REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L095 7.4.2017, p.1)

歐洲議會及歐盟理事會 2017 年 3 月 15 日通過(EU)2017/625 規章，關於為確保落實食品和飼料法、動物健康和福祉規定、植物健康和植物保護產品，而進行的官方管制和其他官方活動，修訂(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 等號歐洲議會和歐盟理事會規章、(EC)1/2005 及(EC)1099/2009 等號歐盟理事會規章和 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 及 2008/120/EC 等號歐盟理事會指令，並廢止(EC)854/2004 及(EC)882/2004 等號歐洲議會和歐盟理事會規章，89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 等號歐盟理事會指令和歐盟理事會 92/438/EEC 決議(**官方管制規章**)

Amended by Commission Delegated Regulation (EU) 2019/478 of 14 January 2019 (L82, p.4) **(M1)**（第 1 次修訂）

Amended by Commission Delegated Regulation (EU) 2019/2127 of 10 October 2019 (L321, p.111 **(M2)**（第 2 次修訂）

Amended by Regulation (EU) 2021/1756 of the the European Parliament and of the Council of 6 October 2021 (L357, p.27 **(M3)**（第 3 次修訂）

Corrected by Corrigendum, OJ L 137, 24.5.2017, p. 40 (2017/625) **(C1)**（第 1 次勘誤）

(Based on the consolidated version of 28/01/2022)（本譯文係參照歐盟 Eur-Lex 網站之該規章 2022 年 1 月 28 日合訂版編校）

中文目錄

英文	中譯
(Text with EEA relevance)	**(與 EEA 相關的文本)**
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	歐洲議會和歐盟理事會，
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114 and Article 168(4)(b) thereof,	考慮到歐盟運作條約，特別是第 43(2)條、第 114 條及第 168(4)(b)條的規定，
Having regard to the proposal from the European Commission,	並考慮到歐盟執委會的提案，
After transmission of the draft legislative act to the national parliaments,	在將立法草案轉交給各國議會後，
Having regard to the opinion of the European Economic and Social Committee[1],	復考慮到歐洲經濟和社會委員會[1]的意見，
Having regard to the opinion of the Committee of the Regions[2],	考慮到區域委員會[2]的意見，
Acting in accordance with the ordinary legislative procedure[3],	按照普通立法程序[3]的規定，
Whereas:	鑑於：
(1) The Treaty on the Functioning of the European Union (TFEU) requires a high level of protection of human and animal health and of the environment to be ensured in the definition and implementation of Union policies and activities. The achievement of that objective should, inter alia, be pursued via measures in the veterinary and phytosanitary fields which have as their final objective the protection of human health.	(1) 歐盟運作條約(簡稱 TFEU)要求人類和動物的健康及環境之高度保護，使歐盟政策和活動的定義與實施得以確保。特別是應經由獸醫和植物衛生領域的措施來實現該項目標，這些措施的最終目標是保護人類健康。
(2) The TFEU also provides that the Union is to contribute to the attainment of a high level of consumer protection by the measures it adopts in the context of the completion of the internal market.	(2) TFEU 還規定，歐盟藉由在完成內部市場的情況下所採取的措施，是為了對高水準的消費者保護做出貢獻。
(3) Union legislation provides for a set of harmonised rules to ensure that food and feed are safe and wholesome, and that activities which might have an impact on the safety of the agri-food chain or on	(3) 歐盟立法提供了一套調和的規範，以確保食品和飼料的安全與衛生，並確保可能對農業食品供應鏈安全或對消費者關於食品與食品資訊之利益

1 OJ C 67, 6.3.2014, p. 166.

2 OJ C 114, 15.4.2014, p. 96.

3 Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 19 December 2016 (not yet published in the Official Journal). Position of the European Parliament of 15 March 2017 (not yet published in the Official Journal)./ 2014年4月15日送歐洲議會(尚未公佈在歐盟公報)及歐盟理事會於2016年12月19日一讀(尚未公佈在歐盟公報)。2017年3月15日送歐洲議會(尚未公佈在歐盟公報)。

the protection of consumers' interests in relation to food and food information are performed in accordance with specific requirements. Union rules exist also to ensure a high level of human, animal and plant health as well as animal welfare along the agri-food chain and in all those areas of activity where a key objective is the fight against the possible spread of animal diseases, in some cases transmissible to humans, or of pests injurious to plants or plant products, and to ensure the protection of the environment from risks that might arise from genetically modified organisms (GMOs) or plant protection products. The correct application of those rules, hereinafter collectively referred to as 'Union agri-food chain legislation', contributes to the functioning of the internal market.

保護產生影響之活動係依據特定要求加以執行。歐盟規範存在也是為了確保在農業食品供應鏈中的人類、動物和植物有高標準的健康狀況以及動物福祉，同時在所有這些活動領域中，其中一個關鍵目標是對抗動物疾病的可能傳播(在某些情況下可能傳染給人類)，或對植物或植物產品有害之害蟲的可能傳播，並確保環境保護，免於來自基因改造生物(GMOs)或植物保護產品可能發生的風險。這些規範的正確適用，以下稱為「歐盟農業食品供應鏈立法」，有助於內部市場的運作。

(4) The basic Union rules with regard to food and feed law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council[4]. In addition to those basic rules, more specific food and feed law covers different areas such as animal nutrition, including medicated feedingstuffs, food and feed hygiene, zoonoses, animal by-products, residues of veterinary medicinal products, contaminants, control and eradication of animal diseases with a human health impact, food and feed labelling, plant protection products, food and feed additives, vitamins, mineral salts, trace elements and other additives, food contact materials, quality and compositional requirements, drinking water, ionisation, novel foods and GMOs.

(4) 歐洲議會及歐盟理事會(EC)178/2002 號規章[4]制定有關食品和飼料法的基本規範。除了這些基本規範之外，更具體的食品和飼料法涵蓋諸如動物營養等不同領域，其中包括藥用飼料、食品和飼料衛生、人畜共通傳染病、動物副產品、動物用藥物殘留、污染物、對人類健康有影響動物疾病的管制和根除、食品和飼料標示、植物保護產品、食品和飼料添加物、維他命、礦物鹽、微量元素和其他添加物、食品接觸物質、品質和成分要求、飲用水、游離輻射、新穎食品以及基因改造生物。

(5) Union legislation on animal health aims to ensure high standards of human and animal health in the Union, the rational development of the agriculture and aquaculture sectors, and to increase productivity. That legislation is necessary to contribute to the completion of the internal market for animals and animal products and to avoid the spread of infectious diseases of Union concern. It covers areas that include intra-Union trade, entry into the Union, disease eradication, veterinary controls and notification of diseases, and also contributes to the safety of food and feed.

(5) 歐盟關於動物健康的立法旨在確保歐盟高標準的人類和動物健康、農業和水產養殖業的合理發展，並提高生產力。上開立法為必要並有助於完成動物和動物產品的國內市場，並避免歐盟關注的傳染病的傳播。它涵蓋了包括歐盟內部貿易、輸入歐盟、疾病根除、獸醫管制和疾病通報等領域，也有助於食品和飼料的安全。

(6) Transmissible animal diseases, including by micro-organisms that have developed resistance to

(6) 傳染性動物疾病，包括對抗生素產生抗藥性的微生物所導致者，可能對公共衛生、食品和飼料安

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 setting out procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1)./ 歐洲議會及歐盟理事會2002年1月28日通過第(EC)178/2002號規章訂定食品法的一般原則和要求、建立歐洲食品安全局並制定食品安全事項程序。

antimicrobials, may have a significant impact on public health, food and feed safety, and animal health and welfare. In order to ensure high standards of animal and public health in the Union, rules on animal health measures and on feed and food safety are laid down at Union level. Compliance with those rules, including the rules that are intended to tackle the problem of antimicrobial resistance, should be subjected to the official controls provided for in this Regulation. Additionally, Union legislation provides for rules on the placing on the market and use of veterinary medicinal products which contribute to coherent action at Union level directed at enforcing the prudent use of antimicrobials at farm level and at minimising the development of antimicrobial resistance in animals and its transmission through food of animal origin. Actions number 2 and 3 advocated by the Communication of 15 November 2011 from the Commission to the European Parliament and to the Council entitled 'Action plan against the rising threats from Antimicrobial Resistance' emphasise the essential role played by the specific Union rules in the area of veterinary medicinal products. Compliance with those specific rules should be subjected to the controls provided for in that Union legislation and, therefore, does not fall within the scope of this Regulation.

全以及動物健康和福祉產生重大影響。為了確保歐盟動物和公共衛生的高標準，動物衛生措施以及飼料與食品安全的規定明定在歐盟層級法規中。符合這些規範(其中包括意欲解決抗生素抗藥性問題的規範)，應該受到本規章所規定的官方管制。此外歐盟立法規定了關於市場銷售和使用動物用藥產品的規範，這些規範有助於在歐盟層級採取一致的行動，以促使在農場端謹慎使用抗生素，並盡量減少在動物間發展抗藥性及其透過動物源性食品傳播。歐盟執委會在 2011 年 11 月 15 日向歐洲議會及歐盟理事會提交的「對抗與日俱增之抗生素抗藥性威脅的行動計畫」中所主張的第 2 號和第 3 號行動，強調了歐盟在具體規範動物用藥產品領域扮演著重要的角色。符合這些具體規範已受到歐盟立法規定的管制，因此不屬於本規章的範圍。

(7) Article 13 TFEU recognises that animals are sentient beings. Union legislation on animal welfare requires animal owners, animal keepers and competent authorities to respect welfare requirements of animals to ensure their humane treatment and avoid causing them unnecessary pain and suffering. Those rules are based on scientific evidence and may improve the quality and safety of food of animal origin.

(7) TFEU 第 13 條認定動物是有知覺能力的生物。歐盟關於動物福祉的立法要求動物擁有者、動物飼養人和權責機關尊重動物的福祉要求，以確保其人道待遇並避免造成其不必要的痛苦和受難。這些規範乃基於科學證據且可能改善動物源性食品的品質和安全性。

(8) Union legislation on plant health regulates the entry, establishment and spread of pests of plants that do not exist, or are not widely present, in the Union. Its objective is to protect the health of Union crops and of public and private green space and forests while simultaneously safeguarding the Union's biodiversity and environment, and ensure the quality of plants and plant products and safety of food and feed made from plants.

(8) 歐盟關於植物健康的立法規定了歐盟境內未發生或未廣泛存在的植物害蟲的輸入、發生和傳播。其目標是保護歐盟作物、公共和私人綠地和森林的健康，同時保護歐盟的生物多樣性和環境，並確保植物和植物產品的品質以及植物做成的食品和飼料之安全。

(9) Union legislation on plant protection products regulates the authorisation, placing on the market, use and control of plant protection products and of any active substances, safeners, synergists, co-formulants and adjuvants, which they might contain or of which they might consist. The objective

(9) 歐盟關於植物保護產品的立法規定了植物保護產品以及這些植物保護產品所可能包括或可能組成這些植物保護產品之任何活性物質、安全劑、增效劑、輔助劑和佐劑的授權、市場銷售、

of those rules is to ensure a high level of protection of both human and animal health and of the environment through evaluation of the risks posed by plant protection products, while improving the functioning of the Union market through harmonisation of the rules for their placing on the market and while also improving agricultural production.

使用與管制。這些規範的目標是透過評估植物保護產品所帶來的風險，以確保人類與動物之健康以及環境的高度保護，同時透過調和其市場銷售的規範來改善歐盟的市場運作，並提高農業生產。

(10) Directive 2001/18/EC of the European Parliament and of the Council[5] and Regulation (EC) No 1829/2003 of the European Parliament and of the Council[6] provide for the prior authorisation, traceability and labelling of GMOs and genetically modified food and feed. GMOs which are not for the purpose of direct consumption, such as seeds used as source material for the production of food and feed, are able to be authorised under Directive 2001/18/EC or under Regulation (EC) No 1829/2003. Irrespective of the legal basis under which GMOs could be authorised, the same rules on official controls should apply.

(10) 歐洲議會和歐盟理事會第 2001/18/EC 號指令[5]以及歐洲議會和歐盟理事會(EC)1829/2003 號規章[6]規定了基因改造生物和基因改造食品與飼料的事先授權、可追溯性和標示。不以直接消費為目的的基因改造生物，例如用作食品和飼料生產原料的種子，可以根據第 2001/18/EC 號指令或(EC)1829/2003 號規章進行授權。不論授權基因改造生物的法律基礎如何，都應適用官方管制的相同規範。

(11) Union legislation on organic production and labelling of organic products provides a basis for the sustainable development of organic production and aims to contribute to the protection of natural resources, biodiversity and animal welfare, and the development of rural areas.

(11) 有機生產和有機產品標示的歐盟立法為有機生產的永續發展奠定了基礎，其目的在於對自然資源、生物多樣性和動物福祉之保護，以及鄉村地區的發展做出貢獻。

(12) Union legislation on agricultural quality schemes for agricultural products and foodstuffs identifies products and foodstuffs farmed and produced to exact specifications whilst encouraging diverse agricultural production, protecting product names and informing consumers about the specific character of agricultural products and foodstuffs.

(12) 歐盟有關農產品與食品的農業品質方案之立法，確保了農產品與食品之畜養與製造都能符合明確的規範，此舉鼓勵了多樣化的農業生產、保護產品名聲並告知消費者關於農產品與食品的特性。

(13) Union agri-food chain legislation is based on the principle that operators at all the stages of production, processing and distribution which are under their control are responsible for ensuring compliance with the requirements relevant to their activities established by Union agri-food chain legislation.

(13) 歐盟農業食品供應鏈之立法所根據的原則是，在生產、加工及配送分銷之所有階段之各運營商應確保這些作業均能在其管制之下運作，該等運營商有責任確保符合歐盟農業食品供應鏈立法對於其活動相關的要求。

5 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106,17.4.2001,p.1)./ 歐洲議會及歐盟理事會 2001 年 3 月 12 日通過第 2001/18/EC 號指令關於將基因改造有機體審慎釋放至環境中並廢除歐盟理事會第 90/220/EEC 號指令。

6 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268,18.10.2003,p.1)./ 歐洲議會及歐盟理事會 2003 年 9 月 22 日通過第(EC) 1829/2003 號規章關於基因改造食品和飼料。

(14) Union rules on marketing standards for fishery and aquaculture products ensure sustainable products and the realisation of the full potential of the internal market; they facilitate marketing activities based on fair competition, thereby helping to improve the profitability of production. These rules ensure compliance with the same requirement both for imports and products originating from within the Union. Union rules on marketing standards for agricultural products contribute to improving the economic conditions for the production and marketing and the quality of such products.

(14) 有關漁業和水產養殖產品營銷標準的歐盟規範，確保了永續發展產品和歐盟內部市場之全部潛力的實現；這些規範促進了基於公平競爭的行銷活動，從而幫助提高生產的獲利能力。這些規範確保進口產品和來自歐盟內部間的產品符合相同要求。歐盟規範中的農產品營銷標準有助於改善生產和銷售的經銷條件以及此類產品的品質。

(15) The responsibility to enforce Union agri-food chain legislation lies with Member States, whose competent authorities monitor and verify, through the organisation of official controls, that relevant Union requirements are effectively complied with and enforced.

(15) 會員國們有執行歐盟農業食品供應鏈法令之責任，其權責機關藉由官方管制機構的監督和確認使歐盟相關要求能被有效符合和執行。

(16) Regulation (EC) No 882/2004 of the European Parliament and of the Council[7] has established a single legislative framework for the organisation of official controls. That framework has significantly improved the efficiency of official controls, the enforcement of Union agri-food chain legislation and the level of protection against risks to human, animal and plant health and animal welfare in the Union and the level of protection of the environment from risks that might arise from GMOs and plant protection products. It has also provided a consolidated legal framework to support an integrated approach towards the performance of official controls along the agri-food chain.

(16) 歐洲議會和歐盟理事會(EC)882/2004 號規章[7]已經為官方管制建立了單一的立法架構。該架構顯著地提高了官方管制的效率，歐盟農業食品供應鏈法令的執行、歐盟對抗人類和動植物健康之風險及動物福祉的保護程度，以及保護環境免於遭受可能來自基因改造生物和植物保護產品之風險的程度。它還提供了一個堅實法律架構，以支持在農業食品供應鏈中執行官方管制作業能有一整合之途徑。

(17) There are a number of provisions in Union agri-food chain legislation, the enforcement of which has not, or has only partially, been governed by Regulation (EC) No 882/2004. In particular, specific official control rules were kept in place in Regulation (EC) No 1069/2009 of the European Parliament and of the Council[8]. Plant health also largely falls outside the scope of Regulation (EC) No 882/2004 with certain rules on official controls being laid down in Council Directive 2000/29/EC[9].

(17) 歐盟農業食品供應鏈法令中有許多規定，其執行尚未或僅部分受到(EC)882/2004 號規章的管轄。特別是，歐洲議會及歐盟理事會(EC)1069/2009 號規章規定了具體的官方管制規範。植物健康也在很大程度上超出了(EC)882/2004 號規章的範圍，其中部分官方

7 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 food and feed law, animal health and animal welfare rules(OJ L 165,30.4.2004,p.1)./ 歐洲議會及歐盟理事會 2004 年 4 月 29 日通過第(EC)882/2004 號規章關於官方管制進行了規定，以確保遵守食品和飼料法、動物健康和動物福祉規範之查證。

8 Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002(Animal by-products Regulation)(OJ L 300,14.11.2009,p.1)./ 歐洲議會和歐盟理事會 2009 年 10 月 21 日通過(EC)1069/2009 號規章制定了關於非供人類食用的動物副產品和衍生產品的健康規範，並廢止(EC)1774/2002 號規章（動物副產品法規）。

管制規範明定於歐盟理事會第 2000/29/EC 號指令中。

(18) Council Directive 96/23/EC[10] also provides a very detailed set of rules that establish inter alia the minimum frequency of official controls and specific enforcement measures to be adopted in cases of non-compliance.

(18) 歐盟理事會 96/23/EC 號指令也提供了一套非常詳細的規範，規定了在不符合的情況下執行官方管制和具體執行措施的最低頻率。

(19) In order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation, the rules applicable to official controls in specific areas should be integrated into a single legislative framework for official controls. For that purpose, Regulation (EC) No 882/2004 and other Union acts currently governing official controls in specific areas should be repealed and replaced by this Regulation.

(19) 為了合理化和簡化整體立法架構，同時為追求更佳化規章之目標，適用於特定領域的官方管制規章應納入官方管制的單一立法架構。為此目的，應廢止(EC)882/2004 號規章和其他目前律定特定領域的官方管制作業之歐盟法規，並由本規章取代。

(20) This Regulation should seek to establish a harmonised Union framework for the organisation of official controls, and official activities other than official controls, along the entire agri-food chain, taking into account the rules on official controls laid down in Regulation (EC) No 882/2004 and in relevant sectoral legislation, and the experience gained from the application of those rules.

(20) 本規章應在整個農業食品供應鏈中，為官方管制的機構以及官方管制作業以外的官方活動，建立起調和的歐盟架構，並考量(EC)882/2004 號規章相關部門法令中制定的官方管制規範和以及應用這些規範時所獲得的經驗。

(21) The rules which set out the requirements for the sustainable use of plant protection products laid down in Directive 2009/128/EC of the European Parliament and of the Council[11] include, in Article 8 thereof, provisions on the inspection of application equipment, which will continue to apply while the rules on official controls of this Regulation do not apply to those inspection activities.

(21) 歐洲議會和歐盟理事會第 2009/128/EC 號指令中規定了要求植物保護產品永續使用的規範，其中第 8 條係關於應用設備之檢查的條款將繼續適用，雖然本規章的官方管制規範不適用於這些檢查活動。

(22) For the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey), a well-established and specific

(22) 為了驗證是否符合農產品(可耕作物、葡萄酒、橄欖油、水果和蔬菜、啤酒花、牛奶和乳製品、牛肉和小牛肉、羊肉、山羊肉和蜂蜜)市場共同組織規範，已經建立了一套完善且具

9 Council Directive 2002/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants products and against their spread within the Community(OJ L 169,10.7.2000,p.1)./ 2002 年 5 月 8 日歐盟理事會 2000/29/EC 號指令，關於防止將對植物或植物產品有害的生物引入歐洲共同體及防止其在歐洲共同體內擴散的保護措施。

10 Council Directive 96/23/EC of 29 Apirl 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)./ 1996 年 4 月 29 日的歐盟理事會 96/23/EC 號指令，關於監測活體動物和動物產品中某些物質及其殘留物的措施，以及廢止 85/358/EEC 號和 86/469/EEC 號指令及 89/187/EEC 號和 91/664/EEC 號決議。

11 Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309,24.11.2009,p.71)./ 歐洲議會和歐盟理事會 2009 年 10 月 21 日 2009/128/EC 號指令，為歐洲共同體落實農藥永續利用的行動建立了架構。

control system is already in place. This Regulation should therefore not apply to the verification of compliance with Regulation (EU) No 1308/2013 of the European Parliament and of the Council[12] governing the common organisations of the markets in agricultural products, except where the controls carried out in relation to marketing standards under Regulation (EU) No 1306/2013 of the European Parliament and of the Council[13] indicate possible cases of fraudulent or deceptive practices.

體的管制系統。因此，本規章不適用於驗證是否符合管理農產品市場共同組織之歐洲議會和歐盟理事會(EU)1308/2013 號規章，但有關依照歐洲議會和歐盟理事會(EU)1306/2013 號規章的營銷標準所執行之管制措施顯示可能存在詐欺或欺騙行為的情況除外。

(23) Certain definitions currently set out in Regulation (EC) No 882/2004 should be adapted to take account of the broader scope of this Regulation, to align them with those set out in other Union acts, and to clarify or, where appropriate, replace terminology having different meanings in different sectors.

(23) 考慮到本規章的範圍更加廣泛，就(EC)882/2004 號規章目前明訂的某些定義應進行調整，使其與歐盟其他法規所明訂的定義保持一致，並闡明適當時，或可依適當情形替代在不同領域有不同涵義的專有名詞。

(24) Where Union agri-food chain legislation requires the competent authorities to verify that the operators comply with the relevant Union rules and that the animals or goods meet specific requirements for the purpose of issuing official certificates or attestations, such verification of compliance should be considered as an official control.

(24) 如果歐盟農業食品供應鏈法令要求權責機關查核運營商符合相關的歐盟規範，且動物或貨物符合核發官方證明書或認證的具體要求，此種查核應被視為官方管制。

(25) Union agri-food chain legislation entrusts additionally the competent authorities of the Member States with specialised tasks to be carried out for the protection of animal health, plant health and animal welfare and for the protection of the environment in relation to GMOs and plant protection products. Those tasks are the public interest activities which the competent authorities of the Member States are required to carry out for the purpose of eliminating, containing or reducing any hazard which may arise for human, animal or plant health, animal welfare or also for the environment. Those other official activities, which include the granting of authorisations or

(25) 歐盟農業食品供應鏈法令另外賦予會員國權責機關執行專門任務，以保護動物健康、植物健康和動物福祉以及與基因改造生物和植物保護產品有關的環境保護。這些任務是會員國權責機關被要求為消除、遏止或減少任何可能對人類、動物或植物健康、動物福祉或環境產生的危害而執行的公共利益活動。其他官方活動，其中包括許可授權或批准、流行病學監視和監控、根除和遏止疾病或害蟲，以及頒發官方證明書或認證，這些活動由執行官方管制的

12 Regulation (EU) No 1308/2013 of the European and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72,(EEC) No 234/79,(EC) No 1037/2001 and (EC)1234/2007 (OJ L 347,20.12.2013,p.671)./ 歐洲議會和歐盟理事會 2013 年 12 月 17 日的 1308/2013 號規章建立了農產品市場共同組織之規範，並廢止了歐盟理事會(EEC)922/72 號、(EEC)234/79 號、(EC)1037/2001 號和(EC) 1234/2007 號規章。

13 Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing,management and monitoring of the common agriculture policy and repealing Council Regulations(EEC) No 352/78,(EC) No 165/94,(EC) No 2799/98,(EC) No 814/2000,(EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347,20.12.2013, p.549)./ 歐洲議會和歐盟理事會 2013 年 12 月 17 日的 1306/2013 號規章，關於共同農業政策的財政、管理和監測，以及廢止歐盟理事會(EEC)352/78 號、(EC)165/94 號、(EC)2799/98 號、(EC)814/2000 號、(EC)1290/2005 號和(EC)485/2008 號規章。

approvals, the epidemiological surveillance and monitoring, eradication and containment of diseases or pests, as well as the issuance of official certificates or attestations, are governed by the same sectoral rules which are enforced through the official controls and therefore by this Regulation.	相同領域規範管轄，因此亦受到本規章的管轄。
(26) Competent authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. While Member States are best placed to identify and decide which are the competent authority or authorities to designate for each area or part thereof, they should also be required to designate a single authority that for each area or part of area ensures appropriately coordinated communication with other Member States' competent authorities and with the Commission.	(26) 對於本規章範圍內的所有領域，應由會員國指定權責機關加以管理。儘管會員國們最有能力確定和決定哪一個或哪些是權責機關，以便指定為每個領域或部分該領域的權責機關，會員國們也應被要求就每個領域或部分該領域指定一個單一權責機關，以確保與其他會員國的權責機關及歐盟執委會之間能有適當協調溝通。
(27) For the performance of official controls aimed at verifying the correct application of Union agri-food chain legislation, and of the other official activties entrusted to Member State authorities by Union agri-food chain legislation, Member States should designate competent authorities which act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality and professionalism. Competent authorities should ensure the quality, consistency and effectiveness of official controls.	(27) 為了就確認正確適用農業食品供應鏈法令而進行之官方管制，以及為了經歐盟農業食品供應鏈法令賦予會員國權責機關進行的其他官方活動之執行，會員國應指定根據公共利益行事、其權責機關具有適當資源與配備，並提供公正性與專業性保證的權責機關。權責機關應確保官方管制的品質、一貫性及有效性。
(28) The correct application and enforcement of the rules falling within the scope of this Regulation require appropriate knowledge of both those rules and the rules of this Regulation. It is therefore important that the staff performing official controls and other official activities are regularly trained on the applicable legislation, in accordance with their area of competence, as well as on the obligations resulting from this Regulation.	(28) 為本規章範圍內的規範正確適用和執行，須對本規章和特定規範均有適當的了解。因此，執行官方管制與其他官方活動的職員，根據其管轄領域之權限以及源於本規章之義務，定期接受所應用法令方面的培訓是重要的。
(29) The competent authorities should carry out internal audits or have audits carried out on their behalf, to ascertain compliance with this Regulation. Those audits should be carried out in a transparent manner and be subject to independent scrutiny.	(29) 權責機關應進行內部稽核或接受他機構取代他們進行稽核，以確定與本規章之符合性。這些稽核應以透明的方式進行，並接受獨立的審查。
(30) Operators should have the right, subject to national law, to appeal against the decisions taken by the competent authorities. The competent authorities should inform operators of that right.	(30) 各會員國運營商依據其國家法律應擁有對權責機關做出的決定提出上訴之權利。權責機關應告知運營商有此項權利。
(31) The competent authorities should ensure that the staff responsible for official controls does not	(31) 權責機關應確保負責官方管制的職員不會洩

disclose information acquired during the performance of those controls where that information is covered by professional secrecy. Unless there is an overriding interest to justify disclosure, professional secrecy should include information which would undermine the purpose of inspections, investigations or audits, the protection of commercial interests or the protection of court proceedings and legal advice. However, professional secrecy should not prevent competent authorities from publishing factual information on the outcome of official controls regarding individual operators when the operator concerned has been allowed to comment upon it prior to the disclosure and such comments have been taken into account, or released alongside the information being disclosed by the competent authorities. The need to respect professional secrecy is also without prejudice to the obligation for competent authorities to inform the general public where there are reasonable grounds to suspect that a food or feed may present a risk for health under Article 10 of Regulation (EC) No 178/2002. The right of individuals to the protection of their personal data as provided for in Directive 95/46/EC of the European Parliament and of the Council[14] should not be affected by this Regulation. These rules should also be without prejudice to situations where disclosure is required by Union or national legislation.

露執行此管制時取得之受到專業保密義務所涵蓋範圍之資訊。除非有優先性利益已證明揭露該等資訊之正當性，否則職業保密範圍應包括檢查、調查或稽核目的，商業利益保護，或法院訴訟程序及法律諮詢保護等資訊。然而，當所涉運營商於權責機關揭露其官方管制資訊前已被允許對該資訊進行評論，且這些評論已被權責機關加以考慮或與被權責機關揭露的訊息一同被發布時，職業保密義務並不應妨礙權責機關公布有關個別運營商之官方管制結果的事實性資訊。於權責機關有合理理由懷疑某食品或飼料可能存在涉及(EC)178/2002號規章第 10 條的健康風險之情形下，尊重職業保密義務之必要性亦不得妨礙權責機關告知公眾的義務。根據歐洲議會及歐盟理事會 95/46/EC 號指令規定本規章不應影響大眾保護其個人資料的權利。這些規範亦不應妨礙歐盟或各會員國國家法令要求揭露資訊的情況。

(32) Competent authorities should perform official controls regularly, on a riskbasis and with appropriate frequency, on all the sectors and in relation to all operators, activities, animals and goods governed by Union agri-food chain legislation. The frequency of official controls should be established by the competent authorities having regard to the need to adjust the control effort to the risk and to the level of compliance expected in the different situations, including the possible violations of the Union agri-food chain legislation perpetrated through fraudulent or deceptive practices. Accordingly, the likelihood of non-compliance with all the areas of the Union agri-food chain legislation which fall within the scope of this Regulation should be taken into account where adjusting the control efforts. In some cases, however, and in view of the issuance of an official

（32） 權責機關應基於風險基礎採取適當頻率，定期對所有領域以及與歐盟農業食品供應鏈法令規定有關的所有運營商、活動、動物及商品進行官方管制。官方管制的頻率應由權責機關考慮是否需要調整管制工作以適應風險及不同情況下所預期的符合性程度，其中包括透過詐欺或虛偽手段違反歐盟農業食品供應鏈法規的各種可能情況。因此，在調整管制工作的努力方向時，應考慮到不符合本規章範圍內之所有領域的歐盟農業食品供應鏈法令之可能性。然而，在某些情況下，有鑑於核發官方證明書或認證是於市場銷售或動物及貨物運輸的先決條件，歐盟農業食品供應鏈法令要求無

14 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31)./ 1995 年 10 月 24 日歐洲議會和歐盟理事會 95/46/EC 號指令用於保護個人數據的處理及自由流動。

certificate or attestation which is a pre-requisite for the placing on the market or for the movements of animals or goods, Union agri-food chain legislation requires that official controls be performed irrespective of the level of risk or the likelihood of non-compliance. In such cases, the frequency of the official controls is dictated by the certification or attestation needs.

