

COMMISSION DELEGATED REGULATION (EU) 2019/625

執委會第(EU) 2019/625號授權規章

of 4 March 2019

2019年3月4日

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

補充歐洲議會和理事會第(EU) 2017/625號規章關於特定供人食用之動物和產品輸銷歐盟之規範

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

歐盟執委會，

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

考量歐洲聯盟運作條約，

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,

考量2017年3月15日歐洲議會和理事會，第(EU) 2017/625號規章，為確保食品和飼料法規、動物健康和福利、植物健康和植物保護產品規定之施行而進行之官方管制和其他官方活動，修正歐洲議會和理事會第(EC) 999/2001、(EC) 396/2005、(EC) 1069/2009、(EC) 1107/2009、(EU) 1151/2012、(EU) 652/2014、(EU) 2016/429及(EU) 2016/2031號規章，理事會第(EC) 1/2005及(EC) 1099/2009號規章，理事會第98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC及2008/120/EC號指令，並廢除歐洲議會和理事會第(EC) 854/2004和(EC) 882/2004規章、理事會指令第89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC及97/78/EC號指令、及議會第92/438/EEC(官方管制規章)⁽¹⁾決定，特別是該決定第126(1)條

Whereas:

然而：

- (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.

第(EU) 2017/625號規章規定歐盟成員國主管機關執行官方管制和其他官方活動之規則，包括為輸銷動物和產品至歐盟之第三國或區域，制定需要滿足之規定，及對此類供人食用產品進行官方管制，以確保其符合歐盟食品 and 食品安全領域之規範。

- (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:

第(EU) 2017/625號規章提供採取授權行動之相關法律依據，以補充該規章中規定特定動物和產品輸銷歐盟之條件。這些附加規定包括查證符合下列情況之保證：

- 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⁾;
符合理事會第96/23/EC號指令⁽²⁾監測供人食用之動物和產品中物質和殘留物之措施；
- 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⁾;
符合歐洲議會和理事會第(EC) 999/2001號規章，預防、管制及根除活體動物和動物源性產品中傳染性海綿狀腦病 (TSEs) 之規則 ⁽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⁾;
符合歐洲議會和理事會第(EC) 178/2002號規章⁽⁴⁾於歐盟和國家層面管理食品和食品安全之一般原則及規範；
- 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⁾;
符合歐洲議會和理事會第(EC) 852/2004號規章⁽⁵⁾食品業者關於食品衛生之一般規則；

(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 852/2004 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).

- 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);
符合歐洲議會和理事會第(EC) 853/2004號規章⁽⁶⁾中食品業者動物源性食品衛生之具體規範；
- 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).
符合執委會第(EU) 2019/624號授權規章⁽⁷⁾及執委會第(EU)2019/627⁽⁸⁾號執行規章中關於製造供人食用動物源性產品之官方管制和主管機關採取行動之特定規範。
- (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.
歐洲議會和理事會第(EC) 854/2004號規章⁽⁹⁾規定供人食用動物源性產品輸銷歐盟之具體條件，而歐洲議會和理事會第(EC) 882/2004號規章⁽¹⁰⁾規定食品輸銷歐盟之一般條件。第(EU) 2017/625號規章取代規定前述兩規章目前涵蓋領域之規範，並自2019年12月14日起廢除前述兩規章。
- (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.
本規章之規範應可使第(EC) 854/2004號規章和第(EC) 882/2004號規章中規範得以延續，以確保衛生受到高標準之保護，並避免中斷輸銷至歐盟之特定供人食用之動物和產品。同時，應將實行此兩規章中規範時獲得之經驗，列入基於風險方法之考量。
- (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.
第(EC) 853/2004號規章規範食品業者輸銷動物源性產品至歐盟之要求。因此，本規章中對於官方管制之附加規定，應和已列於第(EC) 853/2004號規章之規定一致。
- (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 before the expiry of the transitional measures in order to verify compliance with Union rules covering these products.
至2020年12月31日前，第(EC) 854/2004號規章中關於輸入特定動物源性產品（如昆蟲和爬行動物肉類）及含有植物源性成分和動物源性成分（複合性食品）之公共衛生規定，因執委會第(EU) 2017/185號規章⁽¹¹⁾而獲得豁免。為了確保衛生健康受高標準之保護，應於過渡措施到期前制定此類產品輸銷歐盟之規定，以查證這些產品是否符合歐盟規範。
- (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).
昆蟲日漸製造為供人類食用之用途，應確保輸入昆蟲符合歐盟對食品 and 食品安全之規定。昆蟲也應適用於本規章中關於動物源性產品輸銷歐盟之附加規定。昆蟲也可能屬於歐洲議會和理事會第(EU) 2015/2283號規章所認定之新穎食品。
- (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. 2007年10月18日，歐洲食品安全局採納了關於人類食用爬行動物肉類所涉及及公共衛生風險之意見⁽¹³⁾，確認了許多危害，例如沙門氏桿菌和旋毛蟲。此類產品輸銷至歐盟應被查證是否符合歐盟規定，以降低爬行動物肉類產品中這些危害之風險。

(6) 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).

