임된관할관청이해당선박을정기적으로검사하여해당유럽연합요건을지속적으로준수할수있도록보장할것을선언했다.

- 2.

선박은다음세가지요건이모두충족된경우에깃발을게양한제3국의관할관청과깃발을게양한제3국의관할관청이해당선박의검사책임을위임한회원국관할관청의공동통신문에기초하여규정 (EU) 2017/625의제 127(3)항에규정된시설목록에포함시킬수있다.

- (a) 해당선박의모든어류생산물이유럽연합시장이목적지로서해당회원국에직접반입되었다.

- (b) 해당회원국의관할관청이해당선박을검사한후에해당유럽연합요건을준수했음을선언했다.

- (c) 해당회원국의관할관청이정기적으로검사하여해당유럽연합요건을지속적으로준수할수있도록보장할것을선언했다.

3. When consignments of fishery products enter the Union directly from a reefer, factory or a freezer vessel flying the flag of a third country, the official certificate referred to in Article 13(3) of Commission Implementing Regulation (EU) 2019/628⁽¹⁷⁾ may be signed by the captain.

Article 12

Requirements for consignments of composite products

1. Consignments of composite products referred to by the HS codes under headings 1601, 1602, 1603, 1604, 1605, 1901, 1902, 1905, 2004, 2005, 2103, 2104, 2105, 2106 of Part Two of Annex I to Regulation (EEC) No 2658/87 shall enter the Union for placing on the market only if each processed product of animal origin contained in the composite products was either produced in establishments that are located in third countries or regions thereof and authorised to export those processed products of animal origin to the Union in accordance with Article 5 or in establishments located in Member States.

2. Pending the establishment by the Commission of a specific list of third countries or regions thereof authorised to export composite products to the Union, consignments of composite products from third countries or regions thereof may enter into the Union, subject to compliance with the following rules:

- (a) composite products referred to in paragraph 1 that need to be transported or stored under controlled temperatures shall originate from third countries or regions thereof authorised to export each processed product of animal origin contained in the final product to the Union, pursuant to Commission Decision 2007/777/EC, Commission Regulation (EU) No 605/2010, Commission Decision 2006/766/EC, Commission Regulation (EC) No 798/2008 and Decision 2011/163/EU;
- (b) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures containing any quantity of processed meat shall originate from third countries or regions thereof authorised to export to the Union the meat products contained in the composite product pursuant to Commission Decision 2007/777/EC and Commission Decision 2011/163/EU;
- (c) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures and which contain processed products of animal origin other than processed meat, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 shall originate from third countries or regions thereof authorised to export meat products, dairy products, colostrum-based products, fishery products or egg products to the Union on the basis of the Union animal and public health requirements and which are listed at least for one of these products of animal origin pursuant to Commission Decision 2007/777/EC, Commission Regulation (EU) No 605/2010, Commission Decision 2006/766/EC and Commission Regulation (EC) No 798/2008, and in the annex to Commission Decision 2011/163/EU on the basis of a residues control plan approved in accordance with Directive 96/23/EC.

Article 13

Official certificates

1. Each consignment of the following products shall enter the Union only where the consignment is accompanied by an official certificate:

- (a) products of animal origin for which CN codes have been laid down in Chapters 2 to 5, 15 and 16, and HS codes under headings 1506, 1521, 1601, 1602, 1603, 1604, 1605, 2102, 2103, 2105, 2106, 2202, 2301, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110 and 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87, when these products are intended for human consumption;
- (b) live insects referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;
- (c) sprouts and seeds intended for the production of sprouts and referred to by the following HS codes: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90, 0713 10, 0713 33, 0712 34, 0712 35, 0713 39, 0713 40, 0712 50, 0712 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.

⁽¹⁷⁾ Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2003 and Implementing Regulation (EU) 2016/759 as regards these model certificates (see page 101 of this Official Journal).

3. 어류생산물화물올제 3 국의깃발을게양한리퍼선, 공선또는냉동선에서직접유럽연합으로반입하는경우에선장은위원회시행규정 (EU) 2019/628 (25) 제 13(3)항에규정된공식증명서에서명할수있다.