論風險程度或不符合之可能性如何，應執行官方管制。在這種情況下，官方管制的頻率取決於該官方證明書或認證需求。

(33) To preserve the effectiveness of official controls in the verification of compliance, no notice should be given prior to performing controls, unless such prior notice is absolutely necessary for the controls to be carried out (for example, in the case of those official controls performed in slaughterhouses during slaughter operations which require the continuous or regular presence of staff or representatives of the competent authorities in the operator's premises) or the nature of the official control activities requires otherwise (as is particularly the case with regard to audit activities).

(33) 為了維護官方管制在查驗符合性方面的有效性，在執行管制之前不應該發出通知，除非這些事先通知對於管制的實行而言有絕對必要(例如，在屠宰場進行屠宰過程官方管制的情況下，需要權責機關的職員或代表需在運營商處連續或經常的出現)或官方管制活動的性質所要求(特別是在與稽核活動有關之情形時)。

(34) Official controls should be thorough and effective and should ensure that Union legislation is applied correctly. Given that official controls may represent a burden for operators, competent authorities should organise and conduct official control activities taking their interests into account and limiting the said burden to that which is necessary for the performance of efficient and effective official controls.

(34) 官方管制應徹底且有效，並應確保歐盟法令得到正確適用。有鑑於官方管制可能對運營商造成負擔，權責機關應考慮其利益並限制對運營商的負擔，來進行有效和高效率的必需的官方管制。

(35) Official controls should be performed by staff who are independent, that is free from any conflict of interest, and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner. Appropriate arrangements should also be in place to ensure impartiality in cases where official controls are performed on animals, goods, places or activities which belong to a public authority or body.

(35) 官方管制應由獨立之職員執行，即不存在任何利益衝突，特別是不處於直接或間接能影響他們以公正的態度履行其專業職責的情況。在對屬於公共機關或機構轄管的動物、產品、地方或活動進行官方管制的情況下，也應有適當的安排以確保公正性為目的。

(36) Official controls should be performed with the same level of care by the competent authorities of the Member State irrespective of whether the rules being enforced apply to activities which are only relevant on the territory of that Member State or to activities which will have an impact on the compliance with Union legislation on animals and goods which are to be moved or placed on the market in another Member State or exported outside the Union. In the case of exports outside the Union, competent authorities may also be required, in accordance with Union legislation, to verify the conformity of animals and goods with requirements established by the third country of

(36) 官方管制應由會員國權責機關以相同的謹慎的程度進行，無論所執行之規範是否僅適用於在該會員國境內上有關的活動，或適用於對歐盟有關動物和商品法令有影響的活動，而該等動物和商品將在另一個會員國內移動或販售，或出口到歐盟以外的國家。在出口到歐盟以外的情況下，根據歐盟立法，權責機關可能還需要查驗動物和商品是否符合目的地第三國此類動物或商品的要求。再者，關於出口證

destination of such animals or goods. Furthermore, as regards the establishments of models for export certificates, the relevant implementing powers provided for in this Regulation should only apply where such certification is provided for in Union law, and in particular in bilateral agreements concluded between the Union and a third country or an association of third countries.

明書模式之建立，本規章中規定的相關履行權力只適用於在歐盟法律中提供此種驗證的情況，以及特別是在歐盟和第三國或第三國之公(協)會之間達成的雙邊協議。

(37) Without prejudice to traceability requirements laid down in sectorial legislation, and to the extent strictly necessary for organising official controls, operators should be able, in exceptional circumstances, to be required by the competent authorities of a Member State to report the arrival of animals and goods from another Member State.

(37) 在不影響部門法令所明訂之可追溯性情況下，以及在安排官方管制必要的嚴格範圍內，除有特別例外之情況外，運營商應能被某會員國的權責機關要求對從另一個會員國輸入動物和商品進行報告。

(38) To ensure that the Union agri-food chain legislation is correctly enforced, the competent authorities should have the power to perform official controls at all stages of production, processing and distribution of animals and goods concerned by that legislation. To ensure that official controls are thoroughly conducted and effective, the competent authorities should also have the power to perform official controls at all stages of production and distribution of goods, substances, materials or objects which are not governed by Union agri-food chain legislation insofar as it is necessary to fully investigate possible infringements of that legislation and to identify the cause of any such infringement. In order to perform those official controls efficiently, competent authorities should draw up and maintain a list or register of the operators to be controlled.

(38) 為確保歐盟農業食品供應鏈法令得到正確執行，權責機關應有權力對該法令所涉及的動物和產品之生產、加工及配送分銷的各個階段進行官方管制。為確保官方管制徹底執行及有效，權責機關也應有權力對不受歐盟農業食品供應鏈法令管轄的產品、物質、材料或物品，於生產及配送分銷之所有階段進行官方管制。於有必要時全面調查可能違反歐盟農業食品供應鏈法令之處，並查明造成此種違反的原因。為了有效率實行這些官方管制，權責機關應製作並保存要管制的運營商名單或登記冊。

(39) The competent authorities act in the interest of operators and of the general public ensuring that the high standards of protection established by Union agri-food chain legislation are consistently preserved and protected through appropriate enforcement action, and that compliance with such legislation is verified across the entire agri-food chain through official controls. The competent authorities, as well as delegated bodies and natural persons to which certain tasks have been delegated, should therefore be accountable to the operators and to the general public for the efficiency and effectiveness of the official controls they perform. They should provide access to information concerning the organisation and performance of official controls and other official activities, and regularly publish information concerning official controls and the results obtained. Competent authorities should also, subject to certain conditions, be entitled to publish or to make

(39) 權責機關以運營商和一般公眾之利益行事，並確保歐盟農業食品供應鏈法令所建立的高標準保護措施，透過適當的執行行動得到持續地維護和保護，並且在整個農業食品供應鏈中透過官方管制驗證其對這些法令的符合情況。因此，權責機關以及受委託執行特定任務機構和自然人，應就其執行官方管制的效率和有效性對運營商和一般公眾負責。他們應該提供獲取有關官方管制和其他官方活動籌畫與實行的資訊方式，並定期公布官方管制和所得結果的資訊。權責機關也應根據某些條件，被賦予基於官方管制的結果，公布或提供可被外界取得之有關各運營商評級的資訊。倘若這些方案可

available information about the rating of individual operators based on the outcome of official controls. The use of rating schemes by Member States should be allowed and encouraged as a means to increase transparency along the agri-food chain, provided that appropriate guarantees of fairness, consistency, transparency and objectiveness are offered by such schemes. The competent authorities should have the necessary arrangements in place in order for the rating to reflect accurately the actual level of compliance; in particular, competent authorities should be encouraged to ensure that the rating is based on the outcome of several official controls or, when the rating is based on the outcome of one single official control and the findings are unfavourable, that subsequent official controls are carried out within a reasonable time. The transparency of rating criteria is particularly necessary so that best practices can be compared and, in time, the development of a consistent approach at Union level considered.

提供公平性、一致性、透明度和客觀性之適當保證，會員國使用之評級方案應被允許和鼓勵，作為提高農業食品供應鏈透明度的一種方式。權責機關應建立必要的安排，以便上開評級能準確地反映實際符合規定的程度；特別是，權責機關應被鼓勵以確保此種評級是基於數個官方管制的結果，或者，當此種評級是基於單一官方管制的結果且其結果不理想時，應於合理的時間內進行後續的官方管制。評級標準的透明度尤其是必要的，以便可以比較出最佳實務作業，並及時發展歐盟層級的一致作法。

(40) It is of importance that competent authorities as well as delegated bodies and natural persons to which certain tasks have been delegated, ensure and verify the effectiveness and the consistency of the official controls they perform. For that purpose they should act on the basis of written documented procedures and should provide information and instructions to staff performing official controls. They should also have appropriate documented procedures and mechanisms in place to verify continuously that their own action is effective and consistent, and take corrective action when shortcomings are identified.

(40) 重要的是，權責機關以及受委託執行特定任務之機構和自然人應確保並檢查其進行官方管制作業的有效性和一致性。為此目的，他們應依照書面作業程序書執行，並應為執行官方管制的職員提供資訊和指示。他們還應有適當的文件化作業程序書和機制，以持續查驗自己的作業是否有效和一致，並在發現缺點時採取矯正措施。

(41) To facilitate the identification of cases of non-compliance and to streamline the taking of corrective action by the operator concerned, the outcome of official controls should be recorded in a written form and a copy should be given to the operator on request. Where official controls require the continuous or regular presence of the staff of the competent authorities to monitor the operator's activities, a written record of each individual inspection or visit to the operator would be disproportionate. In such cases, written records should be prepared with a frequency that enables the competent authorities and the operator to be informed regularly of the level of compliance and promptly notified of any identified shortcomings or non-compliance.

(41) 為促進確認不符合情況使所涉運營商採取矯正措施能更加順暢，應以書面形式記錄官方管制的結果，並應於向運營商提出請求時提供副本。在官方管制作業要求權責機關的職員連續或定期在場監督運營商活動的情況時，要求每次個別的檢查或對運營商訪查均要做成書面記錄將是不相稱的（即無必要）。在此等情況時，書面紀錄的撰寫頻率應以能使權責機關和運營商定期獲知符合規定的程度即可，並應在運營商有任何已確認的缺失或不符合之情況時即刻通知權責機關和運營商。

(42) Operators should cooperate fully with competent authorities, delegated bodies or natural persons to

(42) 運營商應與權責機關、受委託執行特定任務機

which certain tasks have been delegated, to ensure the smooth performance of official controls and to enable the competent authorities to perform other official activities. Operators responsible for a consignment entering the Union should provide all available information related to that consignment. All operators should provide to the competent authorities at least the information needed to identify themselves, their activities and the operators which they supply and which supply them.

構和自然人就已被指定之充分合作，以確保官方管制的順利進行，並使權責機關能夠開展其他官方活動。負責將某託售貨物進口歐盟的運營商應提供與該託售貨物有關的所有可被外界取得資訊。所有運營商應向權責機關提供至少能辨識其身分、活動與他們的下游廠商或上游供應商等所需資訊。

(43) This Regulation establishes a single legislative framework for the organisation of official controls to verify compliance with Union agri-food chain legislation in all the areas that such legislation covers. In some of those areas, Union legislation lays down detailed requirements to be complied with which require special skills and specific means for the performance of official controls. To avoid diverging enforcement practices which could generate uneven protection of human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, also of the environment, disrupt the functioning of the internal market for animals and goods falling within the scope of this Regulation and distort competition, the Commission should be able to supplement the rules laid down in this Regulation through the adoption of specific official control rules capable of catering for the needs of controls of those areas. In particular, such rules should lay down specific requirements for the performance of official controls and the minimum frequency for such controls, specific or additional measures to those provided for in this Regulation that competent authorities should take in relation to cases of non-compliance, specific responsibilities and tasks of the competent authorities in addition to those provided for in this Regulation and specific criteria for triggering the administrative assistance mechanism provided for in this Regulation. In other cases, such additional rules might become necessary in order to provide a more detailed framework for the performance of official controls in relation to food and feed, where new information emerges about risks to human or animal health or, in relation to GMOs and plant protection products, also to the environment, indicating that in the absence of common specifications for the performance of official controls across the Member States, the controls would fail to deliver the expected level of protection against those risks, as provided for by Union agri-food chain legislation.

（43） 本規章為籌劃官方管制作業建立了一個單一的立法架構，以查驗在此類法令涵蓋的所有領域中符合歐盟農業食品供應鏈法令的情況。在其中一些領域，歐盟法令規定了需要符合的詳細要求，這些要求需要特殊技能和具體手段來執行官方管制。為了避免執法作為不一致所導致可能對人類、動物和植物健康、動物福祉以及基因改造生物和植物保護產品，以及環境產生不均衡保護，擾亂了屬於規章範圍內之動物和商品的內部市場運作，並扭曲了競爭力，歐盟執委會應透過採用適用這些領域管制需要的特定官方管制規則來補充本規章的規定。特別是，這些規範應規定對執行官方管制的具體要求和此類管制的最低頻率、對本規章規定權責機關應對不符合情況採取的具體或額外措施、除了本規章規定之權責機關具體的責任與任務，以及啟動本規章規定的行政協助機制的具體標準。在其他情況下，可能需要制定這些附加規範，當出現關於人類或動物健康風險的新資訊、或者與基因改造生物和植物有關的保護產品有關以及對環境的影響資訊時，能為執行食品和飼料之官方管制作業提供更詳細的架構，表明如果沒有對會員國進行官方管制的通用規範，該等管制作業將無法達到歐盟農業食品供應鏈法令所是對該等風險的預期保護程度。

(44) To enable the efficient organisation of the official controls covered by this Regulation, Member States should have the discretion to identify the most appropriate staff to perform such controls provided that a high level of protection of human, animal and plant health and animal welfare is ensured throughout the agri-food chain and that international standards and obligations are met. However, in certain cases, where their specific skills are necessary to ensure a sound outcome of the official controls, Member States should be required to refer to official veterinarians, plant health officers or other specifically designated persons. That should be without prejudice to the possibility for Member States to also use official veterinarians (including for official controls on poultry and lagomorphs) plant health officers or other specifically designated persons in cases where this is not required in accordance with this Regulation.	(44) 為了有效率地籌畫本規章所涵蓋的官方管制，會員國應有裁量權指定最合適的權責機關職員來執行此類管制，透過農業食品供應鏈以確保在整個過程中提供人類、動物和植物之健康以及動物福祉的高度保護，並且符合國際標準和義務。然而，在為了確保官方管制良好結果而必須具備其特定技能之情況時，會員國應被要求提供官方獸醫、植物衛生官員或其他特別指定的人員。這並不妨礙會員國在本規章未予要求時，也可以使用官方獸醫(其中包括對家禽和兔類動物進行官方管制者)、植物衛生官員或其他專門指定的人員。
(45) For the purpose of developing new control methods and techniques in relation to official controls on meat production, competent authorities should be allowed to adopt national measures to implement pilot projects that are limited in time and scope. Such measures should ensure that competent authorities verify that operators comply with all the fundamental provisions applicable to meat production, including the requirement that meat is safe and fit for human consumption. In order to ensure that the Commission and the Member States have the possibility to assess the impact of such national measures and express their opinion before they are adopted, and take therefore the most appropriate action, those measures should be notified to the Commission in accordance with and for the purposes of Articles 5 and 6 of Directive (EU) 2015/1535 of the European Parliament and of the Council[15].	(45) 為了制定與官方肉類生產管制有關的新管制方法和新技術，應允許權責機關採取國家措施，以執行時間和範圍有限的前導性專案。這些措施應確保權責機關確認運營商符合適用於肉類生產的所有基本法條，其中包括肉類安全且適合人類食用的要求。為確保歐盟執委會和會員國有評估這些國家措施的影響之可能性並在採用這些措施之前發表意見，並因而採取最適當的行動，權責機關應按照以下方式向歐盟執委會通報這些措施：並適用歐洲議會及歐盟理事會(EU)2015/1535 號指令第 5 條和第 15 條的目的。
(46) The competent authorities should be able to delegate some of their tasks to other bodies. Appropriate conditions should be laid down to ensure that the impartiality, quality and consistency of the official controls and of the other official activities are preserved. The delegated body should in particular be accredited according to the International Organisation for Standardisation (ISO)	(46) 權責機關應該能夠將其一些任務委託給其他機構。應明訂適當的條件，以確保官方管制和其他官方活動的公正性、品質和一致性。受委託機構應特別在執行檢查作業部分依據國際標準化組織(ISO)的標準取得認證。

15 Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1)./ 歐洲議會及歐盟理事會 2015 年 9 月 9 日(EU)2015/1535 號指令制定了在技術法規和資訊社會服務規章領域提供資訊的程序。

standard for the performance of inspections.

(47) To ensure the reliability and consistency of official controls and other official activities across the Union, the methods used for sampling and for laboratory analyses, tests and diagnoses should meet scientific standards, satisfy the specific analytical, testing and diagnostic need of the laboratory concerned, and offer sound and reliable analytical, test and diagnostic results. Clear rules should be established for the choice of the method to be used where more than one is available from different sources, such as ISO, the European and Mediterranean Plant Protection Organization (EPPO), the International Plant Protection Convention (IPPC), the World Organization for Animal Health (OIE), European Union and national reference laboratories, or national law.

(48) Operators whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls should have the right to a second expert opinion, at their own expense. Such a right should allow the operator to request a documentary review by another expert of the initial sampling, analysis, test or diagnosis, as well as a second analysis, test or diagnosis of the parts of the sampling material taken initially unless any such second analysis, test or diagnosis is technically impossible or irrelevant. Such would be the case, in particular, where the prevalence of the hazard is particularly low in the animal or good or its distribution particularly sparse or irregular for the purpose of assessing the presence of quarantine organisms or, as the case may be, for performing a microbiological analysis.

(49) For the purposes of performing official controls on trade which take place through the internet or other remote means, competent authorities should be able to obtain samples through anonymously placed orders (also known as mystery shopping) which can then be analysed, tested or subject to a verification of compliance. All steps should be taken by the competent authorities to preserve the rights of the operators to a second expert opinion.

(50) Laboratories designated by the competent authorities to carry out analyses, tests and diagnoses on samples taken in the context of official controls and other official activities should possess the expertise, equipment, infrastructure and staff to carry out such tasks to the highest standards. To ensure sound and reliable results, those laboratories should be accredited for the use of these

(47) 為確保整個歐盟官方管制和其他官方活動的可靠性與一致性，用於取樣和實驗室分析、測試和診斷的方法應符合科學標準，滿足有關實驗室的具體分析、測試和診斷需要，並提供完整且可靠的分析、測試和診斷結果。權責機關應當制定明確的規範，以便在能從不同來源提供多種方法的情況下，得以選擇使用的方法，例如 ISO、歐洲和地中海植物保護組織(EPPO)、國際植物保護公約(IPPC)、世界動物衛生組織(OIE)、歐盟和國家標準實驗室或國家法律。

(48) 運營商在官方管制範圍內之動物或商品接受取樣、分析、測試或診斷時，應有權利自費取得第二份專家意見。除非進行任何此類第二次分析、測試或診斷在技術上是不可能或無關者，這種權利應允許運營商要求另一位專家對最初採樣、分析、測試或診斷進行書面審查，並對最初取樣的部分進行第二次分析、測試或診斷。例如，特別是，當動物或某商品危害的普遍程度特別低，或其分佈格外分散或異常時所執行之檢疫生物體存在性評估，或可能是為進行微生物分析。

(49) 為了對透過網路或其他遠距方式的交易實施官方管制，權責機關應該能夠採用匿名下單(也稱為神秘購物)獲取樣本，然後可以進行分析、測試或符合性驗證。權責機關應採取一切措施，以保護運營商獲得第二份專家意見的權利。

(50) 權責機關所指定從事對官方管制和其他官方活動範疇中抽取的樣品進行分析、測試和診斷的實驗室應具備可以最高標準執行此類任務的專業知識、設備、基礎設施和職員。為了確保完整且可靠的結果，這些實驗室應根據標準

methods according to standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'. The accreditation should be delivered by a national accreditation body operating in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council[16].

EN ISO / IEC 17025「檢測和校正實驗室能力的一般要求」進行認證，以便使用這些方法。本項認證應由按照歐洲議會及歐盟理事會規章(EC)765/2008 號運作的國家認證機構提供。

(51) While accreditation is the instrument of choice to ensure high performance by official laboratories, it is also a complex and costly process, which would result in a disproportionate burden for the laboratory in cases where the method of laboratory analysis, test or diagnosis is particularly simple to perform and does not require specialised procedures or equipment, as is the case for the detection of Trichinella in the context of the inspection and, under certain conditions, in cases where the laboratory only carries out analyses, tests or diagnoses in the context of other official activities and not of official controls.

(51) 雖然認證是官方實驗室用來確保其高效能的工具選項，但這也是一個複雜且昂貴的程序。當實驗室分析、測試或診斷的方法執行起來特別簡單，且不需要專門的程序或設備時，例如在檢查中檢測旋毛蟲的情況，以及在某些情況下，當實驗室僅是在其他官方活動範疇而不是在官方管制下情形進行分析、測試或診斷時，都將對實驗室造成不相稱的負擔。

(52) In order to ensure the flexibility and proportionality of the approach, in particular for animal health or plant health laboratories, provision should be made for the adoption of derogations aimed at allowing certain laboratories not to be accredited for all the methods they use. That happens in particular where validated methods for detecting particular pests of plants are not available. Moreover, accreditation of a laboratory for all the methods that it should use as an official laboratory might not be immediately available in cases where new or recently modified methods are to be used, in cases of emerging risks or in emergency situations. Under certain conditions, official laboratories should therefore be allowed to carry out analyses, tests and diagnoses for the competent authorities before they obtain the relevant accreditation.

(52) 為了確保檢測方法的靈活性及相稱性，特別是對於動物健康或植物健康實驗室，法規應就針對允許對某些實驗室所使用的方法不需全部進行認證之例外的情形予以規定。這種情形特別會發生於檢測植物中特定害蟲之經確認有效的檢驗方法不可得時。此外，當新的或最近修改的方法即將被使用時，例外出現新興的風險或緊急狀況時，對作為官方實驗室之某實驗室而言，對其應使用認證的所有方法進行認證，將可能不會被立即經過認證。因此，在特定情況下，應允許官方實驗室在取得相關認證前可為對權責機關進行分析，測試和診斷任務。

(53) Official controls performed on animals and goods entering the Union from third countries are of key importance since these controls ensure compliance with legislation applicable within the Union and, in particular, with the rules established to protect human, animal and plant health, animal welfare

(53) 對於從第三國進入歐盟的動物和貨物進行官方管制是很重要的，因為這些管制措施將確保符合歐盟的立法，特別是符合為保護人類、動物和植物健康，動物福祉以及關於基因改造生

16 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p.30)./ 歐洲議會和歐盟理事會 2008 年 7 月 9 日第（EC） 765/2008 號規章規定了與產品銷售有關的認證和市場監督的要求，並廢除了第（EEC）339/93 號規章。

and, as regards GMOs and plant protection products, also the environment. Such official controls should take place before the animals or goods are released for free circulation within the Union. The frequency of official controls should adequately address risks to human, animal and plant health, animal welfare and to the environment that animals and goods entering the Union might pose, taking into account the operator's history of compliance with the requirements provided for in Union agri-food chain legislation, the controls already performed on those animals and goods in the third country concerned, and the guarantees given by that third country that animals and goods exported to the Union meet the requirements laid down in Union legislation.

物、植物保護產品以及環境而制定的規章。這種官方管制應該在動物或貨物在歐盟境內自由流通之前即開始進行。官方管制頻率應充分考量這些進入歐盟的動物或貨物對人類、動物及植物健康，動物福祉以及環境所可能造成的風險，並考慮到運營商符合歐盟農業食品供應鏈法令中規定要求的歷史、對該等動物及貨物相關第三國已經進行之管制，以及該第三國擔保其出口至歐盟的動物或貨物符合歐盟之立法規定要求。

(54) It is necessary to provide for the categories of animals and goods which should always be presented at a border control post for official controls to be performed prior to their entry into the Union. It is also necessary to provide for the possibility of requiring that other categories of goods be subject temporarily to the same requirement by virtue of specific measures to that effect, and for the possibility of requiring that certain other categories of goods, and in particular certain foodstuffs containing both products of plant origin and processed products of animal origin (composite products), always be presented for official controls at a border control post prior to their entry into the Union.

(54) 在動物或食品進入歐盟前，有必要規定其種類，並應將之提交予邊境管制站以便進行官方管制。有必要時，亦可要求其他類別的貨物暫時受到相同的規範之可能性，藉由特定的具體措施以達到管制的效果；另亦可能要求某些類別的商品，特別是含有植物源及經加工的動物源產品(複合性產品)，在進入歐盟前，一律提交予邊境管制站進行官方管制。

(55) Given the risks to human, animal or plant health, animal welfare or to the environment that certain animals or goods may pose, they should be subject to specific official controls to be performed upon them on their entry into the Union. Current Union rules require the performance of official controls at Union borders to verify that human health, animal health and animal welfare standards applicable to animals, products of animal origin, germinal products and animal by-products are met and that plants and plant products comply with phytosanitary requirements. Increased controls on entry into the Union are also performed on certain other goods where emerging or known risks so warrant. The specificities of such controls, currently governed by Council Directives 97/78/EC[17],

(55) 考慮到某些動物或貨物可能對人類、動物或植物健康，動物福祉或環境造成風險，他們應該在進入歐盟以前應該受到特別的官方管制。目前歐盟規範要求在歐盟邊境進行官方管制，以查驗動物、動物源製品、胚種的產品和動物副產品符合可適用於人類健康、動物健康和動物福祉標準適用於以及植物、植物製品符合植物檢疫之規定。經證實具有新興的或已知的風險的其他貨物在輸入歐盟時亦增加了管制。這些特殊管制目前由歐盟理事會 97/78/EC、

17 Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries(OJ L 24,30.1.1998,p.9)./ 1997 年 12 月 18 日歐盟理事會 97/78/EC 號指令規定了對從第三國進入歐盟的產品進行獸醫檢查的籌畫原則。

91/496/EEC[18] and 2000/29/EC and Commission Regulation (EC) No 669/2009[19] should be provided for in this Regulation.	91/496/ EEC 及 2000/29/EC 號指令和歐盟執委會(EC)669/2009 號規章規定管制措施的具體情況。
(56) In order to reinforce the efficiency of the Union's official control system, ensure an optimal allocation of official control resources assigned to border controls and facilitate the enforcement of Union agri-food chain legislation, a common integrated system of official controls at border control posts, replacing the current fragmented control frameworks, should be established to handle all consignments which, given the risk they may carry, should be controlled on their entry into the Union.	(56) 為了加強歐盟官方管制系統的效率，確保給邊境管制的官方管制資源為最佳分配，並促進歐盟農業食品供應鏈法令的實施，應該建立一個共同的邊境管制站之官方管制整合系統，取代目前分散的管制架構，以處理所有的貨物，並鑑於其可能帶來的風險，應當在其進入歐盟之時即加以管制。
(57) Official controls should be performed on consignments upon their arrival at border control posts. Those official controls should include documentary checks on all consignments, including where appropriate checks by electronic means, as well as identity checks and physical checks performed at an appropriate frequency dependent on the risk posed by each consignment of animals or goods.	(57) 在貨物抵達邊境管制站時，即應對其進行官方管制。這些官方管制應包括對所有貨物進行文件檢查，其中包括適當時透過電子工具進行檢查，以及根據每批貨物或動物所帶來的風險實施適當頻率的身分識別檢查和物性檢查。
(58) The frequency of physical checks should be determined and modified on the basis of risks to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment. That approach should enable the competent authorities to allocate resources for controls where the risk is highest. The frequency of identity checks should also be subject to reduction or limited to the verification of a consignment's official seal where this is justified by a reduced risk posed by the consignments entering the Union. The risk-based approach to identity checks and physical checks should be pursued by making use of available data sets and information, and of computerised data collection and management systems.	(58) 物性檢查的頻率應根據對於人類、動物或植物健康、動物福祉或基因改造生物和植物保護產品以及環境的風險作決定和修改。這種方法應使權責機關能夠為最高風險應分配管制資源。識別檢查的頻率也應在證實能合理降低貨物進入歐盟之風險時，予以減少或限制貨物之官方封條查驗。這種以風險為基礎的身分識別檢查與物性檢查，應以利用現有的數據庫和資訊，以及電腦化的數據收集和管理系統管理為之。

18 Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directive 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ L 268,24.9.1991,p.56)./ 1991 年 7 月 15 日歐盟理事會第 91/496/EEC 號指令規定了關於籌畫對來自第三國進入共同體的動物進行獸醫檢查的原則，以及修訂了第 89/662/EEC、90/425/EEC 及 90/675/EEC 號指令。

19 Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) NO 882/2004 of the European Parliament and the Council as regards the increased level of official controls on imports of certain food and feed of non-animal origin and amending Decision 2006/504/EC (OJ L 194,25.7.2009,p.11)./ 2009 年 7 月 24 日歐盟執委會規章（EC）669/2009 號規定了實施歐洲議會和歐盟理事會關於提升進口某些非動物源性食品和飼料的官方管制水準的歐洲議會和歐盟理事會 882/2004 號規章，修訂 2006/504/EC 號決議。

(59) In certain cases, and provided that high levels of human, animal and plant health, animal welfare and, in relation to GMOs and plant protection products, also protection of the environment are ensured, official controls normally performed by competent authorities at border control posts could be performed at other control points or by other authorities.

(59) 在某些情況下，為確保高水準的人類、動物和植物健康、動物福祉與基因改造生物和植物保護產品相關事宜，並使環境保護獲得保證，一般由邊境管制站之權責機關所進行的官方管制，也可以在其他管制點或其他權責機關中進行。

(60) For the purpose of organising an efficient system of official controls, consignments arriving from third countries which require controls at their entry into the Union should be accompanied by a common health entry document (CHED), to be used for the prior notification of the arrival of consignments at the border control post, and to record the outcome of official controls performed and of decisions taken by the competent authorities in relation to the consignment which they accompany. The same document should be used by the operator to obtain clearance by customs authorities once all official controls have been performed.

(60) 為了籌畫有效率的官方管制系統，從第三國入境的貨物且需要在其進入歐盟時予以管制者，該貨物應檢附通用健康輸入文件(CHED)，用於事先通知抵達邊境管制站的貨物，並記錄所執行之官方管制的結果以及權責機關就該貨物所作的決定。在所有官方管制作業執行完成後，運營商可使用同一份文件獲得海關的清關證明。

(61) In some Member States, due to specific geographical constraints, such as long coasts or borders, the minimum requirements for border control posts are difficult to fulfil on a permanent basis. Imports of unprocessed logs of wood are usually done in large volumes through specialised ports or control points and with an irregular frequency which make it difficult to have permanently staffed and fully equipped border control posts. Derogations from minimum requirements for border control posts should be allowed to ensure effective official controls on specific unprocessed logs of wood.

(61) 在某些會員國中，由於其特殊的地理限制，例如長的海岸或邊境，邊境管制站的最低要求以長久來看難以獲得滿足，不定期的透過特定的港口或管制點進口大量未經加工的原木，使得雇用長期員工及擁有完善的貨物管制站變得困難。應允許降低邊境貨物管制站的最低要求，以確保對特定未經加工的原木執行有效官方管制。

(62) Official controls on animals and goods entering the Union from third countries should be performed at border control posts designated by Member States in accordance with a set of minimum requirements. The designation of such posts should be withdrawn or suspended when they no longer comply with the minimum requirements or when their activities could pose a risk to human, animal or plant health, animal welfare or, in the case of GMOs and plant protection products, also to the environment. The decision whether to withdraw or suspend such a designation would need to take account of the degree of seriousness of the risk and of the principle of proportionality.