(7) 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 relaying 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).

(8) 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).

(9) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

(10) 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).

(11) 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).

(12) 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).

(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.
複合性食品之成分會影響此類食品之理化特性，導致不同風險。因此，只有符合相關適用規範之複合性食品，特別是構成此類食品之動物源性成分來源、食品本身之來源、或複合性食品隨貨檢附之保證文件，才應核可輸銷至歐盟。而對於人類健康構成低風險之複合性食品，應依本規章而豁免邊境管制站之檢查。
- (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.
當制定特定供人食用之特定動物和產品輸銷至歐盟相關規定時，應參考符合理事會第(EEC) 2658/87號規章⁽¹⁴⁾之產品分類號列，以清楚地識別這些產品和動物。
- (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⁾.
來自第三國或區域供人食用之動物和產品，只有在依據風險分析能夠確保特定供人食用之動物及產品符合相關安全規定，且此第三國或區域正式列於委員會第(EU) 2019/626號實施規章⁽¹⁵⁾中，才核可輸銷至歐盟。
- (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.
除了第(EU) 2017/625號規章中127(3)條之規定外，應制定特定供人食用動物和產品之特定要求，以保證第三國或區域食品安全官方管制之效能。只有在提供證據和保證以證明來自第三國或區域之動物和產品符合歐盟對食品安全之規定，或訂有相關規定與第96/23/EC號指令、第(EC) 999/2001號規章、第(EC) 178/2002號規章、第(EC) 852/2004號規章、第(EC) 853/2004號規章、第(EU) 2017/625號規章、第(EU) 2019/624號授權規章及第(EU) 2019/627號執行規章具等效性時，該第三國或區域才能出現於核可清單。
- (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.
特定供人食用產品運輸、處理或製備之廠場，均應列於第(EU) 2017/625號規章第127(3)(e)條規定所述之清單上，且隨時更新，才可獲准輸銷產品至歐盟。此外，為確保符合歐盟食品衛生規定，或被認定至少與其規定具等效性，第三國於編列及更新第(EU) 2017/625號規章第127(3)(e)條之廠場清單時，應提供符合第(EU) 2017/625號規章第127(3)(e)(i)及(iv)條規定之保證。
- (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.
執委會應向公眾公開第(EU) 2017/625號規章第127條所列之廠場清單，以確保食品業者和消費者清楚瞭解來自哪些廠場之產品可輸銷至歐盟並販售。為確保這些規定之有效性，產品必須隨貨檢附由第三國之主管機關遵循歐盟規定，並於執委會公布核可廠場清單之日期後開立之官方證明文件，會員國才可允許產品輸入。
- (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.
針對只轉運產品之廠場，不適用有關廠場之規定，因從食品安全之角度，此類產品風險較低，且未將動物和產品於歐盟市場販售。此外，第(EC) 853/2004號規章附件III第XV節所述之廠場，包括僅進行初級加工、運輸、不需溫控貯存條件之動物源性產品之貯存，或製造高度精製之硫酸軟骨素、玻璃醛酸、其他水解軟骨產品、幾丁聚糖、葡萄糖糖、凝乳酶、魚膠和氨基酸，不適用有關廠場之規定。

(14) 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).

(15) 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).

- (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.
執委會第(EU) 210/2013號規章⁽¹⁶⁾規定製造芽菜之廠場，須依據第(EC) 852/2004號規章第6條之規定，取得主管機關之核可。為確保符合歐盟食品衛生規定，或被認定至少與其規定具等效性，只有在依據本規章編列和更新清單中廠場所製造之芽菜，才能輸銷至歐盟。
- (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 (slaughter-houses, 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.
為確保符合歐盟食品衛生規定，或被認定至少與其規定具等效性，製造新鮮肉類、碎肉、肉品調配、肉製品、機械分離肉，以及用於製造明膠和膠原蛋白原材料之廠場，只有編列及更新於第(EU) 2017/625號規章第127(3)(e)條規定之清單中，並由執委會公布後，才能輸銷至歐盟。此外，製造這些產品之原材料，應來自符合第(EU) 2017/625號規章第127(3)(e)條規定編列、更新並由執委會公布清單中之廠場(屠宰場、野味處理廠、分切廠及處理水產品之廠場)。
- (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.
活體雙殼類軟體動物、棘皮動物、被囊類動物和海洋腹足類動物之產品，應只有符合第(EU) 2017/625號規章第127(3)(e)條規定編列、更新並由執委會公布清單中之第三國或區域，才可輸銷至歐盟，以確保符合第(EC) 853/2004號規章和第(EU) 2019/627號執行規章中，適用於此類產品之特定要求，或被認定至少與其規定具等效性。這些清單應向公眾公開，確保業者及消費者了解哪些區域製造之活體雙殼類軟體動物、棘皮動物、被囊類動物和海洋腹足動物得以輸銷至歐盟。
- (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.
水產品應只有於符合第(EU) 2017/625號規章第127(3)(e)條規定編列、更新並由執委會公布清單中之陸上廠場、掛有第三國國旗之冷藏、加工或冷凍船中運輸、處理或製備，此類產品才可輸銷至歐盟，以確保符合第(EC) 853/2004號規章和第(EU) 2019/627號執行規章中，適用於水產品之特定要求，或被認定至少與其規定具等效性。這些清單應向公眾公開，確保業者及消費者了解水產品來自之漁船得以輸銷至歐盟。
- (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.
第(EC) 853/2004號規章中動物源性產品輸銷至歐盟之條件不適用於複合性食品。然而，輸入複合性食品之食品業者須確保加工食品中之動物源性成分來源符合該規範之要求。
- (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⁾.
複合性食品相關風險取決於成分之類型及其貯存條件。因此，應制定有關複合性食品之規定，以確保那些具有風險之複合性食品，來源於執委會第2007/777/EC號命令⁽¹⁷⁾、第2006/766/EC號命令⁽¹⁸⁾、第(EC) 798/2008號規章⁽¹⁹⁾、第(EU) 605/2010號規章⁽²⁰⁾及第2011/163/EU號命令⁽²¹⁾核可輸銷至歐盟之國家。