제12조

복합제품화물의요건

1. 규정 (EEC) 제 2658/87 호부록 I 제 2 부의 1601, 1602, 1603, 1604, 1605, 1901, 1902, 1905, 2004, 2005, 2103, 2104, 2105 및 2106 표제하의 HS 코드에규정된복합제품화물은복합제품에함유된가공된각동물유래생산물올제 5 조에따라제 3 국및그지역에소재하고가공된 해당동물유래생산물을유럽연합에수출할수있는시설또는회원국에소재하는시설에서생산한경우에만유럽연합시장에반입해야한다.
2. 제 3 국또는그지역에서반출되는복합제품화물은위원회가복합제품을유럽연합에수출할수있는제 3 국또는그지역의특별목록을작성할때까지는다음규칙에따라유럽연합에반입할수있다.
- (a) 제어된온도상태로운송또는저장해야하는제1항의복합제품은위원회결정 2007/777/EC, 위원회규정 (EU) 제605/2010호, 위원회결정 2006/766/EC, 위원회규정 (EC) 제798/2008호및결정 2011/163/EU 등에따라최종제품에함유된가공된각동물유래생산물을유럽연합으로수출할수있는제3국또는그지역에서반출해야한다.
- (b) 제어된온도상태로운송또는저장해야할필요가없고가공육을함유하고있는제1항의복합제품은위원회결정 2007/777/EC 및위원회결정 2011/163/EU에따라복합제품에함유된육류생산물을유럽연합으로수출할수있는제3국또는그지역에서반출해야한다
- (c) 제어된온도상태로운송또는저장해야할필요가없고가공육이외의가공된기타동물유래생산물을함유하고있으며요건이 규정 (EC) 제853/2004호부록 III에규정되어있는제1항의복합제품은유럽연합의동물및공중보건요건을근거로육류생산물, 유제품, 초유기반제품, 어류생산물또는계란생산물을유럽연합에수출할수있고위원회결정 2007/777/EC, 위원회규정 (EU) 제605/2010호, 위원회결정 2006/766/EC 및위원회규정 (EC) 제798/2008호그리고지침 96/23/EC에의거하여승인된잔류물통제계획에근거한위원회결정 2011/163/EU 부록에따라적어도하나이상의해당동물유래생산물에대해목록에명시된제3국또는그지역에서반출해야한다.

제13조

공식증명서

1. 다음생산물의각화물은해당화물에공식증명서를첨부하는경우에만유럽연합에반입할수있다.
- (a) CN 코드가규정 (EEC) 제2658/87호부록 I 제2부의제2-5장, 15장및 16장에규정되어있고 HS 코드가 1506, 1521, 1601, 1602, 1603, 1604, 1605, 2102, 2103, 2105, 2106, 2202, 2301, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110 및 9602의표제하에작성되어있는동물유래생산물로서, 식용인경우.
- (b) 규정 (EEC) 제2658/87호부록 I 제2부의 CN 코드 0106 49 00에규정된살아있는곤충.
- (c) 싹의생산에사용되고규정 (EEC) 제2658/87호부록 I 제2부의 0704 90, 0706 90, 0708 10, 0708 20, 0708 90, 0713 10, 0713 33, 0712 34, 0712 35, 0713 39, 0713 40, 0712 50, 0712 60, 0713 90, 0910 99, 1201 10, 1201 90, 1207 50, 1207 99, 1209 10, 1209 21, 1209 91 또는 1214 90의 HS 코드에규정된싹및종자.

(25) 특정동물및상품의공식증명서에관해규정하고이모델증명서에관한규정 (EC) 제 2074/2005호및시행규정 (EU) 2016/759를개정한 2019년 4월 8일자위원회시행규정 (EU) 2019/628(본관보의 101페이지참조).

2. The official certificates referred to in paragraph 1 shall certify that the products comply with:
 - (a) the requirements laid down in Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 or provisions recognised to be equivalent to those requirements;
 - (b) any specific requirements for entry into the Union set out in this Regulation.
3. The official certificates referred to in paragraph 1 may include details required in accordance with other Union legislation on public and animal health matters.
4. The official certificate for sprouts and seeds intended for the production of sprouts referred to in paragraph 1(c), shall accompany the consignment until it reaches its destination as indicated in the official certificate. In the case of splitting of the consignment, a copy of the official certificate shall accompany each part of the consignment.

Article 14

Private attestation

1. A private attestation, prepared and signed by the importing food business operator, shall accompany the consignments of composite products as referred to in Article 12(2)(c) confirming that the consignments comply with the applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625.
2. By way of derogation to paragraph 1, for the products exempted from official controls at border control posts, in accordance with Article 48(h) of Regulation (EU) 2017/625, the private attestation shall accompany the products at the time of the placing on the market.
3. The private attestation referred to in paragraph 1 shall ensure the traceability of the consignment and shall include:
 - (a) information regarding the consignor and consignee of the imported goods;
 - (b) the list of products of plant origin and processed products of animal origin contained in the composite products, indicated in descending order of weight, as recorded at the time of their use in the manufacture of the composite product;
 - (c) the approval number of the establishment(s) manufacturing the processed products of animal origin contained in the composite product, as provided for in Article 4(2) of Regulation (EC) No 853/2004 and indicated by the importing food business operator.
4. The private attestation referred to in paragraph 1 shall attest that:
 - (a) the third country or region thereof producing the composite product is listed at least for one of the following category of product of animal origin:
 - (i) meat products;
 - (ii) dairy products or colostrum-based products;
 - (iii) fishery products;
 - (iv) egg products;
 - (b) the establishment producing the composite products fulfils hygiene standards, recognised to be equivalent to those required by Regulation (EC) No 852/2004;
 - (c) the composite product does not need to be stored or transported under controlled temperature;
 - (d) the processed products of animal origin contained in the composite product originate from third countries or regions thereof authorised to export each processed product of animal origin to the Union, or from the Union, and are sourced from listed establishment(s);
 - (e) the processed products of animal origin used in the composite product have undergone at least the treatment provided for those products pursuant to Commission Decision 2007/777/EC and Commission Regulation (EU) No 605/2010 with a brief description of any processes undergone and temperatures applied to the product.