(62) 對於從第三國進入歐盟的動物及貨物之官方管制應於會員國依據最低要求指定的邊境管制站實施。當這些邊境管制站不再符合最低要求或其活動可能對人類、動物或植物健康、動物福祉或甚至對基因改造生物和植物保護產品以及環境造成風險時，其指定資格應予以撤銷或中止。決定是否撤銷或中止該項指定資格須考慮風險的嚴重程度和比例原則。

(63) To ensure the uniform application of official control rules on consignments arriving from third countries, common rules should be established to govern the actions that the competent authorities

(63) 為了確保官方管制規範對來自第三國貨物的適用之一致性，應建立共同的規則，以規範當遇有對不符合情事之懷疑且與不符合或貨物

and operators should take in the event of suspicion of non-compliance, and in relation to non-compliant consignments and of consignments which might pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.

相關時，以及不符合規定的貨物可能對人類、動物或植物健康、動物福祉甚至對基因改造生物和植物保護產品以及環境造成風險的貨物時，權責機關及運營商所應採取的行動。

(64) In order to avoid inconsistencies and duplications in carrying out official controls, to allow consignments which are subject to official controls at border control posts and at other control points to be timely identified and to ensure that controls are performed in an efficient manner, cooperation and exchange of information amongst competent authorities, customs authorities and other relevant authorities dealing with consignments arriving from third countries should be ensured.

(64) 為了避免官方管制的執行有不一致或重複之情形，並允許在邊境管制站或其他管制點之官方管制下的貨物應該及時被識別，並且確保管制是以有效率的方式執行，亦應確保權責機關、海關部門和其他相關單位就處理來自第三國的貨物的合作和資訊交流。

(65) Member States should ensure that adequate financial resources are always available in order to appropriately staff and equip the competent authorities performing official controls and other official activities. Although operators are primarily responsible for ensuring that their activities are carried out in compliance with Union agri-food chain legislation, the system of own controls that they put in place for that purpose should be complemented by a dedicated system of official controls maintained by each Member State to ensure effective market surveillance along the agri-food chain. Such a system is, by its very nature, complex and resource-demanding and should be provided with a stable influx of resources for official controls, and at a level appropriate to the enforcement needs at any given moment. To reduce the dependency of the official control system on public finances, competent authorities should collect fees or charges to cover the costs they incur when performing official controls on certain operators and for certain activities for which Union agri-food chain legislation requires registration or approval in accordance with Union rules on the hygiene of food and feed or rules governing plant health. Fees or charges should also be collected from operators to compensate the costs of official controls performed in view of issuing an official certificate or attestation and costs of official controls performed by the competent authorities at border control posts.

(65) 會員國應確保持續提供充足的財政資源，以對執行官方管制及其他官方活動之權責機關予以適當地配置人力及設備。儘管運營商是確認他們的活動符合歐盟農業食品供應鏈法令的主要負責人，他們為此目的實施的自我管制系統應該由每個會員國加以維護的專用官方管制系統來補足，以確保農業食品供應鏈的有效市場監視。這種系統就其性質而言是複雜且需要資源的，應提供官方管制之穩定的資源挹注，並在任何時刻維持在適合執行需求之水準。為減少官方管制系統對公共財政的依賴，權責機關在執行對某些運營商及某些活動依據與食品或飼料相關之衛生規範或植物健康規範執行歐盟食品供應鏈立法要求的登錄或核准時應收取費用，以負擔其執行時所產生之花費。也應向運營商收取規費以補償因核發官方證書或證明以及在邊境管制站之權責機關執行官方管制時的費用。

(66) Fees or charges should cover, but not exceed, the costs, including overhead costs, incurred by the

(66) 規費應包括但不能超過權責機關因執行官方

competent authorities to perform official controls. Overhead costs could include the costs of the support and organisation necessary for planning and carrying out the official controls. Such costs should be calculated on the basis of each individual official control or on the basis of all official controls performed over a given period of time. Where fees or charges are applied on the basis of the actual cost of individual official controls, operators with a good record of compliance should bear lower overall charges than non-compliant ones, as they should be subject to less frequent official controls. In order to promote compliance with Union legislation by all operators irrespective of the method (based on actual costs or on a flat rate) that each Member States has chosen for the calculation of the fees or charges, when fees or charges are calculated on the basis of overall costs incurred by the competent authorities over a given period of time, and imposed on all operators irrespective of whether they are subject to an official control during the reference period, those fees or charges should be calculated so as to reward operators with a consistent good record of compliance with Union agri-food chain legislation.

管制所產生包括經常性費用內的成本。經常性費用可能包括規劃和執行官方管制所需的支持和籌備成本。這些費用應根據每個官方管制或根據在一段時間內所進行的所有官方管制來計算。如果根據個別官方管制的實際成本來收取規費，那麼具有良好符合紀錄的運營商的總體費用應低於不合規定的運營商，因為他們應較少接受到官方管制。為了促進所有運營商符合歐盟法令，無論每個會員國選擇何種方法(基於實際成本或定額收費)來計算規費，當以權責機關在一段期間內的總體費用為基礎計算費用，並且對所有運營商收取，無論他們是否在參考期間內受到官方管制，這些規費皆應被算入，俾能具有始終如一符合歐盟農業食品供應鏈法令的良好符合紀錄來回報這些運營商。

(67) The direct or indirect refund of fees or charges collected by the competent authorities should be prohibited as it would put at a disadvantage operators not benefitting from the refund and potentially create distortions of competition.

(67) 應禁止權責機關直接或間接退還規費，因其將造成的運營商無法在退費中受益的壞處，且有可能導致競爭力的扭曲。

(68) The financing of official controls through fees or charges collected from operators should be fully transparent, so as to enable citizens and businesses to understand the method and data used to establish fees or charges.

(68) 向運營商收取規費以作為官方管制用之財政作業應該是完全透明的，以使公民和企業了解收取規費所使用的方法和數據。

(69) Union agri-food chain legislation establishes the cases where the placing on the market or the movement of certain animals or goods should be accompanied by an official certificate signed by the certifying officer. It is appropriate to establish a common set of rules laying down the obligations of the competent authorities and the certifying officers with regard to the issuance of official certificates as well as the characteristics that official certificates should have to ensure their reliability.

(69) 歐盟農業食品供應鏈法令規定了將某些動物或貨物在上市銷售或移動時應該附有驗證官員簽署的官方證明書。宜建立一個共同的標準以規範規定權責機關和驗證官員頒發官方證明書的義務以及官方證明應具有的特徵以確保其可靠性作法。

(70) In other cases, the rules falling within the scope of this Regulation provide that the placing on the market or the movement of certain animals or goods are to be accompanied by an official label,

(70) 在其他情況下，本規章範圍內的規範提供某些動物或貨物上市銷售或移動時應附有官方標籤、官方標誌或其他由運營商在權責機關的監

official mark or other official attestation issued by the operators under the official supervision of the competent authorities or by the competent authorities themselves. Official attestations include, for example, plant passports, organic logos and identification marks, where these are required by Union legislation, and marks of protected designations of origin, protected geographical indications or traditional specialities guaranteed. It is appropriate to lay down a minimum set of rules to ensure that also the issuance of official attestations is able to be performed in accordance with appropriate guarantees of reliability.

督下發給的或權責機關自行核發的官方證明書。前述官方證明包括，例如：植物護照、有機標章和根據歐盟立法要求的辨別標誌以及受保護的原產地名稱、受保護的地理標誌或傳統特色產品的保證標誌。宜制定一套最低限度的規範，以確保官方證明的核發能夠根據適當的可靠性保證來執行。

(71) Official controls and other official activities should be based on analytical, testing and diagnostic methods that meet state-of-the-art scientific standards and offer sound, reliable and comparable results across the Union. The methods used by official laboratories as well as the quality and uniformity of analytical, testing and diagnostic data generated by them should therefore be improved continuously. For that purpose, the Commission should be able to designate, and rely on the expert assistance of, European Union reference laboratories in all those areas of the agri-food chain where there is the need for precise and reliable analytical, testing and diagnostic results. The European Union reference laboratories should in particular ensure that national reference laboratories and official laboratories are provided with up-to-date information on available methods, organise or participate actively in inter-laboratory comparative tests and offer training courses for national reference laboratories or official laboratories.

(71) 官方管制和其他官方活動應以符合最先進科學標準的分析、測試和診斷的方法為基礎，並且提供整個歐盟健全的、可靠的及可資比較的結果。因此官方實驗室所使用的方法以及由它們產生的分析、測試和診斷數據的品質和一致性應當不斷改進。為此，歐盟執委會應能夠在需要精確和可靠的分析、測試和診斷結果的農業食品供應鏈中之所有領域委派並信賴歐盟參考標準實驗室專家的協助。歐盟參考標準實驗室應特別確保向各國家參考標準實驗室和官方實驗室提供現有方法的最新資訊，積極籌劃或參與實驗室間之比較測試，並為各國家參考標準實驗室或官方實驗室提供培訓課程。

(72) The first paragraph of Article 32 of Regulation (EC) No 1829/2003 and the first paragraph of Article 21 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council[20] confer respectively on the European Union reference laboratory for genetically modified food and feed and on the European Union reference laboratory for feed additives specific tasks as part of the authorisation procedure for genetically modified food or feed, or feed additives, relating, in particular, to the testing, evaluation and validation of the method of detection or analysis proposed by applicants. Those laboratories therefore should act as European Union reference laboratories

(72) 歐洲議會及歐盟理事會(EC)1829/2003 號規章第 32 條第 1 款和(EC)1831/2003 號規章第 21 條第 1 款分別委任歐盟基因改造食品和飼料參考標準實驗室以及歐盟飼料添加劑參考標準實驗室特別任務小組，作為基因改造食品和飼料或飼料添加劑授權程序的一部分，特別是涉及由申請人提出檢測、評估以及偵測或分析方法之確效。因此，基於本規章之目的，上開實驗室為歐盟參考標準實驗室。

20 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268,18.10.2003,p.29)./ 歐洲議會及歐盟理事會 2003 年 9 月 22 日關於用於動物營養之添加劑的(EC) 1831/2003 號規章。

for the purposes of this Regulation.

(73) For the performance of official controls and other official activities which are aimed at identifying possible violations to the rules including those perpetrated through fraudulent or deceptive practices, and in the field of animal welfare, the competent authorities should have access to updated, reliable and consistent technical data, to research findings, new techniques and expertise necessary for the correct application of Union legislation applicable in those two areas. For that purpose, the Commission should be able to designate, and rely on the expert assistance of, European Union reference centres for the authenticity and integrity of the agri-food chain and for animal welfare.

(74) In order to pursue the objectives of this Regulation and contribute to the smooth functioning of the internal market, ensuring consumer confidence in it, cases of non-compliance with Union agri-food chain legislation requiring enforcement action in more than one Member State should be pursued efficiently and consistently. The Rapid Alert System for Food and Feed (RASFF) established pursuant to Article 50 of Regulation (EC) No 178/2002 already enables competent authorities to rapidly exchange and disseminate information on serious direct or indirect risks to human health in relation to food or feed, or serious risks to human or animal health or to the environment in relation to feed, for the purpose of enabling rapid measures to be taken to counter those serious risks. However, that instrument, while allowing for timely action across all Member States concerned to counter certain serious risks along the agri-food chain, cannot serve the purpose of enabling effective cross border assistance and cooperation between competent authorities to ensure that cases of non-compliance with Union agri-food chain legislation which have a cross-border dimension are effectively pursued not only in the Member State where the non-compliance is first detected but also in the Member State where the non-compliance originated. In particular, administrative assistance and cooperation should enable competent authorities to share information, detect, investigate and take effective and proportionate action to pursue cross-border violations of Union agri-food chain legislation also in cases where potential fraudulent or deceptive practices have or could have a cross-border dimension.

(73) 為了執行官方管制和旨在辨明包括攙偽或假冒等可能違反法規的其他官方活動，以及涉及動物福祉的領域，權責機關應該獲得最新、可靠、和一致的技術資料，以獲取這兩個領域新發現的新技術和必需的專業知識，使歐盟的法令得以正確適用於此二個領域之中。為達此目的，歐盟執委會應能指定及信賴歐盟參考（標準）中心的專家協助，以確保農業食品供應鏈及動物福祉的真實性與完整性。

(74) 為追求本規章的目標並對內部市場的順利運作做出貢獻，確保消費者對之信心，對於不符合歐盟農業食品供應鏈法令的情形，需要在一個以上會員國採取強制作為，應有效率地、堅持地執行根據(EC)178/2002 號規章第 50 條建立的食品和飼料快速預警系統(RASFF)使權責機關能夠迅速地交換和傳播關於食品或飼料對人類健康的嚴重直接或間接風險之資訊，及飼料對人類、動物健康或環境之嚴重的風險，以便迅速採取措施來應對這些嚴重的風險。然而，此系統雖然讓所有有關的會員國及時採取行動，以應對農業食品供應鏈上的某些嚴重風險，但並不能達到權責機關之間提供有效的跨境援助和合作的目的，以確保跨國界性不符合歐盟農業食品供應鏈法令案件不僅在首次被發現該項不能符合案件之會員國，而在該項不符合案件起源之會員國亦均能被有效地追蹤。特別是，行政援助和合作應使權責機關能夠共享資訊、偵測、調查和採取有效和適當的行動，以追查跨境之不符合歐盟農業食品供應鏈立法的案件，以及潛在的攙偽或假冒行為已經或可能有跨境的案件。

(75) Requests for administrative assistance and all notifications should be given appropriate follow-up. In order to facilitate administrative assistance and cooperation, Member States should be required to designate one or more liaison bodies to assist and coordinate communication flows between competent authorities in different Member States. In order to ensure uniform conditions for the implementation of this Regulation and to streamline and simplify cooperation between Member States, implementing powers should be conferred on the Commission to adopt implementing acts establishing the specifications of the technical tools to be used, the procedures for communication between liaison bodies and a standard format for requests for assistance, notifications and responses.	(75) 行政協助之請求和所有通知應給予適當的跟催追蹤。為了促使行政協助和合作，各會員國應須指定一個或數個連絡機構來協助和協調不同會員國間之權責機關的溝通交流。為了確保本規章能於一致的條件下實行，以及使會員國間的合作能更順暢並簡化，應授予歐盟執委會執行權力以採用施行法案，以制定所須使用之技術工具的規格、連絡機構間之溝通程序，以及請求協助、通知與回覆的標準格式。
(76) Each Member State should be required to set up and regularly update a multi-annual national control plan (MANCP) covering all the areas governed by Union agri-food chain legislation and containing information on the structure and organisation of its system of official controls. Such MANCPs are the instrument through which each Member State should ensure that official controls are performed in a manner that is risk-based and efficient across their territory and across the entire agri-food chain, and in compliance with this Regulation. Appropriate consultation with relevant stakeholders in advance of the preparation of the plans should ensure their fitness for purpose.	(76) 每個會員國都應被要求制定並且定期更新一份涵蓋數個年度的國家管制計畫(縮寫MANCP)，這個計畫需包括所有被歐盟農業食品供應鏈立法令管理的領域，以及包括相關其官方管制系統之結構和組織上的資訊。此等 MANCPs 係作爲一項工具，經由該項工具可讓每個會員國應確保其官方管制是以風險做基礎的方式加以執行，並在其國土與整個農業食品供應鏈均有效率且符合本規章之要求。在此計畫的準備之前，和有關的利益相關者開展適當的諮詢應確保適合該等計畫目的之妥適性。
(77) In order to ensure the coherence and completeness of the MANCP each Member State should designate a single body tasked with coordinating the preparation of its MANCP and collecting, as necessary, the information on its implementation, review and update.	(77) 為了確保 MANCP 的連貫性和完整性，每一個會員國應該指定一個單獨的機構，這個機構的任務是協調 MANCP 的準備工作，以及收集必要用來執行、回顧和更新的資訊。
(78) Member States should be required to submit an annual report to the Commission with information on control activities and the implementation of the MANCPs. In order to ensure uniform conditions for the implementation of this Regulation and to facilitate the collection and transmission of comparable data, the subsequent compilation of such data into Union-wide statistics and the preparation of reports by the Commission on the operation of official controls across the Union, implementing powers should be conferred on the Commission to adopt implementing acts in respect of establishing standard model forms for annual reports.	(78) 會員需須提交包括管制活動和 MANCPs 的相關執行情況資訊的年度報告至歐盟執委會。爲了確保執行本規章的一致性，並促進可資比較的數據之蒐集與傳送，並將這些數據後續彙編成歐盟的統計數據，讓歐盟執委會得以準備針對歐盟的官方管制的運作情況作出報告，故應授予歐盟執委會執行權力，以採用關於制定年度報告的標準模式表格之施行法案。

(79) Commission experts should be able to perform controls, including audits, in Member States to verify the application of the relevant Union legislation and the functioning of national control systems and competent authorities. Commission controls should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. At the request of the Member States concerned, Commission experts should also be able to participate in controls performed by the competent authorities of third countries on the territory of that Member State; such controls should be organised in close cooperation between the Member States concerned and the Commission.

(80) Animals and goods from third countries should comply with the same requirements which apply to Union animals and goods, or with requirements which are recognised to be at least equivalent in relation to the objectives pursued by Union agri-food chain legislation. This principle is enshrined in Article 11 of Regulation (EC) No 178/2002, which requires that food and feed imported into the Union comply with the relevant requirements of the Union's food law or with requirements considered to be at least equivalent thereto. Specific requirements to apply that principle are provided for in Union rules on protective measures against pests of plants, which prohibit the introduction into the Union of certain pests which are not present (or only present to a limited extent) in the Union, in Union rules laying down animal health requirements, which allow the entry of animals and of certain products of animal origin into the Union only from third countries which are included in a list set up for that purpose, and in Union rules for the organisation of official controls on products of animal origin intended for human consumption, which also provide for the establishment of a list of third countries from which those products can enter the Union.

(81) In order to ensure that animals and goods entering the Union from third countries comply with all the requirements laid down in Union agri-food chain legislation or with requirements considered equivalent, in addition to the requirements established by Union rules on protective measures against pests of plants, Union rules laying down animal health requirements and Union rules laying down specific hygiene rules for food of animal origin to ensure that the requirements laid down in Union agri-food chain legislation in relation to phytosanitary and veterinary concerns are met, the

(79) 歐盟執委會專家應該能夠在會員國執行包括稽核在內的管制，以驗證相關歐盟法令的應用，以及國家管制系統與權責機關的運作。歐盟執委會之管制作業也適用於調查和收集會員國的執法情形或問題、緊急情況和新的發展之資訊。應所涉會員國的要求，歐盟執委會專家也應能夠參與第三國權責機關在該會員國境內上所執行的管制作業；這些管制作業應在所涉會員國和歐盟執委會之間的密切合作加以籌劃。

(80) 來自第三國的動物和貨物應符合適用歐盟動物和貨物的相同要求，或符合被認可為至少相當於歐盟農業食品供應鏈法令所追求的目標之要求。這一原則被載入(EC)178/2002 號規章第 11 條，要求進口到歐盟的食品和飼料符合歐盟食品法律的相關要求或被認為至少與之同等的要求。在歐盟規範中提供了應用該原則的具體要求，針對植物類的害蟲保護措施，歐盟規範禁止在歐盟中不存在(或僅在有限程度上存在)的特定害蟲被引介進入歐盟；在歐盟規範中亦明訂動物健康要求，僅允許來自登錄在所定的名單上之第三國的動物和某些特定動物源產品進入歐盟；歐盟規範另明訂有關執行提供人類消費的有關動物和動物源產品的官方管制的籌劃，也提供第三國的名單，從該名單可知，哪些來自該等第三國之動物源產品可以進入歐盟。

(81) 除了歐盟規範中針對植物類的害蟲所規定的保護措施；歐盟規範所明訂了動物健康要求；以及歐盟規範所明訂了動物源性食品具體衛生規範，以確保符合從第三國進入歐盟的動物和貨物能符合歐盟農業食品供應鏈法令規定的所有要求或被視為同等的要求中，有關植物檢疫和獸醫方面的歐盟農業食品供應鏈立法所規定的要求，歐盟執委會應被允許為動物和

Commission should be allowed to establish conditions for the entry of animals and goods into the Union to the extent necessary to ensure that those animals and goods comply with all relevant requirements of Union agri-food chain legislation or equivalent requirements. Such conditions should apply to animals or goods or categories of animals or goods from all third countries or from certain third countries or regions thereof.

貨物進入歐盟制定條件，以確保該等動物和貨物符合歐盟農業食品供應鏈法令的所有相關要求同等的要求。至所需的程度上開條件應適用於所有第三國或來自特定的第三國或地區的動物或貨物，或動物或貨物的種類。

(82) Where, in specific cases, there is evidence that certain animals or goods originating from a third country, a group of third countries, or regions thereof, give rise to risks to human, animal or plant health or, as regards GMOs and plant protection products, also to the environment or where there is evidence that widespread serious non-compliance with Union agri-food chain legislation might be taking place, the Commission should be able to adopt measures to contain such risks.

(82) 當在特定情況下，有證據表明，來自某一第三國、多個第三國家或地區的特定貨物或動物，會對人類、動物或植物健康造成危害，或者關於基因改造生物和植物保護產品造成危害，也會對環境造成危害，或者有證據表明將會發生大範圍且嚴重的不符合歐盟農業食品供應鏈法令的情況，歐盟執委會須採取措施以遏止此類風險的發生。

(83) The performance of effective and efficient official controls and other official activities, and ultimately the safety and health of humans, animals and plants, and the protection of the environment, also depends on the availability to the control authorities of well trained staff possessing an appropriate knowledge of all the matters relevant for the correct application of Union legislation. Appropriate and dedicated training should be provided by the Commission to promote a uniform approach to official controls and other official activities by the competent authorities. To promote the knowledge of Union agri-food chain legislation and requirements in third countries, such training should also be addressed to staff of the competent authorities in third countries. In the latter case, the training activities should be designed to take into account the specific needs of developing countries, to support their controls and enforcement actions so that they can meet the requirements applicable to import of animals and goods into the Union.

(83) 有效和有效率的執行官方管制和其他官方活動，以及最終人類、動物和植物安全和健康以及環境保護，也取決於管制機關是否充分擁有受過良好培訓與有可正確應用歐盟法令所有相關事宜的全面知識的職員。歐盟執委會應提供適當和專門的培訓，以促權責機關採取一致的方式進行官方管制和其他官方活動。為了促進第三國了解對歐盟農業食品供應鏈法令的要求，亦應向第三國權責機關的職員提供培訓。在此種情況下，培訓活動的設計應考慮到發展中國家的具體需求，以支持他們的管制和執法活動，使其能符合動物和貨物輸入歐盟的要求。

(84) To promote the sharing of experience and best practices among competent authorities, the Commission should also be able to organise, in cooperation with the Member States, programmes for the exchange between Member States of staff tasked with official controls or other official activities.

(84) 為了促進權責機關之間的經驗和最佳做法的共享，歐盟執委會應能夠與會員國合作，籌劃各會員國從事官方管制或其他官方活動之人員間的交流方案。

(85) It is important for the performance of effective official controls and other official activities that the

(85) 各會員國的職責機關、歐盟執委會和相關運營

competent authorities in the Member States, the Commission and, where relevant, operators be able to exchange data and information related to official controls or results therefrom rapidly and efficiently. Several information systems are established by Union legislation and managed by the Commission to allow such data and information to be handled and managed through Union-wide computerised and internet-based tools. A system dedicated to recording and tracing official control results is the Trade Control and Expert System (Traces system), established by Commission Decisions 2003/24/EC[21] and 2004/292/EC[22] in accordance with Council Directive 90/425/EEC[23] and currently used for the management of data and information on animals and products of animal origin and official controls thereon. This Regulation should allow that system to be maintained and upgraded so as to allow its use for all goods for which Union agri-food chain legislation establishes specific requirements or practical arrangements for official controls. Dedicated computerised systems also exist for the rapid exchange of information between Member States and with the Commission on risks which might arise in the agri-food chain or for animal and plant health. Article 50 of Regulation (EC) No 178/2002 establishes the RASFF which is a system for notifying direct or indirect risk to human health deriving from food or feed, Article 20 of Regulation (EU) 2016/429 of the European Parliament and of the Council[24] a system for the notification and reporting on the measures on listed diseases, and Article 103 of Regulation (EU) 2016/2031 of the European Parliament and of the Council[25] a system for the notification and reporting of the presence of pests

商的權責機關能夠迅速與有效率的交流與官方管制或因此而產生之結果相關的數據和資訊，對有效的官方管制和其他官方活動之執行是重要的，對歐盟法令已建立了若干個資訊系統並由歐盟執委會管理，以讓這些數據和資訊採用歐盟廣泛的電腦化和透過網際網路的工具來處理和管理。一個專門記錄和追蹤官方管制的系統是歐盟貿易管制專家系統(TRACES 系統），由歐盟執委會 2003/24/EC 號和 2004/292/EC 號決定根據歐盟理事會 90/425/EC 號指令所建立，目前用於管理有關動物和動物源性產品以及其官方管制的數據與資訊。本規章應讓該系統得以維持和升級，以使其可用於管理歐盟農業食品供應鏈法令所建立對官方管制用的具體要求或實際安排的所有商品。亦有專門的電腦化系統能讓各會員國間以及會員國與歐盟執委會之間關於農業食品供應鏈或動植物健康風險的資訊得以迅速的交換。(EC)178/2002 號規章第 50 條建立了 RASFF 系統；該系統是用於通知來自食品或飼料而對人類健康的直接或間接風險的系統；歐洲議會及歐盟理事會(EU)2016/429 號規章第 20 條通知和報告有關列管疾病所採取之措施的系統，以及歐洲議會及歐盟理事會

21 Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system (OJ L 8, 14.1.2003,p.44)./ 歐盟執委會於 2002 年 12 月 30 日頒佈了第 2003/24/EC 號決定，該決定係有關於整合性電腦化獸醫系統的發展。

22 Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC (OJ L 94, 31.3.2004,p.63)./ 歐盟執委會於 2004 年 3 月 30 日頒佈了 2004/292/EC 號，該決定是介紹歐盟貿易管制專家系統，和修改 92/486/EEC 號決定。

23 Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p.29)./ 歐盟理事會 1990 年 6 月 26 日頒佈第 90/425/EEC 號指令，有關適用於歐盟會員國間內部共同市場貿易，對特定活動物及產品之獸醫和畜牧技術檢查。

24 Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on the transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84,31.3.2016, p.1)./ 歐洲議會和歐盟理事會於 2016 年 3 月 9 日頒佈了(EU) 2016/429 號規章，係關於可傳染的動物疾病，並修改與廢除動物健康領域的某些法案（動物健康法）。

25 Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No

and the notification of cases of non-compliance. All such systems should work in a harmonious and consistent manner that makes use of synergies between the different systems, avoids duplications, simplifies their operation and makes them more efficient.

(86) To support a more efficient management of official controls, a computerised information system integrating and upgrading as necessary all relevant existing information systems should be set up by the Commission, allowing for the use of advanced communication and certification tools, and for the most efficient use of the data and information related to official controls. In view of avoiding unnecessary duplications of information requirements, the design of such computerised system should take into account the need to ensure, wherever appropriate, the compatibility and inter-operability of such a computerised system with other information systems operated by public authorities and through which relevant data is automatically exchanged or made available. Moreover, the possibility to use electronic signatures within the meaning of Directive 1999/93/EC of the European Parliament and the Council[26] should be provided for, in line with the Digital Agenda for Europe. The European Data Protection Supervisor should be consulted during the development stage of any new functionality of such computerised system, as well as during the development of relevant implementing measures which might affect the processing of personal data and privacy.

(87) In order to ensure uniform conditions for the implementation of this Regulation regarding the proper functioning of the computerised information system, its technical specifications, as well as the duties and prerogatives of the various actors and users involved, taking into account in particular the need to minimise administrative burdens by using, as appropriate, internationally standardised language, message structure and exchange protocols, implementing powers should be conferred

(EU)2016/2031 號規章第 103 條，建立了通知和報告害蟲的出現和不符合情況的系統。所有這些系統應該以協調一致的方式運作，利用不同系統之間的協同作用，避免重複，簡化操作，使它們更有效率。

（86） 為了更有效率地管理官方管制作業，歐盟執委會應依需求建立電腦化資訊系統以整合和更新所有相關的現有資訊系統，以利使用先進的通訊和驗證工具，以及最有效率的使用與官方管制有關的數據和資訊。為了避免不必要的資訊需求重複，這種電腦化系統的設計應考慮到，能確保系統與公家機關所運作的其他資訊系統的相容性和相互間之可操作性之需求。以使相關數據可自動交換或可被取得。此外，應提供歐洲議會和歐盟理事會 1999/93/EC 號指令的涵義內所要求使用電子簽名的可能性，以符合歐洲數位進程。歐洲數據保護監督員應在開發此類電腦化系統的任何新功能的過程中，以及在可能影響個人數據和隱私處理的相關執行措施的發展過程中提供諮詢。

（87） 爲了確保執行本規章的，包括關於電腦化資訊系統的正常運行、其技術規格、以及不同參與者和使用者的職責和權限能有一致性的條件，並特別考慮到，適當時，需要透過適應地使用國際標準化語言、訊息結構和訊息交換協定以使行政負擔最小化，應賦予歐盟執委會中執行的權力。

652/2014 and （EU)No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC(OJ L 317,23.11.2016, p.4)./ 歐洲議會和歐盟理事會於 2016 年 10 月 26 日頒佈了(EU)2016/2031 號規章，係關於植物病蟲害的防護措施，並修改歐洲議會和理歐盟理事會(EU)228/2013 號規章、第 652/2014 號規章和(EU)1143/2014 號規章以及廢除歐盟理事會第 69/464/EEC 號、第 74/647/EEC 號、第 93/85/EEC 號、第 98/57/EC 號、第 2000/29/EC 號、第 2006/91/EC 號及第 2007/33/EC 號指令。

26 Directive 1999/93/EC of the European Parliament and the Council of 13 December 1999 on a Community framework for electronic signatures (OJ L 13, 19.2.2000, p.12)./ 歐洲議會和歐盟理事會於 1999 年 12 月 13 日頒佈了 1999/93/EC 號指令，是關於電子簽名的共同體架構。

on the Commission.

(88) The competent authorities should investigate cases where there is a suspicion of non-compliance with Union agri-food chain legislation and, where non-compliance is established, determine its origin and extent as well as the operators' responsibilities. The competent authorities should also take appropriate measures to ensure that the operators concerned remedy the situation and to prevent further non-compliance. The organisation and performance of investigations and enforcement actions by the competent authorities should duly take into account potential risks and the likelihood of fraudulent or deceptive practices along the agri-food chain.