(16) Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 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).

- (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.
- 依據第(EC) 178/2002號規章建立之食品和飼料快速警報系統中收到通知數量，得知於市場販售供人食用之特定動物和產品，未能符合歐盟食品安全規定之風險逐漸增加，該供人食用之動物及產品因此於輸銷至歐盟販售時，需隨貨檢附個別之證明文件。符合歐盟規定之證明文件也有助於提醒食品業者、第三國或區域之主管機關注意歐盟相關規定。關於轉運之產品，應繼續使用當前具有動物健康證明之專用轉運證明文件。
- (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⁽²²⁾. 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,
- 由於第(EU) 2017/625號規章自2019年12月14日生效，因此本規章也應自該日起適用。豁免第(EC) 853/2004號規章和第(EC) 854/2004號規章中有關複合性食品輸入公共衛生規定之過渡措施，已於第(EU) 2017/185號規章中訂定，並依據執委會第(EU) 2019/759⁽²²⁾號規章此過渡措施將延長至2021年4月20日。本規章之輸入規定應自2021年4月20日起適用於複合性食品，以確保規章順利轉換，

HAS ADOPTED THIS REGULATION:

已通過本規章：

Article 1

第一條

Subject matter and scope

適用主題及範圍

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.
- 本規章補充第(EU) 2017/625號規章關於自第三國或區域輸入供人食用之特定動物和產品輸銷歐盟之規定，以確保它們符合第(EU) 2017/625號規章第1(2)(a)條中之規定，或被認定至少與其規定具等效性。
2. The requirements referred to in paragraph 1 cover:
- 第1款所述之規定包括：
- (a) the identification of animals and goods subject to the following requirements for entry into the Union:
- 確認動物及產品符合下列輸銷歐盟規定：
- (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;
- 規定該動物和產品來自第(EU) 2017/625號規章第126(2)(a)條所列之第三國或區域；
- (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)(e)(ii) and (iii) of Regulation (EU) 2017/625;
- 規定運輸、處理或製備那些動物和產品之廠場符合第(EU) 2017/625號規章第126(1)條之規定，或被認定至少與其規定具等效性，且該廠場列於符合第(EU) 2017/625號規章第127(3)(e)(ii)及(iii)條規定編列及更新之清單中；
- (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 private attestation, in accordance with Article 126(2)(c) of Regulation (EU) 2017/625;
- 依據第(EU) 2017/625號規章第126(2)(c)條，規定每批動物及產品隨貨檢附官方證明文件、官方聲明或任何其他符合第(EU) 2017/625號規章第1(2)(a)條規定之證據，例如私人聲明文件。
- (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;
- 規定輸銷歐盟之特定動物及產品，來自第(EU) 2017/625號規章第127(2)條所列之第三國或區域；
- (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)(e)(ii) and (iii) of Regulation (EU) 2017/625;
- 規定運輸、處理或製備來自第三國特定產品之廠場符合第(EU) 2017/625號規章第126(1)條之規定，或被認定至少與其規定具等效性，且該廠場列於符合第(EU) 2017/625號規章第127(3)(e)(ii)和(iii)條規定編列及更新之清單中。
- (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:
- 除第(EU) 2017/625號規章第126條之規定外，符合以下特定類別產品輸銷歐盟之規定：
- (i) fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen;
- 新鮮肉類、碎肉、肉品調配、肉製品、機械分離肉，以及用於製造明膠和膠原蛋白原料；

⁽²²⁾ 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) (OJL 125, 14.5.2019, p. 11).