2. 제1항에 규정된 공식 증명서는 제품이 다음 사항을 준수하고 있다는 것을 증명해야 한다.
 - (a) 규정 (EC) 제178/2002호, (EC) 제852/2004호 및 (EC) 제853/2004호에 규정된 요건 또는 이 요건에 상당하다고 인정되는 규정.
 - (b) 이 규정에서 규정하고 있는 유럽 연합 반입에 대한 모든 특별 요건.
3. 제1항에 규정된 공식 증명서에는 유럽 연합의 공중 보건 및 동물 건강 문제에 관한 기타 법률에서 요구하는 정보가 포함될 수도 있다.
4.

제1(c)호에 규정된 싹 및 싹의 생산에 사용되는 종자의 공식 증명서는 증명서에 기재된 목적지에도 도달할 때까지 화물에 계속 첨부되어야 한다. 화물을 분할하는 경우에는 공식 증명서의 사본을 각 분할 화물에 첨부해야 한다.

제 14 조

사실 인증서

1. 수입 식품 사업 운영자가 작성 및 서명하는 사실 인증서는 제12(2)(c)호에 규정된 복합 제품 화물에 첨부함으로써 해당 화물이 규정 (EU) 2017/625 제126(1)항에 규정된 해당 요건을 준수하고 있다는 사실을 확인해 줄 수 있어야 한다.
2. 제1항의 적용 면제로서 규정 (EU) 2017/625 제48(h)항에 따라 국경 통제소의 공식 통제 조치가 면제되는 제품의 경우에는 사실 인증서를 제품 출시에 첨부해야 한다.
3. 제1항에 규정된 사실 인증서에서는 해당 화물의 추적성을 보장하며 다음 사항을 기재해야 한다.
 - (a) 수입 화물의 송하인 및 수하인에 관한 정보.
 - (b) 복합 제품에 함유된 식물 유래 생산물 및 가공된 동물 유래 생산물 목록으로서, 복합 제품의 제조 시점에 기록된 중량의 내림차순으로 기재.
 - (c) 규정 (EC) 제853/2004호 제4(2)항에 규정되고 수입 식품 사업 운영자가 지정한, 복합 제품에 함유된 가공된 동물 유래 생산물을 제조한 시설의 승인 번호.
4. 제1항에 규정된 사실 인증서에서는 다음 사항을 증명해야 한다.
 - (a) 복합 제품을 생산한 제3국 또는 그 지역이 적어도 하나 이상의 다음 동물 유래 생산물 범주에 대해 명시되어 있다.
 - (i) 육류 생산물
 - (ii) 유제품 또는 초유 기반 제품.
 - (iii) 어류 생산물.
 - (iv) 계란 생산물.
 - (b) 복합 제품을 생산하는 시설이 규정 (EC) 제852/2004호에서 요구하는 기준에 상당하다고 인정되는 위생 기준을 이행하고 있다.
 - (c) 해당 복합 제품을 제어된 온도 상태로 저장 또는 운송할 필요가 없다.
 - (d)

복합 제품에 함유된 가공된 동물 유래 생산물을 가공된 각 동물 유래 생산물을 유럽 연합에 수출할 수 있는 제3국 또는 그 지역에 서 반출했으며, 목록에 명시된 시설로부터 공급했다.
 - (e) 복합 제품에 사용된 가공된 동물 유래 생산물이 적어도 위원회 결정 2007/777/EC 및 위원회 규정 (EU) 제605/2010호에서 해당 제품에 대해 규정된 처리 과정을 거쳤으며, 제품에 적용된 처리 과정과 온도를 간략하게 기술했다.

*Article 15***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*.

It shall apply from 14 December 2019. However, the requirements laid down in Article 12, and Article (14)(1) and (2) shall apply from 21 April 2021.

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

Done at Brussels, 4 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

제 15 조

효력발생

본규정은유럽연합의관보에게재한때로부터 21 일째되는날에효력을발생한다.

본규정은 2019년 12월 14일에서부터적용된다. 그러나제12조와제14(1)항및 (2)항에규정된요건은 2021년 4월 21일에서부터적용된다.

본규정은모든회원국에서전체내용이직접적용된다.

2019년 3월 4일에브뤼셀에서입안.

위원회위원장

Jean-Claude JUNCKER씨앞