(88) 權責機關應調查疑涉不符合歐盟農業食品供應鏈法令的案件，並在確定係不符合的情況下，應確定其來源、影響程度以及運營商的責任。權責機關應採取適當措施，以確保所涉及之運營商改善情況，並防止進一步違反規定。權責機關於籌劃及進行調查和執法行動時應適當地考慮農業食品供應鏈中潛在的風險和攙偽或假冒行爲的可能性。

(89) The verification of compliance with Union agri-food chain legislation through official controls is of fundamental importance to ensure that, across the Union, the objectives of that legislation are effectively achieved. Disruptions in a Member State's control systems can in certain cases substantially hinder the achievement of those objectives and lead to the emergence of risks to human, animal and plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, independently of the involvement or responsibility of operators or other actors, or lead to situations of widespread serious non-compliance with Union agri-food chain legislation. In order to ensure uniform conditions for the implementation of this Regulation, the Commission should be able, in the event of serious disruptions in a Member State's control system, to react by adopting measures aimed at containing or eliminating those risks from the agri-food chain, pending the necessary action to be taken by the Member State concerned to remedy the disruption in the control system. Implementing powers should therefore be conferred on the Commission.

(89) 透過官方管制來查驗是否符合歐盟農業食品供應鏈法令的情況，對於確保在整個歐盟中有效地實現該法令的目標至關重要。在某些情況下，某一會員國管制系統的中斷會實質地的阻礙了這些目標的實現，並導致對人類、動植物健康、動物福祉或關於基因改造生物和植物保護產品，以及對環境造成風險，不論是否有運營商或其他參與者的涉入或責任；或導致普遍嚴重不符合歐盟農業食品供應鏈法令的情況。為了確保執行本規章能有一致的條件，在某一會員國管制系統嚴重中斷的情況下，歐盟執委會應能採取措施，遏制或消除來自農業食品供應鏈的風險，直到該會員國採取必要行動，以改善其管制系統中斷的情況為止。因此，應授予歐盟執委會執行的權力。

(90) Infringements of the rules of the Union agri-food chain legislation and of this Regulation should be subject to effective, dissuasive and proportionate penalties at national level throughout the Union, the severity of which takes account, inter alia, of the potential damage to human health that may result from infringements, including in cases where operators fail to cooperate during an official control and in cases where false or misleading official certificates or attestations are produced or used. For financial penalties applicable to violations of the rules perpetrated through fraudulent or

(90) 發生違反歐盟農業食品供應鏈規範和本規章的情況時，應接受在整個歐盟範圍內進行國家層級別之有效的、勸阻的和符合比例原則的處罰，其嚴厲程度尤應考慮到由該等違反規範或規章之情事所導致可能對人類健康造成的潛在危害。該等違反的情況其中包括運營商在官方管制作業中不合作之情形，以及偽造的或誤導性的官方證明書或證明被製作和使用之情

deceptive practices to be sufficiently deterrent, they should be set at a level which seeks to exceed the undue advantage for the perpetrator resulting from those practices.

形。對於透過欺詐或欺騙性行為而違反規範情事所處之罰金應予以充分地遏止，該等罰金之訂定應以企求超越犯罪者違法所獲取的不當利益為基準。

(91) Any person should be able to bring new information to the attention of competent authorities which assists them in detecting, and imposing penalties in cases of, infringements of this Regulation and of the rules referred to in Article 1(2). However, whistleblowing could be deterred by the lack of clear procedures or for fear of retaliation. Reporting of infringements of this Regulation is a useful tool to ensure that a competent authority is able to detect and impose penalties for infringements. This Regulation should therefore ensure that adequate arrangements are in place to enable any person to alert the competent authorities to possible infringements of this Regulation and to protect that person from retaliation.

(91) 任何人在發現有涉違反本規章和第 1(2)條所提及之規範的最新資訊時，均應能向權責機關反映以協助權責機關進行偵測和加以處罰。然而，由於缺乏明確的程序或害怕受報復，告密的念頭可能被打消。對違反本規章規定的情事舉發是一個有用的工具，可確保權責機關能夠檢測和處罰違反情事。因此，本規章應確保有適當的安排，使任何人均能夠將可能違反本規章之情事提醒權責機關，並保護該人免遭報復。

(92) This Regulation covers areas that are already covered in certain acts currently in force. To avoid duplications and to establish a coherent legislative framework, the following acts should be repealed and replaced by this Regulation: Regulation (EC) No 882/2004 and Regulation (EC) No 854/2004 of the European Parliament and of the Council[27], Council Directives 89/608/EEC[28], 89/662/EEC[29], 90/425/EEC, 91/496/EEC, 96/23/EC[30], 96/93/EC and 97/78/EC and Council Decision 92/438/EEC[31].

(92) 本規章涵蓋了目前已生效的某些法規所涵蓋的領域。爲了避免重複和建立一個連貫的立法架構，下列法案應被廢止並被本規章所取代：歐洲議會和歐盟理事會(EC)882/2004 號規章和(EC)854/2004 號，歐盟理事會 89/608/EEC 號，89/662/EEC、90/425/EEC 號、91/496/EEC 號、96/23/EC 號、96/93/EC 號和 97/78/EC 號指令和歐盟理事會 92/438/EEC 號決定。

27 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)./ 歐洲議會和歐盟理事會 2004 年 4 月 29 日頒佈(EC)854/2004 號規章明定用於人類消費之動物源產品的官方管制具體規章。

28 Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters (OJ L 351,2.12.1989, p.34)./ 歐盟理事會於 1989 年 11 月 21 日頒佈第 89/608/EEC 號指令，關於會員國行政機構間的相互協助及各會員國和歐盟執委會的合作，以確保正確應用獸醫和動物技術方面的法令。

29 Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ L 351, 2.12.1989, p.13)./ 歐盟理事會 1989 年 12 月 11 日頒佈第 89/662/EEC 號指令，關於歐洲共同體內部貿易之獸醫檢查，以期內部市場之完成。

30 Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products (OJ L 13, 16.1.Q997, p.28)./ 歐盟理事會 1996 年 12 月 17 日頒佈 96/93/EC 號指令，關於動物和動物產品的驗證。

31 Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and Decision 90/424/EEC, and repealing Decision 88/192/EEC (OJ L 243, 25.8.1992, p.27)./ 歐盟理事會於 1992 年 7 月 13 日頒佈 92/438/EEC 號決定，關於獸醫進口程式電腦化(轉換專案)，並修正 90/675/EEC 號、91/496/EEC 號、91/628/EEC 號指令和 90/424/EEC 號決定，以及廢除 88/192/EEC 號決定。

(93) In order to ensure consistency, the following acts should be amended: Regulation (EC) No 999/2001 of the European Parliament and of the Council[32], Council Regulation (EC) No 1/2005[33], Regulation (EC) No 396/2005 of the European Parliament and of the Council[34], Regulation (EC) No 1069/2009, Council Regulation (EC) No 1099/2009[35], Regulation (EC) No 1107/2009 of the European Parliament and of the Council[36], Regulation (EU) No 1151/2012 of the European Parliament and of the Council[37], and Council Directives 98/58/EC[38], 1999/74/EC[39], 2007/43/EC[40], 2008/119/EC[41] and 2008/120/EC[42].	(93) 爲了確保一致性，應修改以下法規：歐洲議會和歐盟理事會(EC) 999/2001 號規章、歐盟理事會(EC) 1/2005 號規章、歐洲議會和歐盟理事會(EC) 396/2005 號規章、(EC) 1069/2009 號規章、歐盟理事會(EC) 1099/2009 號規章、歐洲議會和歐盟理事會(EC) 1107/2009 號規章、歐洲議會和歐盟理事會(EU) 1151/2012 號規章和歐盟理事會 98/58/EC 號、1999/74/EC 號、2007/43/EC 號、2018/119/EC 號和 2008/120/EC 號指令。

32 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)./ 歐盟理事會於 2001 年 5 月 22 日頒佈(EC)999/2001 號規章，以明定定預防、管制和消滅某些傳染性海綿狀腦病的規範。

33 Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directive 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p.1)./ 歐盟理事會於 2004 年 12 月 22 日頒佈第(EC)1/2005 號規章，關於在運輸和相關作業時中動物之保護，以及修正 64/432/EEC 號和 93/119/EC 號指令與(EC)1255/97 號規章。

34 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum levels of pesticides in or on food and feed of plant or animal origin and amending Council Directive 91/414/EEC (OJ L 70,16.3.2005, p.1)./ 歐盟理事會於 2005 年 2 月 23 日頒佈(EC)395/2005 號規章，係關於植物或動物源的食品和飼料中農藥的最高含量，並修訂歐盟理事會 91/414/EEC 號決議。

35 Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.1 1.2009, p.1)./ 歐盟理事會於 2009 年 9 月 24 日頒佈(EC)1099/2009 號規章，係關於屠宰時的動物保護。

36 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p.1)./ 歐盟理事會於 2009 年 10 月 21 日頒佈(EC)1107/2009 號規章，係關於在市場上銷售植物保護產品，並廢除歐盟理事會 79/117/EEC 和 91/414/EEC 號指令。

37 Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p.1)./ 歐盟理事會於 2012 年 11 月 21 日頒佈(EU)1151/2012 號規章，關於農產品與食品之品質方案。

38 Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purpose (OJ L 221. 8.8.1998, p.23)./ 歐盟理事會於 1998 年 7 月 20 日頒佈 98/58/EC 號指令，關於以飼養作為畜養用的動物之保護。

39 Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens (OJ L 203, 3.8.1999, p.53)./ 歐盟理事會於 1999 年 7 月 19 日頒佈 1999/74/EC 號指令，明定了保護產蛋雞的最低標準。

40 Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production (OJ L 182, 12.7.2007, p.19)./ 歐盟理事會於 2007 年 6 月 28 日頒佈 2007/43/EC 號指令，明定了飼養作為肉類生產用雞之保護的最低規範。

41 Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (OJ L 10, 15.1.2009, p.7)./ 歐盟理事會於 2008 年 12 月 18 日頒佈 2008/119/EC 號指令，明定了保護牛犢的最低標準。

42 Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs (OJ L 47, 18.2.2009, p.5)./ 歐盟理事會於 2008 年 12 月 18 日頒佈 2008/120/EC 號指令，明定了保護豬隻的最低標準。

(94) Regulation (EU) No 652/2014 of the European Parliament and of the Council[43] provides a framework for the Union's financing of actions and measures across the agri-food chain in those areas under the multi-annual financial framework 2014-2020. Some of those acts and measures aim to improve the performance of official controls and other official activities across the Union. Regulation (EU) No 652/2014 should be amended to take account of the repeal of Regulation (EC) No 882/2004 by this Regulation.

(95) Considering the specific situation as regards the plant sector, which has so far not been subject to the same level of controls as other goods under this Regulation, it is essential that the introduction of the new system be as smooth and seamless as possible. For that reason, it is necessary to introduce specific provisions regarding the timing of the adoption of relevant delegated acts. It is also clear that it is justified to have an exemption from the obligation of documentary checks to be carried out at border control posts for the plant sector in the case of plants, plant products and other objects posing a low level of risk and to permit documentary checks at a distance from border control posts for plants, plant products and other objects where such checks at a distance are able to provide an equal level of assurance.

(96) In order to amend the references to European standards, and Annexes II and III to this Regulation to take into account of legislative and technical and scientific developments, and to supplement this Regulation with specific rules governing official controls and other official activities in the areas it covers, including rules on the qualification and training of staff, on additional responsibilities and tasks of the competent authorities, on the cases where the accreditation of laboratories is not required, on certain exemptions from official controls at the borders, on the criteria to be used to

(94) 歐洲議會和歐盟理事會(EU)652/2014 號規章爲歐盟在 2014-2020 年的多年度財政架構下的那些領域之農業食品供應鏈上的歐盟財政行動和措施提供了一個框架。那些法規和措施旨在提高官方管制和其他官方活動在整個歐盟的績效。(EU)652/2014 號規章應被修改，以考慮藉由本規章廢止(EC)882/2004 號規章。

(95) 鑑於植物領域的具體情況，到目前爲止還沒有受到與本規章規定的其他貨物相同的管制水準，因此，新系統的導入須盡可能平順和無縫接軌是很重要的。因此，有必要依本規章就採用相關委任法規的時間點訂定具體條文。同樣清楚的是，在植物、植物產品和其他物品是低度風險的情況下，免除該等植物部門在邊境管制站進行的文件檢查義務是合理的，並允許在邊境管制站一定距離外對植物、植物產品和其他物品進行文件檢查，此種檢查能夠提供同等程度的保證。

(96) 爲了修正對歐洲標準的引用情形和本規章附件 II 及 III，以將立法的、技術上的和科學的發展納入考量，並為於本規章中補充本規章所涵蓋範圍之官方管制和其他官方活動具體規範，其中包括關於人員資格許可和培訓的規範、關於權責機關的額外職責和任務、關於不需要實驗室認證的情況、關於某些豁免邊界上的官方管制之情形、關於使用作為決定身分識

43 Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulation (EC) No 178/2002 ,(EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189,27.6.2014, p.1)./ 歐洲議會和歐盟理事會於 2014 年 5 月 15 日頒佈了第 652/2014 號規章，與食品供應鏈、動物健康和動物福利有關的支出管理，並與植物健康和植物生殖材料有關的規定，修訂歐洲議會和歐盟理事會第 98/56/EC 號、第 2000/29/EC 號和第 2008/90/EC 號指令、歐洲議會和歐盟理事會第 178/2002 號、第 882/2004 號和第 396/2005 號規章、歐洲議會和歐盟理事會第 2009/128/EC 號指令和歐洲議會和歐盟理事會第 1107/2009 號規章，以及廢除歐洲議會和歐盟理事會第 66/399/EEC 號、第 76/894/EEC 號和第 2009/470/EC 號決定。

determine the frequency of identity checks and physical checks, on the establishment of conditions to be fulfilled by certain animals or goods entering the Union from third countries, on additional requirements and tasks of European Union reference laboratories and centres and on additional requirements for national reference laboratories, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[44]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

別檢查和物性檢查頻率的規定，關於由第三國進入歐盟的某些動物或貨物所需滿足的條件之制定、關於歐盟參考實驗室和中心的附加要求和任務以及國家參考實驗室的附加要求，根據 TFEU 第 290 條應授予歐盟執委會採用法規的權力。特別重要的是，歐盟執委會應在準備工作中進行適當的協商，其中包括專家層級的諮商，並根據 2016 年 4 月 13 日關於較佳法律制度之「機構間合作協定」所明訂之原則進行協商。特別是，爲了確保授權法規備過程中的平等參與，歐洲議會及歐盟理事會的同時收到所有擬擔任各會員國專家們之文件，該等專家們有系統地參加歐盟執委會專家小組會議以處理授權法規之準備事宜。

(97) In order to ensure uniform conditions for the implementation of this Regulation regarding the designation of European Union reference laboratories and of the European Union reference centres for the authenticity and integrity of the agri-food chain and for animal welfare, the adoption of the programme of the Commission controls in the Member States, and the performance of increased official controls in the event of infringements of Union agri-food chain legislation which require coordinated assistance and follow-up by the Commission, implementing powers should be conferred on the Commission.

(97) 爲了確保有一致的條件以執行本規章中關於為達成歐盟參考標準實驗室和歐盟農業食品供應鏈的真實性和完整性及動物福祉所說的參考中心之指派、在各會員國內採用歐盟執委會的管制計畫，以及在有違反歐盟農業食品供應鏈法令的情事時因需要經歐盟執委會協調透過協助和後續稽催行動所增加之官方管制的績效，因此應賦予歐盟執委會執行權力。

(98) In order to ensure uniform conditions for the implementation of this Regulation, including rules and practical arrangements in respect of audits, the format of certificates and other documents, the establishment of computerised information management systems, the cooperation between operators and competent authorities and amongst competent authorities, customs authorities and other authorities, the methods of sampling and of laboratory analysis, test and diagnosis as well as their validation and interpretation, traceability, the listing of animals or goods subject to controls as well the listing of countries or regions that can export certain animals and goods to the Union, prior

(98) 爲確保執行本規章的一致條件，其中包括稽核的規範和實際安排；證書和其他文件的格式；電腦化資訊管理系統的建立；運營商與權責機關間，以及權責機關與海關和其他機關間的合作；取樣和實驗室分析、測試和診斷的方法以及它們的確致和解釋；可追溯性；受管制的動物或貨物的名單以及可向歐盟出口特定動物和貨物的國家或地區的名單；貨物之事先通知；資訊交流；邊境管制站；隔離檢疫；第三國所規定的出口前管制之認可；為遏制風險或

44 OJ L 123, 12.5.2016. p.1.

notification of consignments, exchanges of information, border control posts, isolation and quarantine, approval of pre-export controls performed by third countries, measures to contain a risk or put an end to a widespread serious non-compliance relating to certain animals or goods originating from a third country or a region thereof, the recognition of third countries or regions that offer equivalent guarantees to those applied in the Union and its repeal, training activities and exchange programmes of staff amongst Member States and on the contingency plans for food and feed for the application of the general plan for crisis management provided for in Article 55(1) of Regulation (EC) No 178/2002, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[45].	終結與源自第三國或其地區的某些動物或貨物有關的廣泛嚴重不符合情勢採取之措施，第三國或地區所提供對在歐盟中適用的保證之認可與撤銷；對會員國從事官方管制及其他官方活動人員之培訓活動和交流計畫，以及(EC)178/2002 號規章第 55(1)條所定關於提供作為於一般危機管理總體計畫的糧食和飼料應急計畫，故應賦予歐盟執委會執行權力。這些權力應按照歐洲議會及歐盟理事會(EU)182/2011 號規章行使。
(99) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to official controls and other official activities performed in view of ensuring the application of Union agri-food chain legislation, cannot be sufficiently achieved by the Member States but can rather, by reason of its effect, complexity, trans-border and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.	(99) 由於本規章的目的，亦即要確保有一個關於為確保歐盟農業食品供應鏈法令的應用方面所執行的官方管制和其他官方活動之調和的途徑，於會員國無法充分達成，但反面基於該目的之效果、複雜性、跨國界和國際性，放由歐盟層級來做可能更好達成，歐盟可以根據「歐盟條約」第 5 條所規定的輔助原則採取措施。依上述條文明定之比例原則，本規章以不超出爲達到該目的所必需的程度為原則。
HAVE ADOPTED THIS REGULATION:	已採用本規章：
TITLE I **SUBJECT MATTER, SCOPE AND DEFINITIONS**	第 I 編 **主題事項、範圍和定義**
Article 1 **Subject matter and scope**	*第 1 條* **主題事項和範圍**
1. This Regulation lays down rules for:	1. 本規章制定以下規範：

45 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, P.13)./ 歐洲議會和歐盟理事會於 2011 年 2 月 16 日頒佈了(EU)182/2011 號規章，規定了各會員國就歐盟執委會行使執行權力的管制機制之規範和一般原則。

(a) the performance of official controls and other official activities by the competent authorities of the Member States;
(b) the financing of official controls;
(c) the administrative assistance and cooperation between Member States in view of the correct application of the rules referred to in paragraph 2;
(d) the performance of controls by the Commission in Member States and in third countries;
(e) the adoption of conditions to be fulfilled with respect to animals and goods entering the Union from a third country;
(f) the establishment of a computerised information system to manage information and data in relation to official controls.

2. This Regulation shall apply to the official controls performed for the verification of compliance with the rules, whether established at Union level or by the Member States, to apply Union legislation, in the areas of:
(a) food and food safety, integrity and wholesomeness at any stage of production, processing and distribution of food, including rules aimed at ensuring fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food;
(b) deliberate release into the environment of Genetically Modified Organisms (GMOs) for the purpose of food and feed production;
(c) feed and feed safety at any stage of production, processing and distribution of feed and the use of feed, including rules aimed at ensuring fair practices in trade and protecting consumer health, interests and information;
(d) animal health requirements;
(e) prevention and minimisation of risks to human and animal health arising from animal by-products and derived products;
(f) welfare requirements for animals;
(g) protective measures against pests of plants;

(a)會員國權責機關官方管制和其他官方活動之執行；
(b)官方管制的資金財政；
(c)會員國間的行政協助和合作以利第2項中提到的規範能被正確運用；
(d)歐盟執委會在會員國及第三國之管制之執行；
(e)對從第三國進入歐盟的動物和貨物須滿足的條件之採用；
(f)電腦化資訊系統之建立以管理與官方管制有關的資訊和數據。

2. 本規章將適用於為查驗是否有符合規範所執行之官方管制作業，無論該規範等是由歐盟層級的或是由會員國所制定，以應用歐盟法令於下列領域：
(a)食品和食品安全，也就是在食品之生產、加工和配送分銷的任何階段之完整性和衛生，其中包括旨在確保貿易公平及保護消費者的利益和資訊，以及可能與食品接觸的原料和物品的製造和使用之規範；
(b)為了生產食物和飼料而對於基因改造生物(GMOs)審慎釋出致環境中；
(c)飼料生產、加工和配送分銷以及飼料使用的任何階段之飼料和飼料安全，其中包括旨在於確保貿易公平及保護消費者健康、利益和資訊的規範；
(d)動物健康需求；
(e)源自動物副產品和衍生產品對人類和動物健康造成的風險之預防及最小化；
(f)動物福祉要求：
(g)對植物害蟲之保護措施;
(h)對植物保護產品於市場流通銷售與使用，以及農藥(農藥是施用設備除外)永續使用的要求；
(i)有機生產和有機產品的標示；
(j)受保護的原產地名稱、受保護的地理標示和受保

(h) requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticides application equipment;	證的傳統產品的使用和標示。
(i) organic production and labelling of organic products;	
(j) use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.	
3. This Regulation shall also apply to official controls performed for the verification of compliance with requirements laid down in the rules referred to in paragraph 2 where those requirements are applicable to animals and goods entering the Union or to be exported from the Union.	3. 本規章亦將適用於查驗與否符合第 2 項中所提到之規範所明定之要求而執行之官方管制作業，上開要求適用於進入歐盟或從歐盟出口之動物或貨物。
4. This Regulation shall not apply to official controls for the verification of compliance with:	4. 本規章將不適用於有檢驗是否符合下列規定之官方管制作業：
(a) Regulation (EU) No 1308/2013; however, this Regulation shall apply to checks pursuant to Article 89 of Regulation (EU) No 1306/2013, where those checks identify possible fraudulent or deceptive practices in respect of the marketing standards referred to in Articles 73 to 91 of Regulation (EU) No 1308/2013;	(a)(EU)1308/2013 號規章；然而，本規章將適用於確認根據(EU)1306/2013 號規章第 89 條進行的檢查，以辨識關於(EU)1308/2013 號規章第 73 條至第 91 條所定營銷標準中可能存在的欺詐或欺騙行為；
(b) Directive 2010/63/EU of the European Parliament and of the Council[46];	(b)歐洲議會和歐盟理事會 2001/63/EU 號指令；
(c) ►**M3** Regulation (EU) 2019/6 of the European Parliament and of the Council[47]; however, this Regulation shall apply to official controls for the verification of compliance with Article 118(1) of that Regulation.◄**M3**	(c)歐洲議會和歐盟理事會(EU)2019/6 規章； 然而本規章應適用於確證符合該規章第 118(1)條的官方管制。
5. Articles 4, 5, 6, 8, Article 12(2) and (3), Articles 15, 18 to 27, 31 to 34, 37 to 42 and 78, Articles 86 to 108, point (b) of Article 112, Article 130 and Articles 131 to 141 shall also apply to other official activities performed by the competent authorities in accordance with this Regulation or with the rules referred to in paragraph 2 of this Article.	5. 第 4、5、6、8、12(2)和(3)2/3 等條、第 15、18 至 27、31 至 34、37 至 42 和 78 等條、第 86 至 108 等條、第 112 條(b)點、第 130 條和第 131 至 141 等條亦適用於其他權責機關根據本規章或本條文第 2 項規範所執行之其他官方活動。
Article 2 **Official controls and other official activities**	*第 2 條* **官方管制和其他官方活動**

46 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33)./ 歐洲議會和歐盟理事會於 2010 年 9 月 22 日頒佈了第 2010/63/EU 號關於保護用於科學目的的動物指令。

47 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43)./ 歐洲議會和歐盟理事會於 2018 年 12 月 11 日頒佈了(EU)2019/6 規章關於與獸醫藥物產品並廢止 2001/82/EC 指令。

1. For the purposes of this Regulation, 'official controls' means activities performed by the competent authorities, or by the delegated bodies or the natural persons to which certain official control tasks have been delegated in accordance with this Regulation, in order to verify: (a) compliance by the operators with this Regulation and with the rules referred to in Article 1(2); and (b) that animals or goods meet the requirements laid down in the rules referred to in Article 1(2), including for the issuance of an official certificate or official attestation. 2. For the purposes of this Regulation, 'other official activities' means activities, other than official controls, which are performed by the competent authorities, or by the delegated bodies or the natural persons to which certain other official activities have been delegated in accordance with this Regulation, and with the rules referred to in Article 1(2), including activities aimed at verifying the presence of animal diseases or pests of plants, preventing or containing the spread of such animal diseases or pests of plants, eradicating those animal diseases or pests of plants, granting authorisations or approvals, and issuing official certificates or official attestations.	1. 就本規章之目的而言，「官方管制」是指由權責機關執行，或由根據本規章委任某些官方管制任務之受委任機關或自然人執行之活動，以查證： (a)運營商是否符合本規章及第 1(2)條條所提及之規範；以及 (b)動物和貨物符合第 1(2)條所提及之規範明訂之要求，其中包括官方證明書或官方證明之頒發。 2. 就本規章之目的而言，「其他官方活動」是指由權責機關或由根據本規章及第 1(2)條所提及之規範委任某些“官方管制”任務之受委任機關或自然人所執行的官方管制以外之活動，其中包括旨在查驗動物疾病或植物害蟲的存在、預防或遏止該等動物疾病或植物害蟲的傳播，根除那些動物疾病及植物害蟲，給予授權或批准，以及頒發官方證明書或官方證明。
Article 3 **Definitions** For the purposes of this Regulation, the following definitions apply: (1) 'food law' means food law as defined in point (1) of Article 3 of Regulation (EC) No 178/2002; (2) 'feed law' means the laws, regulations and administrative provisions governing feed in general and feed safety in particular, whether at Union or national level at any stage of production, processing and distribution or use of feed; (3) 'competent authorities' means: (a) the central authorities of a Member State responsible for the organisation of official controls and of other official activities, in accordance with this Regulation and the rules referred to in Article 1(2); (b) any other authority to which that responsibility has been conferred; (c) where appropriate, the corresponding authorities of a third country; (4) 'organic control authority' means a public administrative organisation for organic production and	*第 3 條* **定義** 就本規章之目的而言，適用下列定義： (1) 「食品法」係指(EC)第 178/2002 號規章第 3 條第(1)點中所定義的食品法； (2) 「飼料法」係指無論是在歐盟或國家層級於飼料生產、加工、配送分銷或使用的任何階段，管理飼料之一般性和特別是有關飼料安全的法律、規章和行政規定； (3) 「權責機關」係指： (a) 根據本規章及在第 1(2)條條中提及的規範，係指負責官方管制及其他官方活動的會員國的中央機關； (b) 任何被授予責任的其他機關； (c) 適當時，第三國的相對應機關； (4) 「有機管制機關」係指某會員國管理有機產品

labelling of organic products of a Member State to which the competent authorities have conferred, in whole or in part, their competences in relation to the application of Council Regulation (EC) No 834/2007[48] , including, where appropriate, the corresponding authority of a third country or operating in a third country;	的有機生產和標示之公家行政組織，其已由權責機關依關於適用歐盟理事會(EC)834/2007 號規章被全部或部分地授予權限，其中包括，在適當時，第三國的或在第三國運作業務上相對應機關；
(5) ‘delegated body’ means a separate legal person to which the competent authorities have delegated certain official control tasks or certain tasks related to other official activities;	(5) 「受委任機構」係指權責機關已委派某些官方管制任務或某些與其他官方活動有關任務之獨立法人；
(6) ‘control verification procedures’ means the arrangements put in place and actions performed by the competent authorities for the purpose of ensuring that official controls and other official activities are consistent and effective;	(6) 「管制查驗程序」是指權責機關為確保官方管制和其他官方活動的一致性和有效性而實施的安排和行動;
(7) ‘control system’ means a system comprising the competent authorities and the resources, structures, arrangements and procedures set up in a Member State to ensure that official controls are performed in accordance with this Regulation and with the rules referred to in Articles 18 to 27;	(7) 「管制系統」係指一個由權責機關及某會員國所設置之資源、架構、安排及程序的系統，以確保官方管制係依照本規章及第 18 至 27 條所提及之規範執行；
(8) ‘control plan’ means a description established by the competent authorities containing information on the structure and organisation of the official control system, and of its operation and the detailed planning of official controls to be performed, over a period of time, in each of the areas governed by the rules referred to in Article 1(2);	(8) 「管制計畫」係指由權責機關制定的說明，包括關於官方管制系統，以及擬於一段時間內，依據第 1(2)條所提及之規範之每個管理領域所執行之官方管制之運作和的詳細規劃之架構和組織的資訊；
(9) ‘animals’ means animals as defined in point (1) of Article 4 of Regulation (EU) 2016/429;	(9) 「動物」係指在(EU)2016/429 號規章第 4 條第(1)點中所定義的動物；
(10) ‘animal disease’ means disease as defined in point (16) of Article 4 of Regulation (EU)2016/429;	(10) 「動物疾病」係指在(EU)2016/429 號規章第 4 條第(16)點中所定義的疾病；
(11) ‘goods’ means all that is subject to one or more of the rules referred to in Article1(2), excluding animals;	(11) 「商品」係指受第 1(2)條中所提及之一項或多項規範所拘束之所有物品，不包括動物；
(12) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002;	(12) 「食品」係指在(EC)178/2002 號規章第 2 條中所定義的食品；
(13) ‘feed’ means feed as defined in point (4) of Article 3 of Regulation (EC) No178/2002;	(13) 「飼料」係指在(EC)178/2002 號規章第 3 條第(4)點中所定義的飼料；
(14) ‘animal by-products’ means animal by-products as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009;	(14) 「動物副產品」係指在(EC)1069/2009 號規章第 3 條第(1)點中所定義的動物副產品；

48 Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p.1)./ 歐盟理事會於 2007 年 6 月 28 日頒佈了第(EC) 834/2007 號關於有機產品的有機生產和標籤以及廢除第(EEC) 2092/91 規章之規章。