- (ii) live bivalve molluscs, echinoderms, tunicates and marine gastropods;
活體雙殼類軟體動物、棘皮動物、被囊類動物和海洋腹足類動物；
- (iii) fishery products;
水產品；
- (iv) composite products;
複合性食品；
- (e) additional requirements for the official certificates, official attestations and private attestations that shall accompany certain animals and goods for entry into the Union.
特定動物和產品輸銷歐盟時應檢附之官方證明文件、官方聲明和私人聲明之附加規定。
3. This Regulation shall not apply to:
本規章不適用於：
- (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;
非供人食用之動物和產品，然而，若動物和產品之目的地於進入歐盟時尚未確定，則適用本規章；
- (b) Animals and goods intended for human consumption only for transit through the Union without being placed on the market.
供人食用之動物和產品，僅於歐盟轉運而不於市場販售。

Article 2

第2條

Definitions

定義

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

下列定義適用於本規章：

- (1) ‘equivalent’ means equivalent as defined in Article 2(1)(e) of Regulation (EC) No 852/2004;
「等效」係指第(EC) 852/2004號規章第2(1)(e)條定義之等效；
- (2) ‘placing on the market’ means placing on the market as defined in point (8) of Article 3 of Regulation (EC) No 178/2002;
「市場販售」係指第(EC) 178/2002號規章第3條第(8)點定義之市場販售；
- (3) ‘establishment’ means an establishment as defined in Article 2(1)(c) of Regulation (EC) No 852/2004;
「廠場」係指第(EC) 852/2004號規章第2(1)(c)條定義之廠場；
- (4) ‘private attestation’ means an attestation signed by the importing food business operator;
「私人聲明」係指輸入食品業者簽署之聲明；
- (5) ‘fresh meat’ means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;
「新鮮肉類」係指第(EC) 853/2004號規章附件I第1.10點定義之新鮮肉類；
- (6) ‘minced meat’ means minced meat as defined in point 1.13 of Annex I to Regulation (EC) No 853/2004;
「碎肉」係指第(EC) 853/2004號規章附件I第1.13點定義之碎肉；
- (7) ‘meat preparations’ means meat preparations as defined in point 1.15 of Annex I to Regulation (EC) No 853/2004;
「肉品調配」係指第(EC) 853/2004號規章附件I第1.15點定義之肉品調配；
- (8) ‘meat products’ means meat products as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004;
「肉製品」係指第(EC) 853/2004號規章附件I第7.1點定義之肉製品；
- (9) ‘mechanically separated meat’ means mechanically separated meat as defined in point 1.14 of Annex I to Regulation (EC) No 853/2004;
「機械分離肉」係指第(EC) 853/2004號規章附件I第1.14點定義之機械分離肉；
- (10) ‘gelatine’ means gelatine as defined in point 7.7 of Annex I to Regulation (EC) No 853/2004;
「明膠」係指第(EC) 853/2004號規章附件I第7.7點定義之明膠；
- (11) ‘collagen’ means collagen as defined in point 7.8 of Annex I to Regulation (EC) No 853/2004;
「膠原蛋白」係指第(EC) 853/2004號規章附件I第7.8點定義之膠原蛋白；
- (12) ‘bivalve molluscs’ means bivalve molluscs as defined in point 2.1 of Annex I to Regulation (EC) No 853/2004;
「雙殼類軟體動物」係指第(EC) 853/2004號規章附件I第2.1點定義之雙殼類軟體動物；
- (13) ‘fishery products’ means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;
「水產品」係指第(EC) 853/2004號規章附件I第3.1點定義之水產品；
- (14) ‘composite product’ means food containing both products of plant origin and processed products of animal origin;
「複合性食品」係指同時含有植物源性成分和動物源性成分之食品；
- (15) ‘reptiles’ means animals belonging to the species *Alligator mississippiensis*, *Crocodylus johnstoni*, *Crocodylus niloticus*, *Crocodylus porosus*, *Timon Lepidus*, *Python reticulatus*, *Python molurus bivittatus* or *Pelodiscus sinensis*;
「爬行動物」係指屬於 *Alligator mississippiensis*, *Crocodylus johnstoni*, *Crocodylus niloticus*, *Crocodylus porosus*, *Timon Lepidus*, *Python reticulatus*, *Python molurus bivittatus* or *Pelodiscus sinensis* 物種之動物；
- (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⁽²³⁾;
「爬行動物肉」係指來自養殖爬行動物未加工或加工之可食用部分，並依據第(EU) 2015/2283號規章核可及列於執委會第(EU) 2017/2470⁽²³⁾號執行規章；

⁽²³⁾ 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).

- (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;
「昆蟲」係指由昆蟲組成、分離或製造之食品，包括處於任何生命期供人食用之昆蟲，並依據第(EU)2015/2283號規章核可及列於執委會第(EU) 2017/2470號執行規章⁽²³⁾；
- (18) 'sprouts' means sprouts as defined in point (a) of Article 2 of Commission Implementing Regulation (EU) No 208/2013⁽²⁴⁾;
「芽菜」係指執委會第(EU) 208/2013號執行規章第2條第(a)點⁽²⁴⁾定義之芽菜；
- (19) 'primary production' means primary production as defined in point (17) of Article 3 of Regulation (EC) No 178/2002;
「初級加工」係指第(EC) 178/2002號規章第3條第(17)點定義之初級加工；
- (20) 'slaughter house' means a slaughterhouse as defined in point 1.16 of Annex I to Regulation (EC) No 853/2004;
「屠宰廠」係指第(EC) 853/2004號規章附件I第1.16點定義之屠宰廠；
- (21) 'game-handling establishment' means a game-handling establishment as defined in point 1.18 of Annex I to Regulation (EC) No 853/2004;
「野味處理廠」係指第(EC) 853/2004號規章附件I第1.18點定義之野味處理廠；
- (22) 'cutting plant' means a cutting plant as defined in point 1.17 of Annex I to Regulation (EC) No 853/2004;
「分切廠」係指第(EC) 853/2004號規章附件I第1.17點定義之分切廠；
- (23) 'production area' means a production area as defined in point 2.5 of Annex I to Regulation (EC) No 853/2004;
「製造區域」係指第(EC) 853/2004號規章附件I第2.5點定義之製造區域；
- (24) 'factory vessel' means a factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;
「加工船」係指第(EC) 853/2004號規章附件I第3.2點定義之加工船；
- (25) 'freezer vessel' means a freezer vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;
「冷凍船」係指第(EC) 853/2004號規章附件I第3.3點定義之冷凍船；
- (26) 'reefer vessel' means a vessel equipped to store and transport palletized or loose cargo (bulk) goods in temperature controlled holds or chambers;
「冷藏船」係指於配備溫控之貨艙或艙室中貯存和運輸墊板或散裝貨物(散裝)之漁船；
- (27) 'food business operator' means a food business operator as defined in point (3) of Article 3 of Regulation (EC) No 178/2002.
「食品業者」係指第(EC) 178/2002號規章第3條第(3)點定義之食品業者。

Article 3

第3條

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

規定動物和產品來源之第三國或區域列於第(EU) 2017/625號規章第126(2)(a)條清單中

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:

以下供人食用動物和產品只能由第(EU) 2019/626號實施規章第3至22條所列清單中之第三國或區域輸銷歐盟：

- (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;
當目的為供人食用之動物源性產品，包括爬行動物肉和整隻昆蟲屍體、昆蟲之部分或加工過之昆蟲，列於第(EEC) 2658/87號規章附件I第2部分中之產品分類號列第2、5、15及16章，和國際產品統一分類代碼前4碼為1702、1806、2102、2103、2105、2106、2202、2301、2822、2932、3001、3002、3501、3502、3503、3504、3507、3913、4101、4102、4103、4110和9602。
- (b) live insects referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87.
活體昆蟲係指第(EEC) 2658/87號規章附件I第2部分中之產品分類號列0106 49 00。

Article 4

第4條

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

來自第三國或區域特定動物和產品輸銷歐盟之附加規定

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:

除了第(EU) 2017/625號規章第127(3)條規定之外，僅當下列要求被執委會確認至少等同於歐盟關於第3條所述動物和產品之相關規定時，執委會才決定將第三國及區域列於該規章第126(2)(a)條之清單中：

- (a) the legislation of the third country on:
第三國之相關規範：
(i) the production of food of animal origin;
製造動物源性食品；

(24) 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).

- (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;
動物用藥產品之使用，包括有關其禁用或核可、經銷及市場銷售之規定，以及相關管理和查驗之規定；
- (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;
飼料之製備和使用，包括添加物之使用程序和藥用飼料之製備和使用，以及製備藥用飼料和終產品之原料衛生品質；
- (b) the hygiene conditions of production, manufacture, handling, storage and dispatch currently applied to products of animal origin destined for the Union;
目前用於製造、製造、處理、貯存和運輸至歐盟動物源性產品之衛生條件；
- (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;
任何第三國動物源性產品輸銷歐盟之經驗，以及任何輸銷歐盟官方管制之結果；
- (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;
如有，執委會於第三國進行其他已列於第(EU) 2017/625號第127(2)條清單之動物和產品相關管制結果，特別是被稽查之第三國主管機關之評估結果，以及主管機關依據執委會稽查後提出之任何建議而採取之行動；
- (e) the existence, implementation and communication of a zoonoses control programme approved by the Commission when applicable;
當適用時，執委會核可之人畜共同傳染病管制計畫之建立、實施和傳達。
- (f) the existence, implementation and communication of a residues control programme approved by the Commission when applicable, in accordance with Directive 96/23/EC.
當適用時，依據第96/23/EC號指令，委員會核可之殘留物監測計畫之建立、實施和傳達。