(15) 'derived products' means derived products as defined in point (2) of Article 3 of Regulation (EC) No 1069/2009;	(15)「衍生產品」係指在(EC)1069/2009 號規章第 3 條第(2)點中所定義的衍生產品；
(16) 'plants' means plants as defined in point (1) of Article 2 of Regulation (EU) 2016/2031;	(16)「植物」係指在(EU)2016/2031 號規章第 2 條第(1)點中所定義的植物；
(17) 'pests of plants' means pests as defined in Article 1(1) of Regulation (EU) 2016/2031;	(17)「植物害蟲」係指(EU)2016/2031 號規章第 1(1)條中所定義的害蟲；
(18) 'plant protection products' means plant protection products as referred to in Article 2(1) of Regulation (EC) No 1107/2009;	(18)「植物保護產品」係指(EC) 1107/2009 號規章第 2(1)條中所指之植物保護產品；
(19) 'products of animal origin' means products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council[49];	(19)「動物源產品」係指歐洲議會和歐盟理事會(EC)853/2004 號規章附件 I 第 8.1 點中所定義的動物源產品；
(20) 'germinal products' means germinal products as defined in point (28) of Article 4 of Regulation (EU) 2016/429;	(20)「胚種產品」係指(EU)2016/429 號規章第 4 條第(28)點中所定義的胚種產品；
(21) 'plant products' means plant products as defined in point (2) of Article 2 of Regulation (EU) 2016/2031;	(21)「植物產品」係指(EU)2016/2031 號規章第 2 條第(2)點中所定義的植物產品；
(22) 'other objects' means other objects as defined in point (5) of Article 2 of Regulation (EU) 2016/2031;	(22)「其他物品」係指(EU)2016/2031 號規章第 2 條第(5)點中所定義的其他物品；
(23) 'hazard' means any agent or condition with the potential to have an adverse effect on human, animal or plant health, animal welfare or the environment;	(23)「危害」係指任何可能對人類、動物或植物健康、動物福祉或環境產生不利影響的因素或條件；
(24) 'risk' means a function of the probability of an adverse effect on human, animal or plant health, animal welfare or the environment and of the severity of that effect, consequential to a hazard;	(24)「風險」係指一個對人類、動物或植物健康、動物福祉或環境產生不利影響，以及因此而造成危害的後果之嚴重性的機率函數；
(25) 'official certification' means the procedure by which assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2) is provided by the competent authorities;	(25)「官方驗證」係指權責機關提供關於符合第 1(2)條所提及之規範中規定一項或多項要求保證的程序；
(26) 'certifying officer' means: (a) any official of the competent authorities authorised to sign official certificates by such authorities; or (b) any other natural person who is authorised by the competent authorities to sign official	(26)「驗證官員」係指： (a) 任何權責機關之官員，其被授權簽署官方驗證證書；或 (b) 任何其他自然人，其經權責機關授權按照第 1(2)條所述規則中簽署官方證書；

49 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)./ 歐洲議會和歐盟理事會 2004 年 4 月 29 日第(EC)853/2004 號規章規定了動物源食品的個別衛生規章。

certificates in accordance with the rules referred to in Article 1(2);

(27) 'official certificate' means a paper or electronic document signed by the certifying officer and providing assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2);

(28) 'official attestation' means any label, mark or other form of attestation issued by the operators under the supervision, through dedicated official controls, of the competent authorities or by the competent authorities themselves, and providing assurance concerning compliance with one or more requirements laid down in this Regulation or in the rules referred to in Article 1(2);

(29) 'operator' means any natural or legal person subject to one or more of the obligations provided for in the rules referred to in Article 1(2);

(30) 'audit' means a systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives;

(31) 'rating' means a classification of operators based on an assessment of their conformity with rating criteria;

(32) 'official veterinarian' means a veterinarian appointed by a competent authority, either as staff or otherwise, and appropriately qualified to perform official controls and other official activities in accordance with this Regulation and the relevant rules referred to in Article 1(2);

(33) 'official plant health officer' means a natural person appointed by a competent authority, either as staff or otherwise, and appropriately trained to perform official controls and other official activities in accordance with this Regulation and the relevant rules referred to in point (g) of Article 1(2);

(34) 'specified risk material' means specified risk material as defined in point (g) of Article 3(1) of Regulation (EC) No 999/2001;

(35) 'long journey' means a long journey as defined in point (m) of Article 2 of Regulation (EC) No 1/2005;

(36) 'pesticide application equipment' means pesticide application equipment as defined in point (4) of Article 3 of Directive 2009/128/EC;

(27)「官方驗證證書」係指由驗證官員簽署的紙本或電子文件，並提供關於符合第 1(2)條所述規則中規定一項或多項要求的保證;

(28)「官方證明」係指由運營商在權責機關專門的官方管制的監督下或由權責機關自身所核發的任何標籤、標記或其他形式的證明，其提供關於符合本規章或第 1(2)條所提及之規範中所提及的一項或多項要求的保證；

(29)「運營商」係指任何受第 1(2)條所提及之規範中所提及一項或多項義務拘束的自然人或法人；

(30)「稽核」係指一個有系統且獨立的檢查，以確定各種活動的和該等活動相關結果是否符合所規劃的安排，以及這些安排是否得到有效地實施並適合達成目標；

(31)「評級」係指根據對運營商依評級標準所作的符合性評鑑結果對運營商進行分類；

(32)「官方獸醫」係指由權責機關任命成為職員或其他身分人員的獸醫，並且具有適當資格可根據本規章和第 1(2)條所述相關規範進行官方管制和其他官方活動；

(33)「官方植物健康官員」係指由權責機關任命成為職員或其他身分人員的自然人，並且經過適當的培訓以按照本規章和第 1(2)條第(g)點所提及之相關規範進行官方管制和其他官方活動；

(34)「特定風險材料」係指(EC) 999/2001 號規章第 3(1)條第(g)點中所定義的特定風險材料；

(35)「長途路程」係指(EC) 1/2005 號規章第 2 條第(m)點所定義的長途路程；

(36)「農藥施用設備」係指第 2009/128/EC 號指令第 3 條第(4)點中所定義的農藥施用設備；

(37)「託運物(貨物)」係指由同一官方證書、官方

(37) 'consignment' means a number of animals or quantity of goods covered by the same official certificate, official attestation or any other document, conveyed by the same means of transport and coming from the same territory or third country, and, except for goods subject to the rules referred to in point (g) of Article 1(2), being of the same type, class or description;

證明或任何其他文件所涵蓋的若干動物或貨物，由同一運輸工具運送且來自同一地區或第三國，並且除了受到第 1(2)條第(g)點中所提及之規範約束者外，皆屬於同一類型式、等級或種類；

(38) 'border control post' means a place, and the facilities belonging to it, designated by a Member State for the performance of the official controls provided for in Article 47(1);

(38)「邊境管制站」係指一個由會員國為執行第 47(1)條所規定的官方管制而指定的場所及其所屬的設備；

(39) 'exit point' means a border control post or any other place designated by a Member State where animals, falling within the scope of Regulation (EC) No 1/2005, leave the customs territory of the Union;

(39)「出口點」係指由一個會員國指定的邊境管制站或任何其他地方，屬於(EC) 1/2005 號規章規範範圍內的動物自此地離開歐盟領地的關稅區；

(40) 'entering the Union' or 'entry into the Union' means the action of bringing animals and goods into one of the territories that are listed in Annex I to this Regulation from outside these territories, except in relation to the rules referred to in point (g) of Article 1(2) for which these terms mean the action of bringing goods into the 'Union territory' as defined in the second subparagraph of Article 1(3) of Regulation (EU) 2016/2031;

(40)「進入歐盟」或「輸入歐盟」係指將動物和貨物從本規章附件Ⅰ所列領土名單以外的地方帶入前述領土之一的行為，但與第 1(2)條第(g)點所提及之規範相關除外，因這些名詞意謂將貨物帶入(EU) 2016/2031 號規章第 1(3)條第 2 款中所定義的「歐盟領域」內之行為；

(41) 'documentary check' means the examination of the official certificates, official attestations and other documents including documents of a commercial nature, which are required to accompany the consignment as provided for by the rules referred to in Article 1(2), by Article 56(1) or by implementing acts adopted in accordance with Articles 77(3), 126(3), 128(1) and 129(1);

(41)「文件檢查」係指依據第 1(2)條所提及之規範第 56(1)條或依第 77(3)條、第 126(3)條、第 128(1)條以及第 129(1)條所採取的施行細則第所要求對附隨於託運物(貨物)的官方證書、官方證明及其他文件其中包括商業性文件進行之檢查；

(42) 'identity check' means a visual inspection to verify that the content and the labelling of a consignment, including the marks on animals, seals and means of transport, correspond to the information provided in the official certificates, official attestations and other documents accompanying it;

(42)「識別檢查」係指目視檢查，以確認託運物(貨物)的內容和標示，包括動物上的標記、圖章和運輸工具，與官方證書、官方證明和附隨的其他文件中提供的資訊相符；

(43) 'physical check' means a check on animals or goods and, as appropriate, checks on packaging, the means of transport, labelling and temperature, the sampling for analysis, testing or diagnosis and any other check necessary to verify compliance with the rules referred to in Article 1(2);

(43)「物性檢查」係指對動物或貨物進行檢查，並適當地檢查包裝、運輸工具、標示和溫度、取樣分析、測試或診斷以及其他所需之檢查，以確認是否符合第 1(2)條所述之規範；

(44) 'transit' means movement from one third country to another third country passing under customs supervision through one of the territories listed in Annex I or from one of the territories listed in

(44)「過境」係指從一個第三國移動至另一個第三國，在採用海關監督後，經過附件Ⅰ所列領土之一；或由附件Ⅰ所列的其中一個領土經過第

Annex I to another territory listed in Annex I after passing through the territory of a third country, except in relation to the rules referred to in point (g) of Article 1(2), for which it means one of the following;	三國領土後至另一個亦列於附件Ⅰ的領土，但與第 1(2)條第(g)點所提及之規範有關者除外，其含義如下：
(a) movement from one third country to another third country, as defined in the first subparagraph of Article 1(3) of Regulation (EU) 2016/2031 passing under customs supervision through the 'Union territory', as defined in the second subparagraph of Article 1(3) of that Regulation; or	(a) (EU)2016/2031 號規章第 1(3)條第 1 款定義了從一個第三國移動至另一個第三國，於採用海關監督後經過「歐盟領域」，所謂「歐盟領域」一詞，則於該規章第 1(3)條第 2 款中定義之；或
(b) movement from the 'Union territory' to another part of the 'Union territory', as defined in the second subparagraph of Article 1(3) of Regulation (EU) 2016/2031, passing through the territory of a third country as defined in the first subparagraph of Article 1(3) of that Regulation;	(b) 自(EU) 2016/2031 規章第 1(3)條第 2 款定義之「歐盟領域」，經過該規章第 1(3)條第 1 款定義之第三國領域，移動至另一「歐盟領域」。
(45) 'supervision by the customs authorities' means customs supervision as defined in point (27) of Article 5 of Regulation (EU) No 952/2013 of the European Parliament and of the Council[50];	(45) 「海關權責機關之監督」係指歐洲議會和歐盟理事會(EU)952/2013 號規章第 5 條第(27)點中所定義的海關監督；
(46) 'control by the customs authorities' means customs controls as defined in point (3) of Article 5 of Regulation (EU) No 952/2013;	(46) 「海關權責機關之管制」係指(EU)952/2013 號規章第 5 條第(3)點中所定義的海關管制；
(47) 'official detention' means the procedure by which the competent authorities ensure that animals and goods subject to official controls are not moved or tampered with pending a decision on their destination; it includes storage by operators in accordance with the instructions and under the control of the competent authorities;	(47) 「官方扣押」係指權責機關憑以確保受官方管制的動物或貨物在他們的目的地作出決定的期間內不被移動或竄改的程序；此包括運營商按照權責機關指示以及在權責機關的管制下所作下儲存；
(48) 'journey log' means the document set out in points 1 to 5 of Annex II to Regulation (EC) No 1/2005;	(48) 「路程紀錄」係指(EC)1/2005 號規章附件 II 第 1 至 5 點所列之文件；
(49) 'official auxiliary' means a representative of the competent authorities trained in accordance with the requirements established under Article 18 and employed to perform certain official control tasks or certain tasks related to other official activities;	(49) 「官方助理員」係指一位由權責機關之代表，其業經依第 18 條所提及的要求進行培訓並用於執行某些官方管制任務或某些與其他官方活動有關之任務；
(50) 'meat and edible meat offal' means, for the purpose of point (a) of Article 49(2) of this Regulation, the products listed in sub-Chapters 0201 to 0208 of Chapter 2 of Section I of Part II of Annex I to Council Regulation (EEC) No 2658/87[51];	(50) 「肉及食用內臟」依本規章第 49(2)條第(a)點之目的而言，係指列於歐盟理事會第(EEC)2658/87 號規章附件 I 第 II 部分第 I 段第 2 章第 0201 至 0208 款中之產品；

50 Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p.1)./ 歐洲議會和歐盟理事會 2013 年 10 月 9 日(EU)952/2013 號規章制定了歐盟海關法。

51 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)./ 歐盟執委會 1987 年 7 月 23 日關於

(51) 'health mark' means a mark applied after the official controls referred to in points (a) and (c) of Article 18(2) have been performed and which attests that the meat is fit for human consumption.	(51) 「健康標誌」係指在執行完第 18(2)條第(a)和(c)點所述之官方管制並且證明該肉類適合人類食用後所使用的標誌。
TITLE II **OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES IN MEMBER STATES** *CHAPTER I* ***Competent authorities***	第 II 編 **會員國內的官方管制和其他官方活動** *第 I 章* ***權責機關***
Article 4 **Designation of competent authorities** 1. For each of the areas governed by the rules referred to in Article 1(2), Member States shall designate the competent authority or authorities on which they confer the responsibility to organise or perform official controls and other official activities. 2. Where, for the same area, a Member State confers the responsibility to organise or perform official controls or other official activities on more than one competent authority, at national, regional or local level, or where the competent authorities designated in accordance with paragraph 1 are allowed by that designation to transfer specific responsibilities for official controls or other official activities to other public authorities, the Member State shall: (a) ensure efficient and effective coordination between all authorities involved, and the consistency and effectiveness of official controls or other official activities across its territory; and (b) designate a single authority, in conformity with Member States' constitutional requirements, responsible for coordinating the cooperation and the contacts with the Commission and with other Member States in relation to the official controls and other official activities performed in each of the areas governed by the rules referred to in Article 1(2). 3. Competent authorities responsible for the verification of compliance with the rules referred to in point (i) of Article 1(2) may confer certain responsibilities related to official controls or other official activities to one or more organic control authorities. In such cases, they shall attribute a code number to each	*第 4 條* **權責機關的指定** 1. 對於受第 1(2)條所提及之規範管轄的的每個領域，各會員國應指定其授權以籌劃或執行官方管制及其他官方活動的權責機關。 2. 如果在同一領域，一個會員國授予一個以上的權責機關在國家、區域或地方層級籌劃或執行官方管制或其他官方活動之責任，或如果根據第 1 項所指定的權責機關基於該項指定而被允許將官方管制或其他官方活動的具體責任移轉給其他公家機關，則該會員國應： (a)確保所有機關間高效率和有效的協調，以及在其境內領土內所進行之官方管制或其他官方活動的一致性和有效性；以及 (b)以符合該會員國的憲法要求的方式指定一個單一的機關，以負責協調歐盟執委會和其他會員國間關於在第 1(2)條所述規範中所管理的每個領域中執行之官方管制和其他官方活動的合作與往來。 3. 負責查驗是否符合第 1(2)條第(i)點所提及之規範的權責機關可能將某些有關官方管制或其他官方活動的責任授予一個或多個有機管制機關。於此等情形時，該等權責機關應將代碼編號

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of them. 4. Member States shall ensure that the Commission is informed of the contact details and of any changes regarding: (a) the competent authorities designated in accordance with paragraph 1; (b) the single authorities designated in accordance with point (b) of paragraph 2; (c) the organic control authorities referred to in paragraph 3; (d) the delegated bodies referred to in Article 28(1). The information referred to in the first subparagraph shall also be made available by Member States to the public, including on the internet.	逐一分派給這些管制機關。 4. 會員國應確保向歐盟執委會通報聯繫細節和有關以下方面的任何變更： (a)根據第 1 項指派的權責機關； (b)根據第 2 項第(b)點指派的單獨機關； (c)第 3 項所述之有機管制機關； (d)第 28(1)條所述之受委託機構； 會員國應將在上開第一款提及的資訊讓公眾可以取得，其中包括置於網路上。
Article 5 **General obligations concerning the competent authorities and the organic control authorities** 1. The competent authorities and the organic control authorities shall: (a) have procedures and/or arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities; (b) have procedures and/or arrangements in place to ensure the impartiality, quality and consistency of official controls and other official activities at all levels; (c) have procedures and/or arrangements in place to ensure that staff performing official controls and other official activities are free from any conflict of interest; (d) have, or have access to, an adequate laboratory capacity for analysis, testing and diagnosis; (e) have, or have access to, a sufficient number of suitably qualified and experienced staff so that official controls and other official activities can be performed efficiently and effectively; (f) have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls and other official activities efficiently and effectively; (g) have the legal powers to perform official controls and other official activities and to take the action provided for in this Regulation and in the rules referred to in Article 1(2); (h) have legal procedures in place in order to ensure that staff have access to the premises of, and documents kept by, operators so as to be able to accomplish their tasks properly;	*第 5 條* **關於權責機關和有機管制機關的一般義務** 1. 權責機關和有機管制機關應： (a)訂有各種程序及/或安排以確保官方管制和其他官方活動的有效性和適當性； (b)訂有各種程序及/或安排以確保每個階段的官方管制和其他官方活動的公正性、品質和一致性； (c)訂有各種程序及/或安排以確保執行官方管制和其他官方活動的職員免於任何利益衝突； (d)擁有或有權獲得一個能勝任分析、測試和診斷的實驗室； (e)擁有或有權使用足夠數量的合格且經驗豐富的職員，以便能夠高效率和有效地執行官方管制及其他官方活動； (f)擁有適當和妥適維護的設施和設備，以確保其職員能夠和高效率和有效地執行官方管制及其他官方活動； (g)具有執行官方管制和其他官方活動，並採取本規章及第 1(2)條所述之規範中所規定的行動之合法權力； (h)訂有法律程序，以確保職員能夠進入運營商之廠址和取得運營商所保有之文件，以便能夠妥適地完成他們的任務；

(i) have contingency plans in place, and be prepared to operate such plans in the event of an emergency, where appropriate, in accordance with the rules referred to in Article 1(2).	(i)訂有應變計畫，於適當時，並準備在緊急情況下根據第 1(2)條所述之規範執行此等計畫。
2. Any appointment of an official veterinarian shall be in writing and shall set out the official controls and the other official activities and related tasks for which the appointment has been made. Requirements imposed on staff of competent authorities that are provided for in this Regulation, including the requirement on freedom from any conflict of interest, shall apply to all official veterinarians.	2. 任何官方獸醫的任用均應採取書面形式，並在任用時即應規定其官方管制和其他官方活動以及相關任務。本規章所規定對權責機關職員的要求，其中包括免於任何利益衝突的要求，應適用於所有官方獸醫。
3. Any appointment of an official plant health officer shall be in writing and shall set out the official controls and the other official activities and related tasks for which the appointment has been made. Requirements imposed on staff of competent authorities that are provided for in this Regulation, including the requirement on freedom from any conflict of interest, shall apply to all official plant health officers.	3. 任何官方植物健康官員的任用應採取書面形式，並於任用時即應規定其官方管制和其他官方活動以及相關任務。本規章所規定之對權責機關職員的要求，其中包括免於任何利益衝突的要求，適用於所有官方植物健康官員。
4. Staff performing official controls and other official activities shall:	4. 執行官方管制和其他官方活動之職員應該：
(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to perform official controls and other official activities in a consistent manner;	(a)接受在其職權領域內之適當的培訓，使他們能夠勝任地承辦他們的職責，並以一致的方式執行官方管制和其他官方活動；
(b) keep up-to-date in their area of competence and receive regular additional training as necessary; and	(b)保持在其職權領域內之知能的更新，並在必要時接受定期額外的培訓；以及
(c) receive training in the subject matters set out in Chapter I of Annex II and on the obligations of the competent authorities resulting from this Regulation, as appropriate. Competent authorities, organic control authorities and delegated bodies shall develop and implement training programmes for the purpose of ensuring that staff performing official controls and other official activities receive the training referred to in points (a), (b) and (c).	(c)接受附件 II 第 I 章所提及主題事項以及關於根據本規章所產生之權責機關適當的義務之培訓。權責機關、有機管制機關以及受委託機構應制定及實施培訓計畫，以確保其執行官方管制和其他官方活動之職員能接受第(a)、(b)和(c)點所提及的培訓。
5. When, within the services of a competent authority, more than one unit is competent to perform official controls or other official activities, efficient and effective coordination and cooperation shall be ensured between the different units.	5. 當在一權責機關的服務範圍內，不只一個單位有能力執行官方管制或其他官方活動時，應確保不同單位間能進行高效率且有效地協調與合作。
Article 6 **Audits of the competent authorities**	*第 6 條* **權責機關的稽核**
1. To ensure their compliance with this Regulation, the competent authorities shall carry out internal audits or have audits carried out on themselves and shall take appropriate measures in the light of	1. 為了確保符合本規章，權責機關應對其自身進行內部稽核或被執行稽核，並應根據稽核結果採取適當措施。

the results of those audits. 2. The audits referred to in paragraph 1 shall be subject to independent scrutiny and carried out in a transparent manner.	2. 在第 1 項所述的稽核應受到獨立審查監督，並以透明的方式進行。
Article 7 **Right of appeal** The decisions taken by the competent authorities in accordance with Article 55, Article 66(3) and (6), Article 67, point (b) of Article 137(3), and Article 138(1) and (2), concerning natural or legal persons shall be subject to such persons' right of appeal in accordance with national law. The right of appeal shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal or plant health, to animal welfare or, as regards GMOs and plant protection products, also to the environment, in accordance with this Regulation and with the rules referred to in Article 1(2).	*第 7 條* **上訴權** 權責機關根據第 55 條、第 66(3)和(6)條、第 67 條、第 137(3)條第(b)點以及第 138(1)和(2)條所做出之決定，與自然人或法人有關者，應根據國家法律規定受到此等人之上訴權的制約。 根據本規章和第 1(2)條所提及之規範，上訴權不應影響權責機關採取迅速行動以消除或遏止，對人類、動物或植物健康、動物福祉或關於基因改造有生物以及植物保護產品，以及對環境風險的義務。
Article 8 **Confidentiality obligations of the competent authorities** 1. Competent authorities shall ensure that, subject to paragraph 3, information acquired when performing their duties in the context of official controls and other official activities is not disclosed to third parties where, under national or Union legislation, that information is, by its nature, covered by professional secrecy. For that purpose, Member States shall ensure that appropriate confidentiality obligations are established for staff and other individuals employed during official controls and other official activities. 2. Paragraph 1 shall also apply to organic control authorities, delegated bodies and natural persons to which specific official control tasks have been delegated and to official laboratories. 3. Unless there is an overriding public interest in the disclosure of information covered by professional secrecy as referred to in paragraph 1, and without prejudice to situations where disclosure is required by Union or national legislation, such information shall include information whose disclosure would undermine: (a) the purpose of inspections, investigations or audits;	*第 8 條* **權責機關的保密義務** 1. 權責機關應確保在第 3 項的規定下，於執行官方管制和其他官方活動之過程中所獲得的資訊，而該資訊在其國家或歐盟法令下，其本質屬專業保密涵蓋之範疇者，不會向第三方揭露。 為達成此目的，會員國應確保對(權責機關之)職員及其他在官方管制或其他官方活期間雇用之個人制定適當的保密義務。 2. 第 1 項亦應適用於有機管制機關、已被委任執行特定官方管制任務的、受委託機構和自然人，以及官方實驗室。 3. 除非有基於公共利益為先而須將第 1 項所述之專業保密所涵蓋範圍之資訊作揭露，並且對歐盟或國家法令要求揭露的情況並不造成妨礙，此類資訊應包括其揭露將造成損害的資訊： (a)檢查、調查或稽核的目的； (b)運營商或任何其他自然人或法人的商業利益之

(b) the protection of commercial interests of an operator or any other natural or legal person; or (c) the protection of court proceedings and legal advice. 4. The competent authorities, when determining whether there is an overriding public interest in the disclosure of information covered by professional secrecy as referred to in paragraph 1, shall take into account inter alia the possible risks to human, animal or plant health, or to the environment, and the nature, severity and extent of such risks. 5. The confidentiality obligations provided for in this Article shall not prevent the competent authorities from publishing or making otherwise available to the public information about the outcome of official controls regarding individual operators, provided, without prejudice to situations where disclosure is required by Union or national legislation, that the following conditions are met: (a) the operator concerned is given the opportunity to comment on the information that the competent authority intends to publish or make otherwise available to the public, prior to its publication or release, taking into account the urgency of the situation; and (b) the information which is published or made otherwise available to the public takes into account the comments expressed by the operator concerned or is published or released together with such comments.	保護；或 (c)法庭訴訟和法律諮詢之保護。 4. 權責機關在決定是否有基於公共利益為先而須將第一項所提及之專業保密所涵蓋範圍之資訊作揭露，尤應考慮到對人類、動物或植物健康或對環境可能造成的風險，以及此些風險的本質、嚴重程度及範圍。 5. 在不妨礙歐盟或國家法令要求揭露的情況下，若滿足以下條件，本條規定的保密義務不得妨礙權責機關公布或以其他方式向公眾提供有關個別運營商的官方管制結果資訊： (a)所涉的運營商能夠被給予機會，衡量情況的急迫性，對權責機關準備公布或以其他方式向公眾提供的資訊發表評論；以及 (b)向所公布或以其他方式向公眾提供的資訊應考量所涉運營商表達的意見，或與此等意見一起公布或發佈。
CHAPTER II **Official controls** Section I **General requirements**	*第 II 章* **官方管制** 第 1 部分 **一般要求**
Article 9 **General rules on official controls** 1. Competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency, taking account of: (a) identified risks associated with: (i) animals and goods; (ii) the activities under the control of operators;	*第 9 條* **官方管制的一般規範** 1. 權責機關應在一風險基礎上，以適當的頻率定期對所有運營商進行官方管制，並考慮到下列事項： (a)鑑定與之相關的風險： (i)動物及貨物； (ii)在運營商管控下的活動； (iii)運營商之活動或運營地點；

(iii) the location of the activities or operations of operators;

(iv) the use of products, processes, materials or substances that may influence food safety, integrity and wholesomeness, or feed safety, animal health or animal welfare, plant health or, in the case of GMOs and plant protection products, that may also have an adverse impact on the environment;

(b) any information indicating the likelihood that consumers might be misled, in particular as to the nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production of food;

(c) operators' past record as regards the outcome of official controls performed on them and their compliance with the s referred to in Article 1(2);

(d) the reliability and results of own controls that have been performed by the operators, or by a third party at their request, including, where appropriate, private quality assurance schemes, for the purpose of ascertaining compliance with the rules referred to in Article 1(2); and

(e) any information that might indicate non-compliance with the rules referred to in Article 1(2).

2. Competent authorities shall perform official controls regularly, with appropriate frequencies determined on a risk basis, to identify possible intentional violations of the rules referred to in Article 1(2), perpetrated through fraudulent or deceptive practices, and taking into account information regarding such violations shared through the mechanisms of administrative assistance provided for in Articles 102 to 108 and any other information pointing to the possibility of such violations.

3. Official controls that are performed prior to the placing on the market, or the movement of certain animals and goods in view of the issuance of the official certificates or official attestations required by the rules referred to in Article 1(2), as a condition for the placing on the market or the movement of the animals or goods shall be performed in accordance with both of the following:

(a) the rules referred to in Article 1(2);

(b) the applicable delegated and implementing acts adopted by the Commission in accordance with Articles 18 to 27.