Article 5

第5條

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

第三國特定產品之製造廠場輸銷歐盟規定

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)(e)(ii) and (iii) of Regulation (EU) 2017/625:
下列產品僅應由符合第(EU) 2017/625號規章第127(3)(e)(ii)及(iii)條編列並更新清單上之廠場運輸、處理或製備以輸銷歐盟：
- (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;
相關規定列於第(EC) 853/2004號規章附件III之動物源性產品，列於第(EEC) 2658/87號規章附件I第2部分中之產品分類號列第2、5、15及16章，和國際產品統一分類代碼前4碼為2102、2103、2105、2106、2202、2301、2822、2932、3001、3002、3501、3502、3503、3504、3507、3913、4101、4102、4103、4110。
- (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.
芽菜係指以下列於第(EEC) 2658/87號規章附件I第2部分國際產品統一分類代碼：0704 90、0706 90、0708 10、0708 20、0708 90或1214 90。
2. Establishments referred to in paragraph 1 of this Article may be placed on the lists referred to in Article 127(3)(e) of Regulation (EU) 2017/625 only if, in addition to the guarantees laid down in Article 127(3)(e)(ii) and (iv) of Regulation (EU) 2017/625, the third country gives the following guarantees:
本條第1款所指之廠場，如欲增列至第(EU) 2017/625號規章第127(3)(e)條清單中，除了提供第(EU) 2017/625號規章第127(3)(e)(ii)及(iv)條之保證外，第三國還須提供下列保證：
- (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;
此類廠場，以及處理用於製造相關產品之動物源性原材料之任何廠場，符合第(EU) 2017/625號規章第126(1)條中適用之規定，尤其是第(EC) 853/2004號規章，或被認定至少與其規定具等效性；
- (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;
於適當情況下，廠場僅處理來自第96/23/EC號指令中針對該產品類別具有核准殘留物監測計畫之第三國或來自成員國之動物源性原材料；
- (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.
若廠場未能滿足相關歐盟規定或被認定至少與其規定具等效性，第三國有實權停止該廠場向歐盟輸出。
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)(e)(iii) of Regulation (EU) 2017/625 and shall publish such lists on its website.
執委會應向成員國提供其依據第(EU) 2017/625號規章第127(3)(e)(iii)條從第三國主管機關收到之任何新增和更新清單，並應將此清單發布於網站。
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.
若第三國列於第1款所述之清單，且其主管機關於增列日期後，依據歐盟相關規定開立隨貨檢附之官方證明文件，成員國應核可第1款所述之產品輸銷至歐盟。

Article 6

第6條

**Establishments not subject to the requirements of Article 5(1)
不適用第5(1)條規定之廠場**

The requirements laid down in Article 5 shall not apply to establishments that only carry out the following activities:
第5條規定不適用於僅進行下列活動之廠場：

- (a) primary production;
初級加工；
- (b) transport operations;
運輸；
- (c) storage of products of animal origin not requiring temperature-controlled storage conditions;
貯存不需溫控條件之動物源性產品；
- (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.
第(EEC) 853/2004號規章附件III第XVI節中所述製造高度精製之硫酸軟骨素、玻璃醛酸、其他水解軟骨產品、幾丁聚醣、葡萄糖氨、凝乳酶、魚膠和氨基酸，及第(EEC) 2658/87號規章附件I第2部分中產品分類號列2833、ex 3913、2930、ex 2932、3507或3503。

Article 7

第7條

**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
新鮮肉類、碎肉、肉品調配、肉製品、機械分離肉以及用於製造明膠和膠原蛋白原材料產品之規定**

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:

下列動物源性產品之原材料，僅當使用來自第(EU) 2017/625號規章第127(3)(e)條編列和更新於清單中之屠宰廠、野味加工廠、分切廠和水產品加工廠時，才可輸銷至歐盟：

- (a) fresh meat;
新鮮肉品；
- (b) minced meat;
碎肉；
- (c) meat preparations;
肉品調配；
- (d) meat products and mechanically separated meat;
肉製品和機械分離肉；
- (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.
第(EEC) 853/2004號規章附件III中第XIV節第1章第4(a)點及第XV節第1章第4(a)點所述之用於製造明膠和膠原蛋白原材料。

Article 8

第8條

Requirements for consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods**活體雙殼類軟體動物、棘皮動物、被囊類動物和海洋腹足動物產品之規定**

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.

第(EEC) 2658/87號規章附件I第2部分中產品分類號列為0307之活體雙殼類軟體動物、棘皮動物、被囊類動物和海洋腹足動物產品，儘管有第6條之規定，這些產品僅當來自符合第(EU) 2017/625號規章第127(3)(e)條並由執委會公布，並列於第三國主管機關編列名單中之製造區域，才可輸銷至歐盟。

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:

下列產品可由未經第三國主管機關依據第(EU) 2017/625號規章第18(6)條分類之製造區域輸銷至歐盟：

- (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;
扇貝科，除了第(EU) 2019/627號執行規章第57條所建立官方監測計畫之資料，能使主管機關依第(EEC) 853/2004號規章附件III第VII節第IX章第(2)點之規定對漁場進行分類之外；
- (b) marine gastropods that are not filter feeders and *Holothuroidea* that are not filter feeders.
非濾食性之海洋腹足動物及非濾食性之海參。

Article 9

第9條

Listing of production areas

製造場域清單

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.

在第三國主管機關增列第8(1)條所述清單之前，應特別注意能保證第三國之主管機關符合第(EU)2019/627號執行規章第52條中針對製造區域分類及管制之規定。

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

執委會應在增列此類清單之前進行現場實地訪視

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 be carried out prior to the addition of a new production area to an existing list established in accordance with Article 5.

第8(1)條所述清單增列，且第三國主管機關對其負責之製造區域管理和管制提供充分保證時，依據第5條現有清單增加新製造區域前，執委會無需進行現場實地查核。

Article 10

第10條

Special requirements for fishery products

水產品之特別規定

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.

第(EEC) 2658/87號規章附件I第2部分中之產品分類號列0301、0302、0303、0304、0305、0306、0307、0308、1504、1516、1603、1604、1605或2106之水產品，其各製造階段，應僅於符合第(EU) 2017/625號規章第127(3)(e)條規定編列、更新並由執委會公布清單中之陸上廠場、加工船、冷凍船或貯存於備有冷藏庫之船或冷藏船中處理、製備、或貯存，才可輸銷至歐盟。

Article 11

第11條

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:

當漁船所掛旗之第三國主管機關和受委任檢查所述漁船之另一第三國主管機關，向執委會提供整合資訊，說明滿足下列所有4項規定，漁船可被列入第(EU) 2017/625號規章第127(3)(e)(ii)條所述之廠場名單中：

- 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; 第三國雙方皆列於第(EU) 2017/625號規章第127(3)條，獲准向歐盟輸銷水產品之第三國或區域名單中。
- 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; 來自所述漁船中擬輸銷歐盟市場之所有水產品，直接於漁船掛旗國所委任檢查漁船之另一第三國境內卸魚貨；
- the delegated competent authorities have inspected the vessel and have declared that it complies with the applicable Union requirements; 受委任之主管機關已查驗漁船並聲明其符合適用之歐盟規定；
- 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. 受委任之主管機關已聲明他們將定期檢查漁船，以確保其持續符合適用之歐盟規定。

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:

當漁船所掛旗之第三國主管機關和受委任查驗所述漁船之歐盟成員國主管機關，向執委會提供整合資訊，說明滿足下列所有三項要求，漁船可被列入第(EU) 2017/625號規章第127(3)(e)(ii)條所述之廠場名單中：

- 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; 來自所述漁船中擬輸銷歐盟市場之所有水產品，直接於歐盟會員國境內卸魚貨；
- the competent authorities of that Member State have inspected the vessel and have declared that it complies with the applicable Union requirements; 該歐盟會員國主管機關已查驗漁船並聲明其符合適用之歐盟規定；
- 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. 受委任之歐盟會員國主管機關已聲明他們將定期查驗漁船，以確保其持續符合適用之歐盟規定。

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⁽²⁵⁾ may be signed by the captain.

當水產品直接從掛旗第三國之冷藏船、加工船或冷凍船輸銷至歐盟時，第(EU) 2019/628號執行規章⁽²⁵⁾第13(3)條所述之官方證明文件，可由船長簽署。

Article 12

第12條

Requirements for consignments of composite products

複合性食品產品之規定

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.

第(EEC) 2658/87號規章附件I第2部分國際產品統一分類代碼1601、1602、1603、1604、1605、1901、1902、1905、2004、2005、2103、2104、2105、2106之複合性食品，僅當複合性食品中所含每種動物源性成分，於符合第5條規定獲准向歐盟輸銷動物源性產品之第三國或區域之廠場或歐盟會員國之廠場中製造時，才可輸銷至歐盟。

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:

在執委會制定核可向歐盟輸出複合性食品之第三國或區域特定清單前，來自第三國或區域可輸銷複合性食品至歐盟，但須遵守下列規定：

(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;

依據第2007/777/EC號指令、第(EU) 605/2010規章、第2006/766/EC號指令、第(EC) 798/2008號規章及第2011/163/EU號指令，第1款中所述需在溫控下運輸或貯存之複合性食品，其終產品內所含各種動物源性成分，皆須來自核可輸銷歐盟之第三國或區域。

(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;

依據第2007/777/EC號指令及第2011/163/EU號指令，第1款中所述不需在溫控下運輸或貯存，且含有任何加工肉成分之複合性食品，其中所含肉產品須來自核可輸銷歐盟之第三國或區域。

(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.