4. Official controls shall be performed without prior notice, except where such notice is necessary and

(iv)可能影響到食品的安全、完整性及健康價值；或飼料安全性、動物的健康或福祉、植物健康；或可能對環境有負面影響的基因改造生物和植物保護產品等方面之產品、流程、材料或物質的使用。

(b)任何指出消費者可能被誤導的資訊，特別是關於本質、身分、性質、成分、數量、耐用性、原產地或出處、食品之製造或食物生產方法；

(c)運營商關於其接受官方管制之結果以及對第1(2)條之符合性的過往紀錄

(d)運營商自己，或第三方應運營商的要求，其中，適當時包括應私人品質保證計畫之需，為確認是否符合第 1(2)條所提及之規範所執行自主管制的可靠性和結果；以及

(e)任何可能指出對第 1(2)條所提及之規範不符合的資訊。

2. 權責機關應該在一風險基礎下以適當的頻率定期執行官方管制，以分辨是否有蓄意違反第1(2)條所提及之規範的可能(例如以詐欺的手法)，並考慮到由第102~108條中行政協助機制所分享的有關這種違規的資訊和其他任何可能導致這種違規的資訊。

3. 有鑑於第1(2)條所提及之規範所要求的官方證書或官方證明之核發而對上市前的特定動物和貨物之移動前所執行之官方管制，以作為上市或動物貨物移動之一個要件，需依以下兩點執行:

(a)第1(2)條所提及的規範；

(b)歐盟執委會根據第18至27條採用之適用的授權法規和施行細則。

4. 官方管制應該在無事前通知下執行，除非此種事

duly justified for the official control to be carried out. As regards official controls upon request from the operator, the competent authority may decide whether the official controls are to be performed with or without prior notice. Official controls with prior notice shall not preclude official controls without prior notice.	前通知對官方管制是必要且有合理佐證。至於應運營商之要求所執行的官方管制，權責機關可決定執行官方管制前是否要通知。有事前通知的官方管制不可排除不作事前通知的官方管制。
5. Official controls shall be performed as much as possible in such a manner that the administrative burden and operational disruption for operators are kept to the minimum necessary, but without this negatively affecting the effectiveness of those controls.	5. 官方管制應儘可能在使運營商的行政負擔和運營中斷維持在最小必須的情況下執行，但若沒有運營商如此配合將對這些管制的有效性造成負面影響。
6. Competent authorities shall perform official controls in the same manner, while taking account of the need to adapt the controls to the specific situations, irrespective of whether the animals and goods concerned are: (a) available on the Union market, whether originating in the Member State where the official controls are performed or in another Member State; (b) to be exported from the Union; or (c) entering the Union.	6. 權責機關應用相同方式執行官方管制，同時考慮到適應特定情況之管制的需求，而不管所涉之動物和貨物是否為以下情形: (a)可在歐盟市場中獲得，不管是否源自執行官方管制的會員國或其他會員國； (b)將從歐盟中出口；或 (c)進入歐盟。
7. To the extent strictly necessary for the organisation of the official controls, Member States of destination may require operators that have animals or goods delivered to them from another Member State to report the arrival of such animals or goods.	7. 為了官方管制的籌劃達到所必要的嚴格程度，目的地的會員國可要求從另一個會員國運送動物或產品的運營商報告該等動物或貨物的抵達時間
Article 10 **Operators, processes and activities subject to official controls** 1. To the extent necessary to ascertain compliance with the rules referred to in Article 1(2), competent authorities shall perform official controls on: (a) animals and goods at any stage of production, processing, distribution and use; (b) substances, materials or other objects which may influence the characteristics or health of animals and goods and their compliance with applicable requirements, at any stage of production, processing, distribution and use; (c) operators as regards activities, including the keeping of animals, equipment, means of transport, premises and other places under their control and their surroundings and on related documentation.	*第 10 條* **須受到官方管制的運營商、流程和活動** 1. 為確認對第 1(2)條所提及規範的符合性至必要的程度，權責機關應就以下事項進行官方管制： (a)在生產、加工、分銷及使用之任何階段的動物和貨物； (b)在生產、加工、分銷及使用之任何階段可能影響動物和貨物的特性或健康以及他們對適用要求之符合性的物質、材料或其他物體； (c)關於各種活動的運營商，該等活動其中包括其動物、設備、運輸工具、運營場所與其他在他們管制下的地方及他們的環境之維護，以及保存在相關文件之上。

2. Without prejudice to the rules concerning existing lists or registers established on the basis of the rules referred to in Article 1(2), the competent authorities shall draw up and keep up-to-date a list of operators. Where such a list or register already exists for other purposes, it may also be used for the purposes of this Regulation. 3. The Commission shall adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the setting out of categories of operators to be exempted from the list of operators referred to in paragraph 2 of this Article where their inclusion in such a list would constitute a disproportionate administrative burden for them compared to the risk related to their activities.	2. 在對以第 1(2)條所提及之規範為基準所建立之現有的(運營商)名單或登錄沒有影響的狀況下，權責機關應建立且持續更新運營商名單。在此一名單或登錄已有為其他目的而存在的情況時，它也可用於本規章之目的中。 3. 歐盟執委會應依據第 144 條應採用授權法規以修訂本規章中關於列出從本條第 2 項中所提及的運營商名單中予以免除之運營商類別，因為將他們列在這個名單中會對他們造成與他們的活動相關的風險相較之下不相稱的行政負擔。
Article 11 **Transparency of official controls** 1. Competent authorities shall perform official controls with a high level of transparency and shall, at least once a year, make available to the public, including through publication on the internet, relevant information concerning the organisation and the performance of official controls. They shall also ensure the regular and timely publication of information on the following: (a) the type, number and outcome of official controls; (b) the type and number of cases of non-compliance detected; (c) the type and number of cases where measures were taken by the competent authorities in accordance with Article 138; and (d) the type and number of cases where the penalties referred to in Article 139 were imposed. The information referred to in points (a) to (d) of the second subparagraph of this paragraph may be provided, where appropriate, through the publication of the annual report referred to in Article 113(1). 2. Competent authorities shall establish procedures to ensure that any inaccuracies in the information made available to the public are appropriately rectified. 3. Competent authorities may publish, or make otherwise available to the public, information about the rating of individual operators based on the outcome of one or more official controls, provided that the following conditions are met: (a) the rating criteria are objective, transparent and publicly available; and	*第 11 條* **官方管制的透明性** 1. 權責機關應以高透明度之標準來執行官方管制，且應至少一年一次向大眾公開發表，其中包括透過網路公布關於籌劃和執行官方管制的相關資訊。 其亦應確保定期並及時公布下列資訊： (a)官方管制的類型、數量和結果； (b)所發現的不符合的案件之類型和數量； (c)權責機關根據第 138 條採取措施的案件之類型和數量；以及 (d)被施以第 139 條中所提及的處罰之的類型和數量； 本項第 2 款(a)至(d)點所提及之資訊，適當時，可藉由第 113(1)條所提及的年度報告提供。 2. 權責機關應建立程序以確保大眾可獲得的資訊中之不正確處都已適當的修正。 3. 若符合下列條件，權責機關可發佈，或以其他方式向大眾提供基於一個或多個官方管制的結果對個別運營商所作的評級資訊: (a)評級標準是客觀、透明且可對大眾公開的；及 (b)有適當的安排以確保評級過程之公平性、一致性及透明性。

(b) appropriate arrangements are in place to ensure the fairness, consistency and transparency of the rating process.	
Article 12 **Documented control procedures** 1. Competent authorities shall perform official controls in accordance with documented procedures. Those procedures shall cover the subject areas for control procedures set out in Chapter II of Annex II and shall contain instructions for staff performing official controls. 2. Competent authorities shall have control verification procedures in place. 3. Competent authorities shall: (a) take corrective actions in all cases where the procedures provided for in paragraph 2 identify shortcomings; and (b) update the documented procedures provided for in paragraph 1 as appropriate. 4. Paragraphs 1, 2 and 3 shall also apply to delegated bodies and organic control authorities.	*第 12 條* **書面的管制程序** 1. 權責機關應按照書面程序執行官方管制。 這些程序應涵蓋附件 2 第 2 章所列管制程序的主題領域，並應載有執行官方管制的職員的指導說明。 2. 權責機關應有(官方)管制之查驗程序。 3. 權責機關應： (a)在所有依第 2 項所示的程序確定為缺點時採取矯正行動;以及 (b)妥為更新第 1 項所示的書面程序。 4. 第 1、第 2 及第 3 項也適用於受委任機構和有機管制機關。
Article 13 **Written records of official controls** 1. Competent authorities shall draw up written records of every official control that they perform. Those records may be on paper or in electronic form. Those records shall contain: (a) a description of the purpose of the official controls; (b) the control methods applied; (c) the outcome of the official controls; and (d) where appropriate, action that the competent authorities require the operator concerned to take as a result of their official controls. 2. Unless the purposes of judicial investigations or the protection of court proceedings require otherwise, the operators subject to an official control shall be provided upon request with a copy of the records provided for in paragraph 1, except where an official certificate or official attestation has been issued. The operator shall be promptly informed in writing by the competent authorities of any	*第 13 條* **官方管制的書面紀錄** 1. 權責機關應為他們所執行的每個官方管制作成書面記錄。該等紀錄可為書面或電子檔。 該等紀錄應要包括: (a)官方管制目的之描述； (b)所用的管制方法； (c)官方管制的結果；以及 (d)適當時，權責機關要求所涉運營商所採取之措施，以及作為他們的官方管制之結果。 2. 除非對司法調查或法院訴訟之保護的目的另有要求，且除官方證書或官方證明已經核發之情形外，否則於受官方管制的運營商有所請求時，運營商應被提供 1 份第 1 項所述紀錄影本。權責機關應立即以書面通知運營商有關任何經官方管

case of non-compliance identified through the official controls. 3. Where official controls require the continuous or regular presence of staff or representatives of the competent authorities on the operator's premises, the records provided for in paragraph 1 shall be produced with a frequency that enables the competent authorities and the operator to be: (a) regularly informed of the level of compliance; and (b) promptly informed of any case of non-compliance identified through the official controls. 4. Paragraphs 1, 2 and 3 shall also apply to delegated bodies, organic control authorities and natural persons to which certain official control tasks have been delegated.	制後被認定為不符合的案件。 3. 當官方管制要求權責機關之職員或代表持續或定期親臨在運營商的運營場所時，則第 1 項所述的紀錄的製作頻率應使權責機關和運營商能夠： (a)被定期通知符合規的程度；以及 (b)被立即通知任何經官方管制後被認定為不符合的案件。 4. 上開第 1、2 及 3 項亦適用於受委任機構、有機管制機關及被委任某些官方管制任務的自然人。
Article 14 **Methods and techniques for official controls** Official control methods and techniques shall include the following as appropriate: (a) an examination of the controls that operators have put in place and of the results obtained; (b) an inspection of: (i) equipment, means of transport, premises and other places under their control and their surroundings; (ii) animals and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals; (iii) cleaning and maintenance products and processes; (iv) traceability, labelling, presentation, advertising and relevant packaging materials including materials intended to come into contact with food; (c) controls on the hygiene conditions in the operators' premises; (d) an assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices, and of procedures based on the principles of hazard analysis critical control points (HACCP); (e) an examination of documents, traceability records and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2), including, where appropriate,	*第 14 條* **官方管制的方法與技術** 官方管制方法和技術應妥為包括以下各項： (a)檢查運營商已實施的管制和所獲得的結果； (b)(對下列事項)檢查： （i）設備、運輸工具、運營場所和其他在他們管制下的地方以及他們的周遭環境的地點； （ii）動物和貨物，其中包括半成品、原料、成分、加工輔助劑以及其他用來準備和生產貨物或餵食和治療動物的產品； （iii）清潔和維護產品及程序； （iv）可追溯性、標示、說明、廣告和相關的包裝材料，其中包括可能會接觸到食品的材料； (c)管制運營商處的衛生條件之管控； (d)對良好生產作業、良好衛生作業及良好畜養作業和程序，以及根據危害分析重點管制點系統(HACCP)原則所提及之程序所作之評鑑 (e)對可能與評估是否符合第 1(2)條所提及之規範有關的文件，可追溯性紀錄和其他紀錄之檢查，其中適當時，包括隨附於食品、飼料和任何進入或離開廠場之物質或材料的文件； (f)與運營商和其職員的面談； (g)對運營商所執行的量測和其他測試結果之查驗； (h)取樣、分析、診斷及測試； (i)運營商之稽核；

documents accompanying food, feed and any substance or material entering or leaving an establishment; (f) interviews with operators and with their staff; (g) the verification of measurements taken by the operator and other test results; (h) sampling, analysis, diagnosis and tests; (i) audits of operators; (j) any other activity required to identify cases of non-compliance.	(j)為識別不符合案件所需的任何其他活動。
Article 15 **Obligations of operators** 1. To the extent that this is necessary for the performance of official controls or of other official activities, operators shall, where required by the competent authorities, give staff of the competent authorities access to: (a) the equipment, means of transport, premises and other places under their control and their surroundings; (b) their computerised information management systems; (c) the animals and goods under their control; (d) their documents and any other relevant information. 2. During official controls and other official activities, operators shall assist and cooperate with the staff of the competent authorities and organic control authorities in the accomplishment of their tasks. 3. The operator responsible for a consignment entering the Union shall, in addition to the obligations set out in paragraphs 1 and 2, make available, on paper or in electronic form, and without delay, all information concerning the animals and goods. 4. The Commission may, by means of implementing acts, lay down rules on the cooperation and exchange of information between operators and competent authorities related to the arrival and unloading of the animals and goods referred to in Article 47(1) where it is necessary to ensure their complete identification and the efficient performance of official controls on such animals and goods. Those implementing acts shall be adopted in accordance with the examination procedure referred to	*第 15 條* **運營商之義務** 1. 為官方管制或其他官方活動之執行達到所需之程度，經權責機關要求時，運營商應向權責機關的職員提供以下進入(或使用)之權利： (a)設備、運輸工具、運營場所和其他在他們管制下的地方以及他們的周遭環境； (b)他們的電腦化的資訊管理系統； (c)在他們的管制下之動物和貨物； (d)他們的文件和其他相關資訊。 2. 在官方管制和其他官方活動期間，運營商應幫助並與權責機關以及有機管制機關的職員合作以完成其工作。 3. 除了第 1 及第 2 項所述規定的義務外，負責將託運務(貨物)輸入歐盟的貨物運營商，還應以書面或電子形式，及時提供有關動物和貨物的所有資訊。 4. 歐盟執委會可透過施行細則，制訂關於運營商和權責機關之間在第 47(1)條所提及之動物和貨物的到達和卸載方面之合作和資訊交流之規範，該等規範必須確保對此類動物及貨物的完全識別和官方管制的有效率執行。上開施行細則應按照第 145(2)條所提及之審查程序予以採用。

in Article 145(2). 5. For the purpose of Article 10(2) and subject to Article 10(3), operators shall provide the competent authorities with at least the following updated details: (a) their name and legal form; and (b) the specific activities they carry out, including activities undertaken by means of distance communication, and the places under their control. 6. The obligations of operators set out in this Article shall also apply in cases where official controls and other official activities are performed by official veterinarians, official plant health officers, delegated bodies, control authorities and natural persons to which certain official control tasks or certain tasks related to other official activities have been delegated.	5. 為了第 10(2)條的目的，並在符合第 10(3)條規定下，運營商應至少提供權責機關以下更新的細節： (a)他們名稱及法定的表格；以及 (b)他們執行的特定活動，其中包括透過遠距通訊的活動，以及在他們管制之下的地點 6. 本條中所訂之運營商的義務也應適用在由官方獸醫、官方植物健康官員、受委託機構、管制機關、以及執行的被委任某些官方管制任務或某些與官方活動相關的任務之自然人所執行之官方管制及其他官方活動。
Section II **Additional requirements for official controls and other official activities in certain areas**	第 2 部分 **某些領域的官方管制和其他官方活動的額外要求**
Article 16 **Additional requirements** 1. In the areas governed by the rules provided for in this Section, those rules shall apply in addition to the other rules set out in this Regulation. 2. When adopting delegated acts and implementing acts provided for in this Section, the Commission shall take into account the following: (a)the experience gained by competent authorities and food and feed business operators when applying the procedures referred to in Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council[52] and Article 6 of Regulation (EC) No 183/2005 of the European Parliament and of the Council[53]; (b) scientific and technological developments;	*第 16 條* **額外要求** 1. 於本部分所述之規範所管理領域範圍內，該等規範及本規章所提及之其他規範均適用。 2. 當採用本部分所述的授權法規於依本節規定採用授權法規和施行細則時，歐盟執委會應考慮到以下情形： (a)於權責機關以及食品與飼料運營商執行歐洲議會和歐盟理事會(EC)852/2004 號規章之第 5 條和(EC)183/2005 號規章中第 6 條所提及的程序時所獲得的經驗； (b)科學和科技的發展； (c)消費者對食物組成和消費模式變化的期望； (d)對和動物及貨物相關的人類與動物健康及植物

52 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)./ 歐洲議會及歐盟理事會 2004 年 4 月 29 日第(EC)852/2004 規章關於食品的衛生。

53 Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p.1)./ 歐洲議會及歐盟理事會在 2005 年 1 月 12 日第(EC)183/2005 規章制定了對飼料衛生的要求。

(c) consumer expectations with regard to food composition and changes in patterns of consumption of food; (d) risks to human and animal health and plant health associated with animals and goods; and (e) information on possible intentional violations perpetrated through fraudulent or deceptive practices. 3. When adopting delegated acts and implementing acts provided for in this Section, and insofar as this does not prevent the achievement of the objectives pursued by the rules referred to in Article 1(2), the Commission shall also take into account the following: (a) the need to facilitate the application of the delegated acts and implementing acts, taking into account the nature and the size of small businesses; (b) the need to enable the continued use of traditional methods at any stage of production, processing or distribution of food, and the production of traditional foods; and (c) the needs of operators situated in regions that are subject to specific geographical constraints.	健康的風險；以及 (e)關於經由欺詐或欺騙行為之可能的故意犯罪的資訊。 3. 於採用本部分所述的授權法規和施行細則時，且如果這不妨礙第 1(2)條條所提及之規範所追求的目標之實現，歐盟執委會還應考慮到以下因素： (a)促進授權法規和施行細則之應用的需求，並考慮到小企業的本質和規模； (b)使在生產、加工或分銷以及傳統食品之生產的任何階段能繼續使用的傳統方法之需求；和 (c)位於受特定地理限制的地區之運營商的需求。
Article 17 **Specific definitions** For the purpose of Article 18: (a) 'under the responsibility of the official veterinarian' means that the official veterinarian assigns the performance of an action to an official auxiliary; (b) 'under the supervision of the official veterinarian' means that an action is performed by an official auxiliary under the responsibility of the official veterinarian and the official veterinarian is present on the premises during the time necessary to perform that action; (c) 'ante-mortem inspection' means the verification, prior to slaughtering activities, of human and animal health and animal welfare requirements, including, where appropriate, the clinical examination of each individual animal, and the verification of the food chain information as referred to in Section III of Annex II to Regulation (EC) No 853/2004; (d) 'post-mortem inspection' means the verification in the slaughterhouse or game-handling establishment of compliance with requirements applicable to: (i) carcases as defined in point 1.9 of Annex I to Regulation (EC) No 853/2004 and offal as defined in	*第 17 條* **特別定義** 以下之定義將用於第 18 條： (a)「在官方獸醫之職責監督之下」意指官方獸醫分配某一行動給官方助理員。 (b)「在官方獸醫的監督下」意指某行動是由在官方獸醫之職責監督下的官方助理員所執行，且在執行該行動所需的時官方獸醫是在場(運營商處所)的； (c)「屠前檢查」意指在屠宰前對人和動物健康以及動物福祉之要求的查驗，其中，適當時，包括在(EC) 853/2004 號規章附件二的第三部分中所提到的對每隻動物進行的臨床檢查和食物鏈資訊的查驗； (d)「屠後檢查」意指就屠宰場或獵物處理廠場對以下事項所適用要求之符合性的查驗： (i) 在(EC) 853/2004 號規章附件一第 1.9 點中定義之屠宰後的動物軀體和該附件第 1.11 點中定義的內臟，以決定該肉品是否適合人

point 1.11 of that Annex, for the purpose of deciding if the meat is fit for human consumption, (ii) safe removal of specified risk material, and (iii) the health and welfare of the animals.	類食用， （ii）特定風險物質之安全去除，以及 （iii）動物的健康與福祉。
Article 18 **Specific rules on official controls and for action taken by the competent authorities in relation to the production of products of animal origin intended for human consumption** 1. Official controls performed to verify compliance with the rules referred to in Article 1(2) of this Regulation in relation to products of animal origin intended for human consumption shall include the verification of compliance with the requirements laid down in Regulations (EC) No 852/2004, (EC) No 853/2004, (EC) No 1069/2009 and (EC) No 1099/2009 as applicable. 2. The official controls referred to in paragraph 1 performed in relation to the production of meat shall include: (a) the ante-mortem inspection performed in the slaughterhouse by an official veterinarian who may, as regards pre-selection of animals, be assisted by official auxiliaries trained for that purpose; (b) by way of derogation from point (a), as regards poultry and lagomorphs, the ante-mortem inspection performed by an official veterinarian, under the supervision of the official veterinarian or, where sufficient guarantees are in place, under the responsibility of the official veterinarian; (c) the post-mortem inspection performed by an official veterinarian, under the supervision of the official veterinarian or, where sufficient guarantees are in place, under the responsibility of the official veterinarian; (d) the other official controls performed in slaughterhouses, cutting plants and game-handling establishments, by an official veterinarian, under the supervision of the official veterinarian or, where sufficient guarantees are in place, under the responsibility of the official veterinarian, to verify compliance with the requirements applicable to: (i) the hygiene of meat production; (ii) the presence of residues of veterinary medicinal products and contaminants in products of animal origin intended for human consumption;	*第 18 條* **關於官方管制和權責機關就生產供人類消費的動物源產品所採取行動之具體規範** 1. 為查驗是否符合本規章第 1(2)條中與供人類可消費的動物源產品有關的規範而進行的官方管制，應包括對(EC) 852/2004 號、(EC) 853/2004 號、(EC) 1069/2009 號和(EC)1099/2009 號等規章所明訂要求之適用部分的符合性之查驗。 2. 第 1 項中所提及之用以執行與生產肉品生產相關的官方管制，應包括： (a)由官方獸醫於屠宰場執行的屠前檢查，其對於動物的預先選擇之作業，可以由為該目的而培訓的官方助理員協助； (b)作為第(a)點規定的例外，關於禽類和兔類動物，“由官方獸醫”“在官方獸醫的監督下”，或於有充分保證的情況時，在官方獸醫之職責(監督)之下所執行之屠前檢查； (c)由官方獸醫在官方獸醫監督下，或於有充分保證的情況時，在官方獸醫之職責(監督)之下所執行之屠前檢查。 (d)在屠宰場、分切場和獵物處理廠場，由官方獸醫在官方獸醫監督下或於有充分保證之情況時，在官方獸醫之職責(監督)之下所執行的其他官方管制，以查驗以下事項所適用要求之符合性： （i）肉品生產的衛生； （ii）用於人類消費的動物源性產品中動物用藥殘留物和污染物的存在； （iii）根據危害分析重點管制點系統（HACCP）原則對良好衛生作業和程序所作之稽核； （iv）用以偵測人畜共通傳染病源和動物疾病的存在以及查驗是否符合歐盟執委會

(iii) audits of good hygiene practices and procedures based on HACCP principles;

(iv) laboratory tests to detect the presence of zoonotic agents and animal diseases and to verify compliance with the microbiological criterion as defined in point (b) of Article 2 of Commission Regulation (EC) No 2073/2005[54];

(v) the handling and disposal of animal by-products and of specified risk material;

(vi) the health and welfare of the animals.

(EC)2073/2005 號規章第 2 條(b)點中所定義之微生物標準的實驗室；

(v) 動物副產品及特定風險材料之處理和處置；

(vi) 動物的健康及福祉。

3. The competent authority may, on the basis of a risk analysis, allow slaughterhouse staff to assist in the performance of tasks relating to the official controls referred to in paragraph 2 in establishments slaughtering poultry or lagomorphs, or, in establishments slaughtering animals of other species, to carry out specific sampling and testing tasks relating to such controls, on condition that staff:

(a) act independently from the production staff of the slaughterhouse;

(b) have undergone appropriate training to carry out these tasks; and

(c) carry out these tasks in the presence and following the instructions of the official veterinarian or of the official auxiliary.

3. 權責機關可根據風險分析，允許屠宰場員工協助執行第 2 項所提及的官方管制任務，在屠宰禽類或兔類動物的廠場，或在屠宰其他物種動物之廠場中，執行與此類管制有關的具體取樣和測試任務，只要該等員工符合下列條件：

(a)扮演與屠宰場的生產員工獨立的角色；

(b)經歷過適當的訓練以執行此等任務；以及

(c)在官方獸醫及官方輔助人員在場時執行此等任務並遵守他們的指示。

4. Where the official controls referred to in points (a) and (c) of paragraph 2 have not identified any shortcoming that would make the meat unfit for human consumption, the health mark shall be applied to domestic ungulates, farmed game mammals other than lagomorphs, and large wild game, by the official veterinarian, under the supervision of the official veterinarian, under the responsibility of the official veterinarian, or, in compliance with the conditions laid down in paragraph 3, by the slaughterhouse staff.

4. 若第 2 項之(a)和(c)點中提到的官方管制中沒有發現使肉類不適合人類食用的任何缺點，則健康商標誌應”由官方獸醫”、”在其監督下”、”在官方獸醫的職責(監督)之下”、或”符合第 3 項所明訂之條件下”，由屠宰場員工標貼於家畜、除兔類動物外的飼養供獵用哺乳類、以及供獵用之大型野生動物。

5. The official veterinarian shall remain responsible for the decisions taken following official controls provided for in paragraphs 2 and 4, even if the performance of an action is assigned by him or her to the official auxiliary.

5. 官方獸醫應對第 2 和第 4 項所規定的官方管制後作出的決定負責，即使該次行動係由其指示給官方輔助人員。

54 Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p.1)./ 歐盟執委會 2005 年 11 月 15 日(EC)2073/2005 號規章，係關於食品的微生物標準。

6. ►M3 For the purpose of the official controls referred to in paragraph 1 performed in relation to live bivalve molluscs, echinoderms, tunicates and marine gastropods, the competent authorities shall classify production and relaying areas. ◄M3

7. The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning specific rules for the performance of the official controls referred to in paragraphs 2 to 6 of this Article on:

(a) criteria and conditions to determine, by way of derogation from point (a) of paragraph 2, when the ante-mortem inspection in certain slaughterhouses may be performed under the supervision or under the responsibility of an official veterinarian, provided that the derogations do not affect the achievement of the objectives of this Regulation;

(b) criteria and conditions to determine, as regards poultry and lagomorphs, when sufficient guarantees are met for the official controls to be performed under the responsibility of an official veterinarian in regard to the ante-mortem inspections referred to in point (b) of paragraph 2;

(c) criteria and conditions to determine, by way of derogation from point (a) of paragraph 2, when the ante-mortem inspection may be performed outside the slaughterhouse in case of emergency slaughter;

(d) criteria and conditions to determine, by way of derogation from points (a) and (b) of paragraph 2, when the ante-mortem inspection may be performed at the holding of provenance;

(e) criteria and conditions to determine when sufficient guarantees are met for the official controls to be performed under the responsibility of an official veterinarian with regard to the post-mortem inspection and auditing activities referred to in points (c) and (d) of paragraph 2;

(f) criteria and conditions to determine, by way of derogation from point (c) of paragraph 2, when, in case of emergency slaughter, the post-mortem inspection is to be performed by the official veterinarian;

(g) ►M3 criteria and conditions to determine, by way of derogation from paragraph 6, when production and relaying areas are not to be classified in relation to:

(i) Pectinidae; and

(II) where they are not filter feeders; echinoderms and marine gastropods; ◄M3

6. 為了達到第 1 項所提及與活雙枚貝類、棘皮動物、被囊動物和海洋腹足類動物有關之官方管制目的，權責機關應將生產和轉運的區域加以分類。

7. 歐盟執委會應根據第 144 條採納授權法規，以補充本規章關於執行本條第 2 至 6 節所提及之官方管制有關以下事項的具體規範：

(a)用以決定何時於某些屠宰場的屠前檢查可”在官方獸醫的監督下”或”由官方獸醫之職責(監督)下”執行之標準和條件以作為第 2 項第(a)點規定之例外，若該等例外情況不會影響本規章目標之達成；

(b)關於禽類和兔類動物，用以決定何時已具備充分保證之標準和條件，以利於第 2 項(b)點中所提及關於屠前檢查事宜可“在官方獸醫職責(監督)下”執行其官方管制；

(c)於緊急屠宰時之情況，用以決定何時屠前檢查可在屠宰場外執行之標準和條件，以作為第 2 項(a)點規定之例外；

(d)用以決定何時可在原產地執行屠前檢查之標準和條件，以作為第 2 項(a)點規定之例外；

(e)用以決定何時已具備充分保證之標準和條件，以利於第 2 項(c)和(d)點所提及關於屠後檢查和稽核活動事宜，可 “在官方獸醫之職責(監督)下”執行其官方管制措施;

(f)於緊急屠宰之情況時，用以決定何時由官方獸醫執行屠後檢查之檢查標準和條件，以作為第 2 項(c)點規定之例外；

(g)作為第 6 項規定之例外，決定何時生產及轉運的區域不須加以分類為下列標準和條件:

(i) 扇貝類；和

(ii)非濾食性的動物；棘皮動物和海洋腹足類；

(h)關於馴鹿、柳雷鳥、岩雷鳥的特定例外，以延續長期以來當地及傳統的習俗與做法，若此等例外情況不會影響此規章目標之達成；

(i)用以決定何時在切肉場的官方管制可由權責機

(h) specific derogations in respect to Rangifer tarandus tarandus, Lagopus lagopus and Lagopus mutus, in order to allow the continuation of longstanding local and traditional customs and practices, provided that the derogations do not affect the achievement of the objectives of this Regulation;

(i) criteria and conditions to determine, by way of derogation from point (d) of paragraph 2, when the official controls in cutting plants may be performed by staff designated by the competent authorities for that purpose and appropriately trained;

(j) specific minimum requirements for the staff of the competent authorities and for official veterinarian and official auxiliary in order to ensure an adequate performance of their tasks provided for in this Article, including specific minimum training requirements;

(k)appropriate minimum training requirements for the slaughterhouse staff assisting in the performance of tasks relating to official controls and other official activities in accordance with paragraph 3.

8. The Commission shall, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls referred to in this Article regarding:

(a) specific requirements for the performance of official controls and the uniform minimum frequency of those official controls, having regard to the specific hazards and risks which exist in relation to each product of animal origin and the different processes it undergoes, where a minimum level of official controls is necessary to respond to recognised uniform hazards and risks which might be posed by products of animal origin;

(b) ►M3 the conditions for the classification and monitoring of classified production and relaying areas for live bivalve molluscs, echinoderms, tunicates and marine gastropods; ◄M3

(c) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Articles 137(2) and 138(2);

(d) The practical arrangements of the ante-mortem and post-mortem inspections referred to in points (a), (b) and (c) of paragraph 2, including the uniform requirements necessary to ensure that sufficient guarantees are met when the official controls are performed under the responsibility of the official veterinarian;

(e) the technical requirements of the health mark and the practical arrangements for its application;

關為該目的而指定且為經適當訓練的職員執行之標準和條件，以作為第 2 項(d)點規定之例外；

(j)對權責機關職員以及官方獸醫與官方輔助人員的具體最低要求，以確保本條中所規定之他們的任務的充分履行，其中包括具體的最低培訓要求；

(k)根據第 3 項，協助執行與官方管制和其他官方活動有關的任務的屠宰場員工的適當最低培訓要求。

8. 委員會應藉由施行細則，明訂關於對執行本條所提及之官方管制有關以下事宜之統一的實際安排之規範：

(a)官方管制之執行的具體要求和該等官方管制之統一的最低頻率，並已考慮到與每種動物源產品及其經歷的不同過程相關之存在的具體危害和風險，於此，最低程度的官方管制是必要的，以因應動物源產品所可能造成之公認一致性的危害和風險；

(b)活雙枚貝類、棘皮動物、被囊動物和海洋腹足類動物分類生產和轉運區域之分類和監控的條件；

(c)權責機關就特定不符合的情事擬採取第 137(2)條和第 138(2)條中所提及之一項或多項措施時之情形；

(d)第 2 項(a)、(b)、(c)點中所提及之屠前及屠後檢查的實際安排，其中包括必要之統一的要求以確保當官方管制在官方獸醫之職責(監督)下執行時已具備充分保證；

(e)健康標章的技術要求和其應用的實際安排；

(f)關於原料奶、奶製品和漁產品執行官方管制的之具體要求和統一的最低頻率，於此，最低程度的

(f) specific requirements for the performance of official controls and the uniform minimum frequency for those official controls on raw milk, milk products and fishery products, where a minimum level of official controls is necessary to respond to recognised uniform hazards and risks they might pose. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	官方管制是必要的，以因應公認他們可能造成的一致性的危害和風險。 上開施行細則應根據第 145(2)條所提及之檢查程序加以採用。
9. While complying with the objectives of this Regulation and in particular as regards food safety requirements, the Member States may adopt national measures implementing pilot projects limited in time and extent, to evaluate alternative practical arrangements for the performance of official controls on the production of meat. Those national measures shall be notified in accordance with the procedure laid down in Articles 5 and 6 of Directive (EU) 2015/1535. The outcome of the evaluation conducted through the pilot projects shall be communicated to the Commission as soon as available.	9. 於符合本規章的目標時，特別是關於食品安全之要求，會員國在有限的時間與範圍內，可採取國家措施執行先導計畫，以評估實施關於肉類生產之官方管制的替代性實務安排。上開國家措施應根據(EU) 2015/1535 號指令中第 5、6 條明訂的程序被通知。透過先導計畫所執行的評估結果應儘快送至歐盟執委會。
10. For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.	10. 為達第 30 條之目的，應允許將本條所提及之某些官方管制任務專任給一個或多個自然人。
Article 19 **Specific rules on official controls and for action taken by the competent authorities in relation to the residues of relevant substances in food and feed**	*第 19 條* **有關食物及飼料中相關物質殘留物之官方管制及權責機關所採取行動的具體規範**
1. Official controls to verify compliance with the rules referred to in points (a) and (c) of Article 1(2) shall include official controls, to be performed at any stage of production, processing and distribution, on relevant substances including substances to be used in food contact materials, contaminants, non-authorised, prohibited and undesirable substances whose use or presence on crops or animals or to produce or process food or feed may result in residues of those substances in food or feed.	1. 為查驗對第 1(2)條的(a)及(c)點所提及之規範的符合性所作之官方管制須包括在生產、加工及分銷的任何階段都必須執行相關物質之官方管制，而其中相關物質包括了與食物接觸的材料；汙染物；未被授權的、被禁止的、不受歡迎的物質，而該等物質之使用在或出現在農作物或動物上或是產製或加工食品或飼料，都可能會造成那些物質之殘留物在食物或飼料上。
2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of the official controls referred to in paragraph 1 of this Article and for action to be taken by the competent authorities following those official controls. Those delegated acts shall lay down rules on:	2. 歐盟執委會被授權基於第 144 條規定採用授權法規，藉由制定為執行本條第 1 項所提及之官方管制以及為權責機關於前述官方管制之後所採取的行動之規範，以補充本規章。上開授權法規應制訂關於下列事項之規範：
(a) specific requirements for the performance of official controls, including, where appropriate, the range of samples and the stage of production, processing and distribution where the samples are to be	(a)執行官方管制之具體要求，適當時，其中包括，樣本的範圍以及在製造、加工及分銷之須予取樣

taken in compliance with the methods to be used for sampling and laboratory analyses established in accordance with points (a) and (b) of Article 34(6), having regard to the specific hazards and risks related to substances referred to in paragraph 1 of this Article;	的階段以符合依據的 34(6)條的(a)、(b)點所制定用來制作為取樣與實驗室分析之方法，並已考量到與本條第 1 項所提及的物質相關的特定危害與風險；
(b) the cases where the competent authorities in relation to non-compliance or suspicion thereof are to take one or more of the measures referred to in Articles 137(2) and 138(2);	(b)權責機關就與不符合及疑似不符合的情事相關而擬採取第 137(2)條與 138(2)條所提及之一項或多項的措施時之情形；
(c) the cases where the competent authorities in relation to non-compliance or suspicion thereof of animals and goods from third countries are to take one or more of the measures referred to Articles 65 to 72.	(c)權責機關就與來自第三國的動物及貨物之不符合及疑似不符合的情事相關於擬採取第 65 條到 72 條所提及之一項或多項的措施時之情形；
3. The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls referred to in paragraph 1 and for action to be taken by the competent authorities following those official controls, regarding:	3. 歐盟執委會得，藉由施行細則，為就第 1 項所提及之官方管制的執行以及權責機關於該等官方管制之後，所採取的行動制定統一確切而務實的安排且關於下列各項事宜之相關規範。
(a) uniform minimum frequency of such official controls, having regard to the hazards and risks related to substances referred to in paragraph 1;	(a)此等官方管制之一致的最低頻率，並已考慮到第 1 項所提及的與物質有關之風險與危害；
(b) specific additional arrangements and specific additional content to those provided for in Article 110, for the preparation of the relevant parts of the multi-annual national control plan (MANCP) provided for in Article 109(1);	(b)依關於第 110 條內容之具體的額外安排及具體的額外內容，以為第 109(1)條之“多年度的國家管制計畫“(MANCP)之相關部分準備；
(c) specific practical arrangements for the activation of the mechanism of administrative assistance provided for in Articles 102 to 108. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	(c)為第 102 條至 108 條內容所述的行政協助機制之活化的具體務實安排。 上開施行細則應根據第 145(2)條所提及之檢查程序加以採用。
4. For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.	4. 為達第 30 條之目的，應允許將本條所提及之某些官方管制任務委任給一個或多個自然人。
Article 20 **Specific rules on official controls and for action taken by the competent authorities in relation to animals, products of animal origin, germinal products, animal by-products and derived products**	*第 20 條* **有關動物、動物源產品、胚種產品、動物副產品及衍生產品之官方管制及權責機關所採取之行動的具體規範**
1. Official controls to verify compliance with the rules referred to in points (a), (c), (d), and (e) of Article 1(2) shall include official controls, to be performed at any stage of production, processing and	1. 為查驗對第 1(2)條之 (a)、(c)、(d)及(e)點所提及之規範之符合性所執行之官方管制必須包括應關於動物、動物源產品、胚種產品、動物副

distribution, on animals, on products of animal origin, on germinal products, on animal by-products and on derived products.

2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls on animals, on products of animal origin, on germinal products, on animal by-products and on derived products to verify compliance with the Union rules referred to in points (d) and (e) of Article 1(2) and for action taken by the competent authorities following official controls. Those delegated acts shall lay down rules on:

(a) specific requirements for the performance of official controls on animals, products of animal origin and germinal products to respond to recognized hazards and risks to human and animal health by means of official controls performed to verify compliance with disease prevention and control measures laid down in accordance with the rules referred to in point (d) of Article 1(2);

(b) specific requirements for the performance of official controls on animal by-products and derived products to respond to specific hazards and risks to human and animal health by means of official controls performed to verify compliance with the rules referred to in point (e) of Article 1(2);

(c) the cases where the competent authorities in relation to non-compliance or suspicion thereof are to take one or more of the measures referred to in Articles 137(2) and 138(2).

3. The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of official controls referred to in paragraph 1 regarding:

(a) uniform minimum frequency of such official controls on animals, products of animal origin and germinal products where a minimum level of official controls is necessary to respond to recognized uniform hazards and risks to human and animal health by means of official controls performed to verify compliance with disease prevention and control measures laid down in accordance with the rules referred to in point (d) of Article 1(2); and

(b) uniform minimum frequency of such official controls on animal-by-products and derived products where a minimum level of official controls is necessary to respond to specific hazards and risks to human and animal health by means of official controls performed to verify compliance with the rules

產品及衍生產品之製造、加工及分銷的任何階段所執行之官方管制。

2. 歐盟執委會被授權依據第 144 條規定採用授權法規，藉由制定在為執行關於動物、動物源產品、胚種產品、動物副產品及衍生產品的官方管制以查驗是否符合第 1(2)條之(d)及(e)點所提及之歐盟規範，以及為權責機關於官方管制之後所採取的行動之規範，以補充本規章。上開授權法規應制定有關下列事宜的規範：

(a)關於動物、動物源產品及胚種產品執行官方管制之具體規範，以藉由所執行之官方管制加以檢驗對依據第 1(2)條之(d)點所提及之規範所明訂之疾病預防與管制措施之符合性，以因應該等對人類及動物健康之公認的危害與風險；

(b)關於動物副產品及衍生產品執行官方管制之具體規範，以藉由所執行之官方管制加以檢驗對依據第 1(2)條之(e)點所提及之規範所明訂之疾病預防與管制措施之符合性，以因應該等對人類及動物健康之公認的危害與風險；

(c)權責機關就與不符合及疑似不符合之情事相關而擬採取第 137(2)條及第 138(2)條所提及之一項或多項的措施時之情形。

3. 歐盟執委會得，藉由施行細則，制定關於為執行第 1 項所提及的官方管制與下列事宜有關之一致性的務實安排之規範：

(a)關於對動物、動物源產品及胚種產品之此等官方管制之一致性，而有最低程度的官方管制是必要的，以藉由所執行之官方管制加以查驗對依據第 1(2)條之(d)點及規範所明訂之疾病預防與管制措施之符合性，以因應該等對人類及動物健康之公認一致性的危害及風險；以及

(b)關於動物副產品及衍生產品之此等官方管制之一致性，而有最低程度的官方管制是必要的，以藉由所執行之官方管制加以查驗對依據第 1 (2)條之(e)點所提及規範之符合性，以因應該等對人類及動物健康之公認一致性的危害及風險。

referred to in point (e) of Article 1(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). 4. For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.	上開施行細則應依據第 145(2)條所提及之檢查程序加以採用。 4. 為達第 30 條之目的，應允許將本條所提及之某些官方管制任務委任給一個或多個自然人。
Article 21 **Specific rules on official controls and for action to be taken by the competent authorities in relation to the welfare requirements for animals** 1. Official controls to verify compliance with the rules referred to in point (f) of Article 1(2) shall be performed at all relevant stages of production, processing and distribution along the agri-food chain. 2. Official controls to verify compliance with the rules laying down welfare requirements for animals in the event of their transport, in particular with Regulation (EC) No 1/2005, shall include: (a) in the case of long journeys between Member States and with third countries, official controls performed prior to the loading to check the fitness of the animals for transport; (b) in the case of long journeys between Member States and with third countries, of domestic equidae other than registered equidae and domestic animals of the bovine, ovine, caprine and porcine species, and prior to those journeys: (i) official controls on journey logs to verify that the journey log is realistic and indicates compliance with Regulation (EC) No 1/2005; and (ii) official controls to verify that the transporter indicated in the journey log has a valid transporter authorization, certificate of approval for the means of transport for long journeys and certificates of competence for drivers and attendants; (c) at border control posts provided for in Article 59(1) and at exit points: (i) official controls on the fitness of the animals being transported and on the means of transport to verify compliance with Chapter II of Annex I to Regulation (EC) No 1/2005 and where applicable Chapter VI thereof; (ii) official controls to verify that transporters comply with applicable international agreements and	*第 21 條* **關於動物之福祉要求之官方管制及權責機關所採取之行動的具體規範** 1. 為查驗對第 1(2)條(f)點所提及之規範及符合性之官方管制，應沿著農業食品供應鏈於製造、加工及分銷之所有相關階段加以執行。 2. 為查驗對明訂動物於運送之情形時的福祉要求之規範的符合性所執行之官方管制，尤其是與規章(EC)1/2005 號規章之符合性之官方管制，應包括下列各項： (a)如果是在兩個會員國或與第三國間之長途的路程，裝貨之前所執行之官方管制先檢查動物的身體狀況是否適合運送。 (b)如果是在兩個會員國或與第三國間之長途的旅程，除了已登錄之馬科動物以外的國內馬科動物，及牛科、綿羊科、山羊科、豬科等品種的國內動物，以及在這些旅途之前之下列 2 項情事： (i) 關於旅途日誌上之官方管制，須要查驗旅途日誌是實際的並指出符合(EC)1/2005 號規章；且 (ii) 為查驗在旅途日誌裡提出之運輸人具有有效的運輸車輛認可、長途運輸方式的許可證書以及駕駛與隨員之能力的證書； (c)在第 59(1)條規定的邊境管制站及出口點： (i)關於被運送動物的身體狀況以及關於運輸方式之官方管制，以查驗對(EC)1/2005 號規章的附件 1 第 2 章，以及適用時，包括第 6 章；

have valid transporter authorizations and certificates of competence for drivers and attendants; and	（ii）為查驗運輸車輛是否符合國際協議以及擁有有效的認可以及駕駛與隨員之能力的證書所作的官方管制；及
(iii) official controls to verify whether domestic equidae and domestic animals of bovine, ovine, caprine and porcine species have been or are to be transported over long journeys.	（iii）為查驗國內的馬科動物及牛科、綿羊科、山羊科、豬科等品種的國內動物是否已或將被作長途的運送。
3. During the performance of official controls and other official activities, the competent authorities shall take the necessary measures to prevent or reduce to a minimum any delay between the loading of the animals and their departure, or during the transport. The competent authorities shall not detain animals during the transport unless it is strictly necessary for animal welfare or animal or human health reasons. If animals have to be detained during transport for more than two hours, the competent authorities shall ensure that appropriate arrangements are taken for their care and, where necessary, their feeding, watering, unloading and accommodation.	3. 在官方管制以及其他官方活動執行的期間，權責機關須採取必要措施來預防將動物裝載及出發之間，或運送期間的任何延誤情勢降到最低。權責機關不得在運送期間任意的扣留動物，除非為了動物福祉及動物與人類的健康考量有嚴重地必要。如果動物必須要在運送期間被扣留超過兩小時，則權責機關必須確保會妥善地照顧牠們以及供給牠們食物、水和妥善地卸載與住居場所。
4. Where a non-compliance is established following the official controls referred to in point (b) of paragraph 2 and is not corrected by the organizer prior to the long journey, by making appropriate changes to the transport arrangements, the competent authorities shall prohibit that long journey.	4. 如果在第 2 項(b)點所提及的官方管制後有不符合規定的事實成立且在長途旅程前並未被籌劃藉由將運送安排事宜作適當變更而加以補正，權責機關應禁止該趟長途旅程。
5. Where, following the official controls referred to in point (c) of paragraph 2, the competent authorities establish that animals are not fit to complete the journey, they shall give the order that animals be unloaded, watered, fed and rested until fit to continue their journey.	5. 如果在執行第 2 項(c)點所提及的官方管制後權責機關認定動物並不適合完成這趟旅途，他們必須下指令讓動物卸載、喝水、被餵食和休息直到適合繼續他們的旅途。
6. A notification of non-compliance with the rules referred to in paragraph 1 of this Article for the purposes of Articles 105 and 106 shall be made: (a) to the Member States that granted the authorization to the transporter; (b) where non-compliance with any such rule applicable to the means of transport is identified, to the Member State that granted the certificate of approval of the means of transport; (c) where non-compliance with any such rule applicable to drivers is identified, to the Member State that issued the driver's certificate of competence.	6. 為達第 105 條和第 106 條之目的，應對以下對象發出不符合本條第 1 項所提及之規範的通知： (a)核發運輸車輛許可的會員國； (b)給核發運輸方式批核證書的會員國，若經確認該運輸方式不符合任何適用規範； (c)給核發駕駛能力證書的會員國，若經確認該駕駛不符合任何適用規章。
7. For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.	7. 為達第 30 條之目的，應允許將本條所提及之某些官方管制任務委任給一個或多個自然人。 8. 歐盟執委會被授權依據第 144 條規定，採用授權

8. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls to verify compliance with Union rules referred to in point (f) of Article 1(2). Those delegated acts shall take into account the animal welfare risk related to the farming activities and to the transport, slaughter and killing of animals, and shall lay down rules on: (a) specific requirements for the performance of such official controls to respond to the risk associated with different animal species and means of transport, and the need to prevent non-compliant practices and to limit the suffering of animals; (b) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Articles 137(2) and 138(2); (c) the verification of animal welfare requirements at border control posts and at exit points and the minimum requirements applicable to those exit points; (d) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Articles 102 to 108; (e) the cases and conditions where official controls to verify compliance with animal welfare requirements may include the use of specific animal welfare indicators based on measurable performance criteria, and the design of such indicators on the basis of scientific and technical evidence. 9. The Commission shall, by means of implementing acts, lay down rules on uniform practical arrangements on official controls performed to verify compliance with the Union rules referred to in official controls, regarding:point (f) of Article 1(2) laying down animal welfare requirements and on action taken by the competent authorities following such official controls, regarding: (a) uniform minimum frequency of such official controls, where a minimum level of official control is necessary to respond to the risk associated with different animal species and means of transport, and the need to prevent non-compliant practices and to limit the suffering of animals; and (b) the practical arrangements for keeping written records of official controls performed and their retention period.	法規，藉由制定用以查驗是否符合第 1(2)條之(f)點所提及的歐盟規範之官方管制的執行規範以補充本規章。該等授權法規必須將與畜養活動以及動物的運輸、屠宰和宰殺有關的動物福祉風險納入考量，並須在以下事項上制定規範： (a)對於此等官方管制執行的具體要求，以因應與不同動物品種及運輸方式相關的風險，以及為避免不符合規定的做法與限制動物之受苦程度的需要。 (b)在權責機關就與具體不符合規定之情事相關而擬採取第 137 條 (2)及 138(2)條所提及之一項或多項措施時之情事。 (c)在邊境管制站及出口點的動物福祉要求的查驗以及適用於該等出口點的最低要求。 (d)為在第 102 條至第 108 條內容所述的行政協助機制之活化的具體標準與條件。 (e)用以查驗對動物福祉要求條件的符合性之官方管制，可包括基於可測量的執行標準之具體動物福祉指標之使用，以及這項基於科學與技術的證據。 9. 歐盟執委會應藉由施行細則，制定關於用以查驗對與訂定動物福祉要求之第 1(2)條第(f)點所提及的歐盟規範之符合性所執行之官方管制，以及關於權責機關在此等官方管制後所採取的行動的統一實務的安排之規範，此等規範是關於下列 2 項事宜： (a)此等官方管制之一致的最低頻率，而於此處最低程度的官方管制是有必要的以因應與不同動物品種及運輸方式相關的風險，以及為避免不符合規定的做法與限制動物之受苦程度的需求；及 (b)保留所執行的官方管制之書面紀錄及其保留期間的實務安排。 上開施細則應根據第 145(2)條所提及之檢查程序加以採用。

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	
Article 22 **Specific rules on official controls and for action taken by the competent authorities in relation to plant health** 1. Official controls to verify compliance with the rules referred to in point (g) of Article 1(2) shall include official controls on pests, plants, plant products and other objects, and on professional operators and other persons subject to those rules. 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls on plants, plant products and other objects in order to verify compliance with Union rules referred to in point (g) of Article 1(2) applicable to those goods and for action taken by the competent authorities following the performance of those official controls. Those delegated acts shall lay down rules on: (a) specific requirements for the performance of such official controls on the introduction into and movement in the Union of particular plants, plant products, and other objects subject to the rules referred to in point (g) of Article 1(2), to respond to recognized hazards and risks to plant health in relation to specific plants, plant products and other objects of a particular origin or provenance; and (b) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Articles 137(2) and 138(2). 3. The Commission shall, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of official controls on plants, plant products and other objects in order to verify compliance with Union rules referred to in point (g) of Article 1(2) applicable to those goods and for action taken by the competent authorities following such official controls on: (a) uniform minimum frequency of such official controls, where a minimum level of official control is necessary to respond to recognized uniform hazards and risks to plant health in relation to specific plants, plant products and other objects of a particular origin or provenance; (b) uniform frequency of official controls performed by competent authorities on operators authorized to	*第 22 條* **關於植物健康之官方管制及權責機關所採取之行動的具體規範** 1. 為查驗對第 1(2)條之(g)點所提及之規範的符合性所執行之官方管制應包括對害蟲、植物、植物產品和其他物體，以及對專業運營商和受這些規範約束的其他人員之官方管制。 2. 歐盟執委會被授權依據第 144 條規定，採用授權法規，藉由制定為執行關於植物、植物產品和其他物品的官方管制以查驗是否符合可適用於該等貨物的第 1(2)條之(g)點所提及之歐盟規範，以及為權責機關於該等官方管制之後所採取的行動之規範，以補充本規章。該等授權法規應明訂關於以下事項之規範： (a)為執行關於頒受在第 1(2)條之(g)點所提及之規範約束的特定植物、植物產品及其他物品的引入歐盟及在歐盟內運送之官方管制的具體要求，以回應出關於特定地區或出處的特定植物、植物產品和其他物體之對植物健康之公認的危害和風險；且 (b)在權責機關就與具體不符合規定之情事相關而擬採取 137(2)條及 138(2)條所提及之一項或多項措施時之情形。 3. 歐盟執委會應，藉由施行細則，制定關於用以查驗對與第 1(2)條之(g)點所提及可適用於植物、植物產品和其他物品的歐盟規範之符合性所執行之官方管制，以及為權責機關於此等官方管制後所採取的行動之統一實務的安排之規範，此等規範係關於下列 3 項事宜： (a)此等官方管制之一致的最低頻率，而於此處有最低程度的官方管制是有必要的，以因應關於特定地區或出處的特定植物、植物產品和其他物體之

issue plant passports in accordance with Article 84(1) of Regulation (EU) 2016/2031 having regard to whether those operators have implemented a pest risk management plan as referred to in Article 91 of that Regulation for the plants, plant products and other objects they produce; (c) uniform frequency of official controls performed by competent authorities on operators authorized to apply the mark referred to in Article 96(1) of Regulation (EU) 2016/2031 or to issue the official attestation referred to in point (a) of Article 99(2) of that Regulation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). 4. For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.	對植物健康之公認一致的危害和風險； (b)權責機關對獲得授權依據(EU)2016/2031 號規章第 84(1)條之規定發放植物護照之運營商所執行的官方管制之一致的頻率，並已考量到該等運營商是否已執行本規章第 91 條所提及關於他們所生產的植物、植物產品及其他產品之害蟲風險管理計畫； (c)權責機關對獲得授權貼用依(EU)2016/2031 號規章第 96(1)條所提及之標誌，獲核發該規章第 99(1)條第(a)點所提及之官方證明的運營商所執行的官方管制。 上開施行細則應根據第 145(2)條所提及之檢查程序加以採用。 4. 為達第 30 條之目的，應允許將本條所提及之某些官方管制任務委任給一個或多個自然人。
Article 23 **Specific rules on official controls and for action taken by the competent authorities in relation to GMOs for the purpose of food and feed production and genetically modified food and feed** 1. Official controls to verify compliance with the rules referred to in points (a), (b) and (c) of Article 1(2) shall include official controls on GMOs for the purpose of food and feed production and on genetically modified food and feed performed at all relevant stages of production, processing and distribution along the agri-food chain. 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of the official controls referred to in paragraph 1 of this Article and for action to be taken by the competent authorities following such official controls. Those delegated acts shall take into account the need to ensure a minimum level of official controls to prevent practices that infringe the rules referred to in point (b) of Article 1(2), and lay down: (a) specific requirements for the performance of official controls to respond to recognized uniform hazards and risks of: (i) the presence in the agri-food chain of GMOs for food and feed production and of genetically	*第 23 條* **關於與為了食物和飼料的生產之目的的基因改造生物基因改造食物和飼料有關的官方管制及權責機關採取之行動的具體規範** 1. 為查驗對第 1(2)條之(a)、(b)及(c)點所提及之規範的符合性所執行之官方管制應包括在農業食品供應鏈中於製造、加工及分銷等相關階段所執行關於為了食物飼料的生產之目的基因改造生物及關於金因改造食物和飼料之官方管制。 2. 歐盟執委會被授權依據第 144 條規定，採用授權法規，藉由制定為執行本條第 1 項所提及的官方管制，以及權責機關在該等官方管制後所採取的行動之規範，已補充本規章。該等授權法規再考量可以確保有最低程度的官方管制之需求，以防止有違背第 1(2)條之(b)點所提及的規範之情事，並明訂以下規定： (a)執行官方管制之具體要求，以因在下列之公認一致的危害與風險： (i) 於農業食品供應鏈中所存在未經歐盟第 2001/18/EC 號指令或(EC) 1829/2003 號規章授權之為食物和飼料生產之用的基因改

modified food and feed which have not been authorized in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003; (ii) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in point (e) of Article 13(2) of Directive 2001/18/EC and in point (b) of Article 5(5) and point (b) of Article 17(5) of Regulation (EC) No 1829/2003; (b) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Articles 137(2) and 138(2). 3. The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls referred to in paragraph 1, taking into account the need to ensure a minimum level of official controls to prevent practices that infringe those rules regarding uniform minimum frequency of such official controls where a minimum level of official control is necessary to respond to recognized uniform hazards and risks of: (a) the presence in the agri-food chain of GMOs for food and feed production and of genetically modified food and feed which have not been authorized in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003; (b) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in point (e) of Article 13(2) of Directive 2001/18/EC and in point (b) of Article 5(5) and point (b) of Article 17(5) of Regulation (EC) No 1829/2003. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). 4. For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.	造生物及基因改造食物和飼料； (ii) 為食物和飼料生產之用的基因改造生物之培養，以及於歐盟第 2001/18/EC 號指令的第 13(2)條之(e)點及(EC) 1829/2003 號規章的第 5(5)條之(b)點與第 17(5)條第(b)點所提及的監控計畫之正確應用。 (b)權責機關就與具體不符合規定之情事相關，而擬採取第 137(2)條及 138(2)條所提及之一項或多項措施時之情形。 3. 歐盟執委會可，藉由施行細則，制定有關為執行第 1 項所提及之官方管制之統一實務的安排之規範，並將可以確保有最低程度的官方管制的需求納入考量，以防止有違背該等關於此等官方管制之一致的最低頻率之規範的情事，此時需要最低程度的官方管制來因應以下之公認一致的危害和風險： (a)於農業食品供應鏈中所存在之未經歐盟第 2001/18/EC 號指令或歐盟(EC) 1829/2003 號規章授權之為了食物和飼料生產之用的基因改造生物及基因改造食物和飼料； (b)為食物和飼料生產之用的基因改造生物之培養，以及於歐盟第 2001/18/EC 號指令的第 13(2)條之(e)點及歐盟(EC) 第 1829/2003 號規章的第 5(5)條之(b)點與第 17(5)條之(b)點所提及的監控計畫之正確使用。 上開施行細則應依第 145(2)條所提及的查驗程序加以採用。 4. 為達第 30 條之目的，應允許將本條所提及之某些官方管制任務委任給一個或多個自然人。
Article 24 **Specific rules on official controls and for action taken by the competent authorities in relation to plant protection products** 1. Official controls to verify compliance with the rules referred to in point (h) of Article 1(2) of this Regulation shall include official controls on active substances and safeners, synergists,	*第 24 條* **關於植物保護產品之官方管制及權責機關所採取之行動的具體規範** 1. 為查驗是否對本規章第 1(2)條之(h)點所提及之規範的官方管制應包括對(EC)1107/2009 號規章之第 2(2)及(3)條所提及的活性物質、安全劑、

co-formulants and adjuvants as referred to in Article 2(2) and (3) of Regulation (EC) No 1107/2009.

2. For the purpose of establishing the frequency of risk based official controls referred to in paragraph 1, competent authorities shall take into account also the following:

(a) results of relevant monitoring activities including those on pesticides residues carried out for the purpose of Article 32(2) of Regulation (EC) No 396/2005 and of Article 8 of Directive 2000/60/EC of the European Parliament and of the Council[55] ;

(b) information on non-authorized plant protection products, including illegal trade of plant protection product, and results of relevant controls by the authorities referred to in Article 8 of Regulation (EU) No 649/2012 of the European Parliament and of the Council [56]; and

(c) information on poisoning related to plant protection products, including information available in accordance to Article 56 of Regulation (EC) No 1107/2009, and information on emergency health responses made available by the centres referred to in Article 45(1) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council[57] .

3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls referred to in paragraph 1 of this Article. Those delegated acts shall lay down rules on:

(a) specific requirements for the performance of such official controls to respond to recognized uniform hazards and risks which might be posed by plant protection products, concerning the manufacture, placing on the market, entry into the Union, labelling, packaging, transport, storage and use of plant protection products to ensure their safe and sustainable use and to combat their illegal trade; and

(b) the cases where the competent authorities in relation to specific non-compliances are to take one or

增效劑、助劑、佐劑的官方管制。

2. 為了達到建立基於第 1 項所提到的官方管制的風險頻率之目標，權責機關應亦也將下列事項納入考量：

(a)相關監控行動之結果，其中包括為達成歐盟(EC)396/2005 號規章第 32(2)條條及歐洲議會與歐盟理事會第 2000/60/EC 號指令第 8 條之目的而對農藥殘留物執行監控的結果；

(b)關於未經授權之植物保護產品的資訊，其中包括植物保護產品的非法交易，及由歐洲議會與歐盟理事會之(EU)649/2012 號規章第 8 條所提及的機關所作的相關管制之結果。

(c)與植物保護產品有關的中毒之資訊，其中包括根據歐盟(EC)第 1107/2009 號規章第 56 條規定，可獲得的資訊，以及由在歐洲議會與歐盟理事會(EC)1272/2008 號規章第 45(1)條中所提到的中心所提供之關於緊急健康答覆的資訊。

3. 歐盟執委會被授權依據第 144 條規定採用授權法規，藉由制定為執行第 1 項所提到的官方管制之規範，以補充本規章。上開授權法規應制定關於以下事項之規範：

(a)執行此等官方管制之具體要求，以因應可能由植物保護產品所造成之關於製造、上市、進入歐盟、標示、包裝、運送、儲存及其使用之公認一致的危害及風險，以確保它們安全的，與可持續的使用並對抗它們的非法交易；以及

(b)權責機關就與具體不符合規定之情事相關，而擬採取第 137(2)條及第 138(2)條所提及一項或多

55 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1)./ 歐洲議會及歐盟理事會 2000 年 10 月 23 日第 2000/60/EC 號關於在水政策領域建立共同體行動框架指令。

56 Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)./ 歐洲議會及歐盟理事會 2012 年 7 月 4 日(EU)第 649/2012 號關於危險化學品的進出口規章。