依據第2007/777/EC號指令、第(EU)605/2010規章、第2006/766/EC號指令、第(EC) 798/2008號規章及第2011/163/EU號指令之附件，第1款中所述不需在溫控下運輸或貯存，且含有除加工肉類以外，於第(EC) 853/2004號規章附件III中規定之動物源性成分複合性食品，基於歐盟動物和公共衛生規定，其動物源性成分須來自核可輸出肉製品、乳製品、初乳製品、水產品及蛋製品至歐盟之第三國或區域，且複合性食品中至少含有一項上述動物源性成分。此外，此類動物源性成分須有依據第96/23/EC核可之殘留物監測計畫。

Article 13

第13條

Official certificates

官方證明文件

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

下列產品之每批貨品，僅當隨貨檢附官方證明文件之情況下才能輸銷至歐盟：

(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;

第(EEC) 2658/87號規章附件I第2部分中之產品分類號列第2、5、15及16章，和國際產品統一分類代碼前4碼為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和9602之動物源性產品，且當這些產品目的為供人食用時。

(b) live insects referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;

第(EEC) 2658/87號規章附件I第2部分中之產品分類號列0106 49 00之活體昆蟲。

(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.

第(EEC) 2658/87號規章附件I第2部分國際產品統一分類代碼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或1214 90之芽菜及製造芽菜之種子。

(25) Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (see page 101 of this Official Journal).

2. The official certificates referred to in paragraph 1 shall certify that the products comply with:
第1款中所述之官方證明文件，應能確保產品符合：
- (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;
第(EC) 178/2002號、第(EC) 852/2004號及第(EC) 853/2004號規章之規定，或被認為等效於這些規定之條文；
- (b) any specific requirements for entry into the Union set out in this Regulation.
本規章對於輸銷歐盟之任何特定規定。
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.
第1款中所述之官方證明文件可能包含符合其他歐盟公共和動物健康規範中要求之細節。
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.
用於第1(c)款所述芽菜及製造芽菜種子之官方證明文件，應隨貨檢附直至證書中所載之目的地。在分批運輸產品之情況下，每批產品均應檢附正式證明文件之副本。

Article 14

第14條

Private attestation

私人聲明

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.
由輸入食品業者準備和簽署之私人聲明，應隨貨檢附於第12(2)(c)條所述之複合性食品，確保產品符合第(EU) 2017/625號規章第126(1)條中適用之規定。
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.
針對於邊境管制站免受官方管制之產品，依據第(EU) 2017/625號規章第48(h)條規定，私人聲明應於產品上市銷售時隨貨檢附，此情況可豁免第1款之規定。
3. The private attestation referred to in paragraph 1 shall ensure the traceability of the consignment and shall include:
第1款所述之私人聲明應確保貨物之可追溯性，並應包括：
- (a) information regarding the consignor and consignee of the imported goods;
輸入貨品收貨人及發貨人之資訊；
- (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;
複合性食品中所含之植物源性產品和動物源性加工產品按重量降序顯示之清單，以及這些原料用於製造複合性食品時之製造紀錄；
- (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.
由輸入業者指出製造複合性食品中所含動物源性成分之廠場核准號，此核准號是依據第(EC) 853/2004號規章第4(2)條規定而獲得。
4. The private attestation referred to in paragraph 1 shall attest that:
第1款所述之私人聲明應證明：
- (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:
製造複合性食品之第三國或區域至少被列為核可輸銷下列動物源性產品之一：
- (i) meat products;
肉製品；
- (ii) dairy products or colostrum-based products;
乳製品或初乳製品；
- (iii) fishery products;
水產品；
- (iv) egg products;
蛋製品；
- (b) the establishment producing the composite products fulfils hygiene standards, recognised to be equivalent to those required by Regulation (EC) No 852/2004;
製造複合性食品之廠場，被認證為等效於第(EC) 852/2004號規章規定之衛生標準；
- (c) the composite product does not need to be stored or transported under controlled temperature;
複合性食品不需於溫控下貯存或運輸；
- (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);
複合性食品中之動物源性成分來自核可輸出個別動物源性成分至歐盟之第三國或區域，或來自歐盟會員國，並且來自核可清單中之廠場。
- (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.
複合性食品中之動物源性成分，至少依據第2007/777/EC號決定和第(EU) 605/2010號規章之要求，對這些成分進行處理，並簡要描述處理之任何過程和溫度。

Article 15

第15條

Entry into force

生效

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

本規章自其在歐盟官方公報上公布日起第20天生效。

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.

自2019年12月14日起適用。但是，第12條和第(14)(1)和(2)條之規定，應自2021年4月21日起適用。

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

本規章應具有全面之約束力，並直接適用於所有成員國。

Done at Brussels, 4 March 2019.

完成於布魯塞爾，2019年3月4日

For the Commission

The President

Jean-Claude JUNCKER