57 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)./ 歐洲議會及歐盟理事會 2008 年 12 月 16 日第(EC)1272/2008 號關於物質和混合物的分類、標籤和包裝，修改和廢除第 67/548/EEC 號與第 1999/45/EC 號指令，以及修訂第(EC)1907/2006 號規章。

more of the measures referred to in Articles 137(2) and 138(2). 4. The Commission may, by means of implementing acts, lay down detailed rules on uniform practical arrangements for the performance of official controls on the products referred to in paragraph 1 regarding: (a) uniform minimum frequency of such official controls, where a minimum level of official control is necessary to respond to recognized uniform hazards and risks which might be posed by plant protection products, concerning the manufacture, placing on the market, entry into the Union, labelling, packaging, transport, storage and use of plant protection products to ensure their safe and sustainable use and to combat their illegal trade; (b) the collection of information, monitoring and reporting on suspected poisonings from plant protection products; (c) the collection of information, and the monitoring of and reporting on non-authorized plant protection products including illegal trade of plant protection products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). 5. For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.	項措施時之情形。 4. 歐盟執委會可，藉由施行細則，制定關於執行第1項所提及產品的官方管制之有關以下事項統一實務安排的詳細規範： (a)此等官方管制之一致的最低頻率，而於此處最低程度的官方管制是有必要的，以因應可能由植物保護產品所造成關於製造、上市、進入歐盟、標示、包裝、運送、儲存及其使用公認一致危害與風險，以確保它們安全的與可持續的使用並對抗它們的非法交易； (b)關於來自植物保護產品之受懷疑的中毒事件之資訊、監控與報導的資訊的蒐集； (c)關於未獲授權的植物保護產品，包括其非法交易之資訊蒐集以及對其之監控與報導報導與監控。上開施行細則應依第 145(2)條所提及的檢查程序加以採用。 5. 為達第 30 條之目的，應允許將本條所提及之某些官方管制任務委任給一個或多個自然人。
Article 25 **Specific rules on official controls and other official activities for organic production and labelling of organic products** The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of official controls to verify compliance with the rules referred to in point (i) of Article 1(2), regarding: (a) specific requirements and additional content to that provided for in Article 110 to prepare the relevant parts of the MANCP provided for in Article 109(1), and specific additional content to the report provided for in Article 113; (b) specific responsibilities and tasks for the European Union reference centres in addition to those	*第 25 條* **關於有機製造及有機產品標示的官方管制及其他官方活動的具體規範** 歐盟執委會藉由施行細則，關於為查驗是否符合第1(2)條(i)點所提及的規範所執行之官方管制的統一實際安排且關於下列事宜之規範： (a)對第 110 條所述內容的具體要求與額外的內容以用來準備第 109(1)條所述的“多年度的管制計畫”(MANCP)的相關部分，以及對 113 條所述的報告之具體額外的內容； (b)除了第 98 條所規定的內容之外，歐盟參考(標準)中心的具體責任及任務；

provided for in Article 98; (c) practical arrangements for activating the mechanisms of administrative assistance provided for in Articles 102 to 108, including the exchange of information concerning instances of non-compliance or the likelihood of non-compliance between competent authorities and delegated bodies; (d) the methods to be used for sampling and for laboratory analyses and tests, excluding any rules involving the setting of thresholds. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	(c)為活化於第 102 條至第 108 條所述的行政協助機制之務實安排，其中包括關於不符合規定的案例之資訊交流或權責機關與受委任機構間之不一致情事的可能性； (d)擬用於取樣及實驗室之分析與測試的方法，須排除任何包括門檻值之設定的規範。 上開施行細則應依第 145(2)條所提及的檢查程序加以採用。
Article 26 **Specific rules on official controls and other official activities performed by the competent authorities in relation to protected designations of origin, protected geographical indications and traditional specialities guaranteed** 1. By way of derogation from Article 31(3), in relation to the rules referred in point (j) of Article 1(2), where competent authorities have delegated the decisions concerning the authorization to use the registered name of a product, they may also delegate the application of the following measures: (a) ordering that certain activities of the operator be subject to systematic or increased official controls; (b) ordering the operator to increase the frequency of own controls; (c) ordering the alteration of label in order to comply with the product specifications and the rules referred in point (j) of Article 1(2). 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls to verify compliance with the rules referred to in point (j) of Article 1(2). Those delegated acts shall lay down rules on: (a) requirements, methods and techniques referred to in Articles 12 and 14 for official controls performed to verify compliance with product specifications and labelling requirements; (b) specific methods and techniques referred to in Article 14 for the performance of official controls aimed at ensuring the traceability of goods and animals falling within the scope of the rules referred to in point (j) of Article 1(2) at all stages of production, preparation and distribution, and at providing	*第 26 條* **關於由權責機關對受保護的原產地名稱、受保護的地理標示以及受保護的傳統特產品所執行的官方管制及其他官方活動的具體規範** 1. 在作為第 31(3)條規定的例外，而與第 1(2)條(j)點的規定相關，在權責機關已經將關於使用已註冊的產品名稱之授權的決定予以委任辦理時，他們同時亦得採取以下措施之應用予以委任辦理： (a)責令特定活動的運營商應受系統性的或增加的官方管制之約束； (b)責令運營商增加其自我管制的頻率； (c)責令更換標記以符合產品規格及第 1(2)條之(j)款所提及的規定。 2. 歐盟執委會被授權依據第 144 條規定，採用授權法規，藉由制定用以查驗是否符合第 1(2)條之(j)點所提及的規範之官方管制的執行規範，以補充本規章。該等授權法規應明訂關於下列事項訂立規範： (a)在第 12 及第 14 條所提及的為執行用以查驗是否符合產品規格和標示要求之官方管制的要求、方法及技術； (b)第 14 條所提及的為確保落於第 1(2)條(j)點所提及的規範之範圍內的貨物和動物在各製造、準備

assurances as to compliance with those rules; (c) the cases where the competent authorities, in relation to specific non-compliances, are to take one or more of the actions and measures referred to in Article 138(1) and (2). 3. The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls to verify compliance with the rules referred to in point (j) of Article 1(2) regarding: (a) specific practical arrangements for activating the mechanisms of administrative assistance provided for in Articles 102 to 108, including the exchange of information concerning instances of non-compliance or the likelihood of non-compliance between competent authorities and delegated bodies; and (b) specific reporting obligations of the delegated bodies. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). 4. For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.	及分銷的所有階段的追溯性，以及為提供符合該等規範之保證所執行的官方管制之具體方法和技術； (c)在權責機關就與具體不符合規定之相關情事而擬採取第 138(1)條及(2)所提及的一項或多項行動與措施時之情形。 3. 歐盟執委會可藉由施行細則，制定關於為執行用以查驗是否符合第 1(2)條(j)點所提及的規範之官方管制的統一實務的安排之規範，該等規範係關於以下各項事宜: (a)為活化於第 102 條至第 108 條所述的行政協助機制之具體實務安排，其中包括關於不符合規定的案例之資訊交流或權責機關與受委任機構間之不一致情事的可能性；以及 (b)受委託機構之具體的報告義務。 上開施行細則應依第 145 之（2）所提及的檢查程序加以採用。 4. 為達第 30 條之目的，應允許將本條所提及之某些官方管制任務委任給一個或多個自然人。
Article 27 **Specific rules on official controls and for action taken by the competent authorities in cases of newly identified risks in relation to food and feed** 1. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls on certain categories of food or feed to verify compliance with the rules referred to in points (a) to (e) of Article 1(2) and for action to be taken by the competent authorities following such official controls. Those delegated acts shall address newly identified risks which may arise through food or feed to human or animal health or, in relation to GMOs and plant protection products, also to the environment, or any such risks emerging from new patterns of production or consumption of food or feed, and which cannot be effectively addressed in the absence of such common rules. Those delegated acts shall lay down rules on:	*第 27 條* **對新鑑定與食物和飼料相關風險之情形時權責機關所採取之官方管制及行動的具體規範** 1. 歐盟執委會被授權依據第 144 條，採用授權法規，藉由制定為執行關於特定類別的食物或飼料之官方管制，以查驗對第 1(2)條之(a)到第(e)點所提及之規範之符合性，以及為權責機關在該等官方管制後所採取的行動之規範，以補充本規章。此等授權法規須著眼於可能採用食物或飼料而對人類及動物之健康或與基因改造生物及植物保護產品有關，同時亦對環境所產生之新確認的風險；或任何從過食物或飼料之新的生產或消費模式中出現且無法在欠缺此等共同規範的情況下予以有效地解決之此類風險。上開授權法規應明定關於以下情況之規範：

(a) uniform specific requirements for the performance of official controls to respond to the specific hazards and risks which exist in relation to each category of food and feed and the different processes it undergoes; and (b) the cases where the competent authorities, in relation to specific non-compliances, are to take one or more of the measures referred to in Articles 137(2) and 138(2). 2. The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements on official controls performed on certain categories of food or feed to verify compliance with the rules referred to in points (a) to (e) of Article 1(2) to address newly identified risks which may arise through food or feed to human or animal health or, in relation to GMOs and plant protection products, also to the environment, or any such risks emerging from new patterns of production or consumption of food or feed, and which cannot be effectively addressed in the absence of such common rules regarding uniform minimum frequency of such official controls, where a minimum level of official control is necessary to respond to the specific hazards and risks which exist in relation to each category of food and feed and the different processes it undergoes. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). 3. On duly justified imperative grounds of urgency relating to cases of serious risks to human or animal health or to the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 145(3).	(a)為因應關於每一類型的食物和飼料及所經歷的不同加工程序所存在的特定危害和風險所執行之官方管制之統一的具體要求；以及 (b)權責機關就與具體不符合規定之情事相關而擬採取按第 137(2)條第 138(2)條所提及之一項或多項措施時之情形。 2. 歐盟執委會可，藉由施行細則，制定關於對特定種類的食物或飼料所執行用以查驗第 1(2)條之(a)到第(e)點所提及之規範的符合性之官方管制的統一實務的安排之規範，以解決可能透過食物或飼料而對人類及動物之健康或與基因改造生物與植物保護產品有關聯，同時亦對環境所產生之新確認的風險；或任何從食物與飼料之新的生產或的消費模式中出現，且無法在欠缺關於此等官方管制之統一最低標準的此等共同規範的情況下予以有效地解決之此類風險，此時最低程度的官方管制是有必要的以因應關於每種類型的食物和飼料及所經歷的不同加工程序中所存在的特定危害和風險。上開施行細則應依第 145(2)條條所提及的查驗程序加以採用。 3. 基於對人類或動物健康或環境具嚴重危害之迫切理由，委員會應依據第 145(3)條所述程序立即採取適當的實施法案。
CHAPTER III ***Delegation of certain tasks of the competent authorities***	*第 III 章* ***權責機關的特定任務委託***
Article 28 **Delegation by the competent authorities of certain official control tasks** 1. Competent authorities may delegate certain official control tasks to one or more delegated bodies or natural persons in accordance with the conditions provided for in Articles 29 and 30 respectively. The competent authority shall ensure that the delegated body or natural person, to which such tasks have been delegated, have the powers needed to effectively perform these tasks. 2. Where a competent authority or a Member State decides to delegate certain official control tasks for	*第 28 條* **權責機關委託官方管制任務之委託** 1. 權責機關可分別依據第 29 條及第 30 條規定的條件將特定的官方管制任務委託給一個或多個受委任機構或自然人。權責機關在確保在任務被委託後，受委任的機構或自然人有足夠的權力有效地執行此等任務。 2. 當一個權責機關或會員國決定要用以查驗是否符合第 1(2)條之(i)點所提及的規範之官方管制

the verification of compliance with the rules referred to in point (i) of Article 1(2) to one or more delegated bodies, it shall attribute a code number to each delegated body, and shall designate relevant authorities responsible for their approval and supervision.	任務委託給一個或多個受委任機構時，其應給予各個受委任機構一個代號，並應指定相關機關負責予以稽核及監督。
Article 29 **Conditions for delegating certain official control tasks to delegated bodies** The delegation of certain official control tasks to a delegated body referred to in Article 28(1) shall be in writing and shall comply with the following conditions: (a) the delegation contains a precise description of those official control tasks that the delegated body may perform, and the conditions under which it may perform those tasks; (b) the delegated body: (i) has the expertise, equipment and infrastructure required to perform those official control tasks delegated to it; (ii) has a sufficient number of suitably qualified and experienced staff; (iii) is impartial and free from any conflict of interest and in particular is not in a situation which may, directly or indirectly, affect the impartiality of its professional conduct as regards the performance of those official control tasks delegated to it; (iv) works and is accredited in accordance with standards relevant to the delegated tasks in question, including standard EN ISO/IEC 17020 'Requirements for the operation of various types of bodies performing inspection'; (v) has sufficient powers to perform the official control tasks delegated to it; and (c) there are arrangements in place ensuring efficient and effective coordination between the delegating competent authorities and the delegated body.	*第 29 條* **將特定官方管制任務委託予受委任機構之條件** 將特定官方管制任務委託給第 28(1)條所提及之受委任機構，應以書面為之，並應符合下列條件： (a)此種委託包括對受委任機構可能執行的官方管制任務內容之明確描述，以及該機構可執行該等任務的條件； (b)受委任機構(必須符合以下條件)： (i)具備執行該等委託給它的官方管制任務所需的專業知識、設備和基礎設施； (ii)擁有足夠數量的合格且經驗豐富的職員； (iii)是公正的且不存在任何利益衝突，特別是不會在一個可能直接或間接地影響關於其履行委託給它的官方管制任務之專業行為的公正性的狀態； (iv)按照與所涉的受委託任務之相關的標準，其中包括標準 EN ISO/IEC 17020「執行檢查的各類機構的操作要求」進行工作和接受認證； (v)有足夠的權力履行委託給它的官方管制任務；以及 (c)有適當的安排，以確保在委託之權責機關與受委任機關間能有效率且有效的協調。
Article 30 **Conditions for delegating certain official control tasks to natural persons** Competent authorities may delegate certain official control tasks to one or more natural persons, where the rules provided for in Articles 18 to 27 so allow. Such delegation shall be in writing and shall comply with the following conditions:	*第 30 條* **委託特定官方管制任務予自然人之條件** 如第 18 到 27 條所允許的，權責機關可將特定的官方管制任務委派予一位或多位自然人。此種委託應以書面為之，並應符合以下條件： (a)此種委託包括對受託之自然人可執行的官方管

(a) the delegation contains a precise description of those official control tasks that the natural persons may perform and the conditions under which the natural persons may perform those tasks; (b) the natural persons: (i) have the expertise, equipment and infrastructure required to perform those official control tasks delegated to them; (ii)are suitably qualified and experienced; (iii)act impartially and are free from any conflict of interest as regards the exercise of those official control tasks delegated to them; and (c) there are arrangements in place ensuring efficient and effective coordination between the delegating competent authorities and the natural persons.	制任務內容之明確描述，以及此等自然人執行該等任務的條件； (b)此等自然人(必須符合以下條件)： (i)具備執行該等委託給他們的官方管制任務所需的專業知識、設備和基礎設施； (ii)具備適當的資格和經驗； (iii)公正行事且在執行委託給他們的官方管制任務方面不存在任何利益衝突；及 (c)有適當的安排以確保在委託在權責機關與自然人之間能有效率且有效的協調。
Article 31 **Conditions for delegating certain tasks related to other official activities** 1. The competent authorities may delegate certain tasks related to other official activities to one or more delegated bodies subject to compliance with the following conditions: (a) the rules referred to in Article 1(2) do not prohibit such delegation; and (b) the conditions laid down in Article 29 are fulfilled with the exception of that laid down in point (b)(iv). 2. The competent authorities may delegate certain tasks related to other official activities to one or more natural persons subject to compliance with the following conditions: (a) the rules referred to in Article 1(2) allow such delegation; and (b) the conditions laid down in Article 30, applied mutatis mutandis, are fulfilled. 3. Competent authorities shall not delegate to a delegated body or to a natural person the decision concerning the tasks provided for in point (b) of Article 138(1) and in Article 138(2) and (3).	*第 31 條* **委託有關其他官方活動的特定任務之條件** 1. 權責機關可將與其他官方活動相關的特定任務委託予一個或數個符合以下條件之受委託機構： (a)第 1(2)條所提及之規範不禁止此種委託； (b) 除第 29 條(b)(iv)點所述內容外，必須達成該條所提及之條件。 2. 權責機關可將與其他官方相關活動之特定任務委託予一名或多名符合下列條件的自然人： (a)第 1(2)條所提及之規範允許此種委託； (b)必須達成經適度修正後之第 30 條所提及之條件。 3. 權責機關不應將關於第 138(1)條之(b)點和第 138(2)條和(3)條所述任務之決定委託予受委任機構或是自然人。
Article 32 **Obligations of the delegated bodies and natural persons** Delegated bodies or natural persons to which certain official control tasks have been delegated in accordance with Article 28(1), or certain tasks related to other official activities have been delegated in accordance with Article 31, shall:	*第 32 條* **受委任機構及受託自然人之義務** 依照第 28(1)條規定受託特定官方管制任務之受委任機構或受託自然人；或是依照第 31 條規定受託有關於其他官方活動之特定任務之機構或自然人，應： (a)向委託之權責機關定期以及當權責機關要求

(a) communicate the outcome of the official controls and other official activities performed by them to the delegating competent authorities on a regular basis and whenever those competent authorities so request; (b) immediately inform the delegating competent authorities whenever the outcome of the official controls indicate non-compliance or point to the likelihood of non-compliance, unless specific arrangements established between the competent authority and the delegated body or the natural person concerned provides otherwise; and (c) give competent authorities access to their premises and facilities and cooperate and provide assistance.	時，回報受託之官方管制任務及其他受託執行之官方任務的結果。 (b)除非權責機關與所涉的受委任機構或有關自然人之間所提及的具體安排另有規定，否則只要官方管制的結果顯示有不符合情事或指向有不符合情事的可能性時，應立即通知委託權責機關；以及 (c)給予委託之權責機關得以進入其運營處所和設施之許可，並須合作且提供協助。
Article 33 **Obligations of the delegating competent authorities** Competent authorities that have delegated certain official control tasks to delegated bodies or natural persons in accordance with Article 28(1), or certain tasks related to other official activities to delegated bodies or natural persons in accordance with Article 31, shall: (a) organise audits or inspections of such bodies or persons, as necessary and avoiding duplication, taking into account any accreditation referred to in point (b)(iv) of Article 29; (b) fully or partly withdraw the delegation without delay where: (i) there is evidence that such a delegated body or natural person is failing to properly perform the tasks delegated to it; (ii)the delegated body or the natural person fails to take appropriate and timely action to remedy the shortcomings identified; or (iii)the independence or impartiality of the delegated body or natural person has been shown to be compromised. This point shall be without prejudice to the competence of the competent authorities to withdraw the delegation for reasons other than those referred to in this Regulation.	*第 33 條* **委託之權責機關的義務** 依照第 28(1)條委託特定官方管制任務予受委任機構或受託自然人，或是依照第 31 條委託與其他官方活動相關之特定任務予受委任機構或受託自然人之委託權責機關，應： (a)以如所需要之程度及避免重複的方式籌劃對該等機構或個人的稽核或檢查，並將第 29 條(b)(iv)點中所提及的任何認證納入考量 (b)在有下列情況時，立即全部或部分撤銷所委託之任務： (i)有證據顯示該受委任機構或自然人未能妥善履行受委託的任務； (ii)受委任機構或自然人未能採取適當且及時的行動來補救被發現的缺點；或 (iii)受委任機構或自然人的獨立性或公正性已被證明受到損害。 本點不應妨礙權責機關以本規章所提及之規定以外的理由撤銷該等委託任務的權限。
CHAPTER IV ***Sampling, analyses, tests and diagnoses***	*第 IV 章* ***取樣、分析、測試和診斷***

Article 34 **Methods used for sampling, analyses, tests and diagnoses**	*第 34 條* **用於取樣、分析、測試和診斷之方法**
1. Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods.	1. 在官方管制下和其他官方活動中用於取樣和用於實驗室分析、測試和診斷的方法應符合建立該等方法的歐盟規範或該等方法的執行標準。
2. In the absence of the Union rules as referred to in paragraph 1, and in the context of official controls and other official activities, official laboratories shall use one of the following methods according to the suitability for their specific analytical, testing and diagnostic needs:	2. 如果沒有第 1 項所提及之歐盟規範，並且在官方管制和其他官方活動的範圍內，官方實驗室應根據其特定的分析、測試和診斷的需要的適用性採用下列方法之一：
(a) available methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted; or relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols;	(a)符合相關國際公認規範或協議中的可用方法，其中包括該等歐洲標準化委員會(CEN)已接受的規範或協議；或是 由歐盟參考標準實驗室所開發，並依據國際間所接受的科學協議確效過的相關方法；
(b) in the absence of the suitable rules or protocols, as referred to in point (a), methods which comply with relevant rules established at national level, or, if no such rules exist, relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols.	(b)在沒有適當如(a)點所提及的規範或議定書的情況下，要採用符合以國家層級所制定的相關規範的方法，或者，如果此類規範不存在，則由國家參考標準實驗室所開發或所建議並根據國際間所接受的科學協議確效過的相關方法；或是 採用相關所開發的方法，該等方法並兼根據國際間所接受的科學協議之實驗室間或實驗室內之方法確效研究加以確效。
3. Where laboratory analyses, tests or diagnoses are urgently needed and none of the methods referred to in paragraphs 1 and 2 of this Article exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 37(1) may use methods other than those referred to in paragraphs 1 and 2 of this Article until the validation of an appropriate method in accordance with internationally accepted scientific protocols.	3. 如果迫切需要進行實驗室分析、測試或診斷，且本條第 1 項和第 2 項所提及之方法均不存在，則相關的國家參考標準實驗室，或者，如果不存在此類國家參考標準實驗室，則依照第 37(1)條所指定之任何其他實驗室，可使用本條第 1 項和第 2 項所提及的方法以外之方法，直到根據國際間所接受的科學協議之適當的方法獲得確效為止。
4. Wherever possible, methods used for laboratory analyses shall be characterised by the relevant criteria set out in Annex III.	4. 在可能的情況下，用於實驗室分析的方法應以附件 III 中列出的相關標準予以特色化。
5. Samples shall be taken, handled and labelled in such a way as to ensure their legal, scientific and	5. 樣品應以確保其合法、科學和技術的有效性的方

technical validity. 6. The Commission may, by means of implementing acts, lay down rules on: (a) the methods to be used for sampling and for laboratory analyses, tests and diagnoses; (b) performance criteria, analysis, test or diagnosis parameters, measurement uncertainty and procedures for the validation of those methods; (c) the interpretation of analytical, testing and diagnostic results. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	式加以採樣、處理和標示。 6. 歐盟執委會得，藉由施行細則，制定關於以下事項之規範： (a)用於取樣和用於實驗室分析、測試和診斷的方法； (b)執行標準、分析，測試或診斷之參數、量測不確定度以及該等方法之確效的程序； (c)對分析、測試和診斷結果的解釋。 上開施行細則應依第 145(2)條所提及之檢查程序加以採用。
Article 35 **Second expert opinion** 1. The competent authorities shall ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to a second expert opinion, at the operator's own expense. The right to a second expert opinion shall entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another recognised and appropriately qualified expert. 2. Where relevant, appropriate and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, the competent authorities shall: (a) when taking the sample, and if so requested by the operator, ensure that a sufficient quantity is taken to allow for a second expert opinion and for the review referred to in paragraph 3, should this prove necessary; or (b) where it is not possible to take a sufficient quantity as referred to in point (a), inform the operator thereof This paragraph shall not apply when assessing the presence of quarantine pests in plants, plant products or other objects for the purpose of verifying compliance with the rules referred to in point (g) of Article 1(2). 3. Member States may decide that, where there is a dispute between the competent authorities and the	*第 35 條* **第二方專家意見** 1. 權責機關應確保該等有動物或貨物在官方管制範圍內須被執行取樣、分析、測試或診斷的運營商有權獲得第二方專家意見，費用由運營商自行承擔。 獲得第二方專家意見的權利應使運營商有權要求由另一名經過認可且具有適當資格的專家對取樣、分析、測試或診斷進行文件審查。 2. 在有相關、適當和技術上可行時，並已特別考慮到動物或貨物中危害的普遍性和分佈、樣品或貨物的易腐壞性以及可用基質的數量的情況下，權責機關應： (a)在取樣時，如果運營商如此提出要求，應確保有足夠的取量樣品數俾可提供作為獲得第二方專家意見之用，以及若證明有必要時，可作為第 3 項所提及的審查之用；或者 (b)如無法取得(a)點所提及之足夠數量，則須通知該運營商。 當評估在植物、植物產品或其他物體中檢疫性害蟲生物是否存在，以查驗是否符合第 1(2)條(g)點所提及之規範時，本項將不適用。 3. 會員國可以決定，如果權責機關與使用基於第 1 項所提及之第二方專家意見的運營商之間存在爭議時，運營商可要求以自費方式對初始分析、

operators that is based on the second expert opinion referred to in paragraph 1, the operators may request, at their own expense, the documentary review of the initial analysis, test or diagnosis and, where appropriate, another analysis, test or diagnosis by another official laboratory. 4. The application by the operator for a second expert opinion under paragraph 1 of this Article shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal and plant health, or to animal welfare or, as regards GMOs and plant protection products, also to the environment, in accordance with this Regulation and with the rules referred to in Article 1(2).	測試或診斷進行書面文件審查，並在適當時，可由另一個官方實驗室進行另一次分析、測試或診斷。 4. 經運營商根據本條第 1 項提出的第二方專家意見的申請，根據本規章第 1(2)條條所提及之內容，不應影響權責機關立即採取行動以消除或遏制對人體、動物和植物健康，或對動物福祉，或關於基因改造生物及植物保護產品時，亦應考量對環境的風險。
Article 36 **Sampling of animals and goods offered for sale by means of distance communication** 1. In the case of animals and goods offered for sale by means of distance communication, samples ordered from operators by the competent authorities without identifying themselves may be used for the purposes of an official control. 2. Competent authorities, once they are in possession of the samples, shall take all steps to ensure that the operators from whom these samples have been ordered in accordance with paragraph 1: (a) are informed that such samples have been taken in the context of an official control and, where appropriate, are analysed or tested for the purposes of such official control; and (b) where the samples referred to in that paragraph are analysed or tested, are able to exercise the right to a second expert opinion, as provided for in Article 35(1). 3. Paragraphs 1 and 2 shall apply to delegated bodies and natural persons to which certain official controls tasks have been delegated.	*第 36 條* **藉由遠程通訊提供銷售動物和貨物之取樣** 1. 對於藉由遠程通訊方式提供銷售動物和貨物，權責機關以不表明其身份的方式從運營商處訂購的樣品，可作為官方管制之用。 2. 權責機關於一獲得樣品時，即應採取下述一切措施以確保權責機關已按照第 1 項的規定從中訂購這些樣品的該等運營商瞭解以下事宜： (a)被告知此等樣品是在官方管制的情況下取得的，並在適當時，該等樣品將被進行分析或測試以作為此項官方管制之用； (b)如果該項中提及的樣品被進行分析或測試時，則其能夠行使如第 35(1)條第二方專家意見的權利。 3. 第 1 項和第 2 項適用於被委託特定官方管制任務的受委任機構和自然人。
Article 37 **Designation of official laboratories** 1. The competent authorities shall designate official laboratories to carry out the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities, in the Member State in whose territory those competent authorities operate or in another Member State or a third country that is a Contracting Party to the Agreement on the European Economic Area.	*第 37 條* **官方實驗室之指定** 1. 權責機關應指定官方實驗室，對在權責機關運營的會員國，或在另一個會員國或歐洲經濟區協定締約方的第三國的官方管制和其他官方活動中取得的樣品，進行實驗室分析、測試和診斷。

2. Competent authorities may designate as an official laboratory a laboratory located in another Member State or third country that is a Contracting Party to the Agreement on the European Economic Area, subject to compliance with the following conditions:

(a) appropriate arrangements are in place under which the competent authorities are enabled to perform the audits and inspections referred to in Article 39(1) or delegate the performance of such audits and inspections to the competent authorities of the Member State or third country that is a Contracting Party to the Agreement on the European Economic Area where the laboratory is located; and

(b) that laboratory is already designated as an official laboratory by the competent authorities of the Member State on whose territory it is located.

3. The designation of an official laboratory shall be in writing and shall include a detailed description of:

(a) the tasks that the laboratory carries out as an official laboratory;

(b) the conditions under which it carries out the tasks referred to in point (a); and

(c) the arrangements necessary to ensure efficient and effective coordination and collaboration between the laboratory and the competent authorities.

4. The competent authorities may only designate as an official laboratory a laboratory which:

(a) has the expertise, equipment and infrastructure required to carry out analyses or tests or diagnoses on samples;

(b) has a sufficient number of suitably qualified, trained and experienced staff;

(c) ensures that the tasks conferred upon it as set out in paragraph 1 are performed impartially and which is free from any conflict of interest as regards the exercise of its tasks as an official laboratory;

(d) can deliver in a timely manner the results of the analysis, test or diagnosis carried out on the samples taken during official controls and other official activities; and

(e) operates in accordance with the standard EN ISO/IEC 17025 and is accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008.

5. The scope of the accreditation of an official laboratory as referred to in point (e) of paragraph 4:

(a) shall include those methods of laboratory analysis, test or diagnosis required to be used by the

2. 權責機關可指定位於另一會員國或歐洲經濟區協定締約方第三國之實驗室作為官方實驗室，但該實驗室須符合下列條件：

(a)已備有適當的安排，使權責機關能夠據以執行第39(1)條所提及之稽核和檢查，或將此類稽核和檢查的執行委託給會員國或是實驗室所在之歐洲經濟區協定締約方第三國之權責機關；以及
(b)該實驗室已被其所在地區的會員國之權責機關指定為官方實驗室。

3. 官方實驗室的指定應採用書面形式，並應包括以下內容的詳細說明：
(a)實驗室作為官方實驗室所執行的任務；
(b)所據以執行(a)點所提及之任務的條件；以及
(c)有確保實驗室與權責機關之間得以進行有效率和有效的協調與合作所必須的安排。

4. 權責機關可只指定具有下列條件的實驗室作為官方實驗室：
(a)具備執行關於樣品的分析、測試或診斷所需的專業知識、設備和基礎設施；
(b)擁有足夠的合格、訓練有素且經驗豐富的職員；
(c)確保第1項所列之被賦予的任務在執行時是公正的，並且在執行其作為官方實驗室的任務時不存在任何利益衝突；
(d)能夠及時提供對官方管制和其他官方活動中所取得樣品的分析、測試或診斷結果；以及
(e)按照 EN ISO/IEC 17025 標準運作，並由依據(EC)765/2008 號規章運作的國家認證機構按照該標準進行認證採用。

5. 第4項(e)點所提及的官方實驗室之認證的範圍如下：
(a)在實驗室以官方實驗室身分運作時，應包括該等

laboratory for analyses, tests or diagnoses, when it operates as an official laboratory; (b) may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods; (c) may be defined in a flexible manner, so as to allow the scope of accreditation to include modified versions of the methods used by the official laboratory when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratory's own validations without a specific assessment by the national accreditation body prior to the use of those modified or new methods. 6. Where no official laboratory designated in the Union or in a third country that is a Contracting Party to the Agreement on the European Economic Area in accordance with paragraph 1 has the expertise, equipment, infrastructure and staff necessary to perform new or particularly uncommon laboratory analyses, tests or diagnoses, the competent authorities may request a laboratory or diagnostic centre which does not comply with one or more of the requirements set out in paragraphs 3 and 4 to carry out those analyses, tests and diagnoses.	用於實驗室分析、測試或診斷的實驗室分析、測試或診斷方法； (b)可包括一種或多種實驗室分析、測試或診斷方法或方法組； (c)可以彈性的方式定義，以便允許認證範圍包括官方實驗室在獲得認證當時使用的方法之修改版本，或除了該等方法之外之新方法，而該等修改後的方法或新方法在使用前係基於實驗室自己做的確效而未經國家認證機構具體評估。 6. 當歐盟或在依第 1 項所述之歐洲經濟區協定締約方的第三國所指定的官方實驗室沒有執行新的或特別罕見的實驗室分析、測試或診斷所需的專業知識、設備，基礎設施和職員，權責機關可要求不符合第 3 項和第 4 項所提及的一項或多項要求的實驗室或診斷中心執行該等分析、測試和診斷。
Article 38 **Obligations of official laboratories** 1. Where the results of an analysis, test or diagnosis carried out on samples taken during official controls or other official activities indicate a risk to human, animal or plant health, or, as regards GMOs and plant protection products, also to the environment, or point to the likelihood of non-compliance, official laboratories shall inform immediately the competent authorities which designated them for that analysis, test or diagnosis and, where relevant, delegated bodies or natural persons to which tasks have been delegated. However, specific arrangements between the competent authorities, delegated bodies or natural persons to which tasks have been delegated and the official laboratories may specify that this information is not required to be provided immediately. 2. Upon request by the European Union reference laboratory or national reference laboratory, official laboratories shall take part in inter-laboratory comparative tests or proficiency tests that are organised for the analyses, tests or diagnoses they perform as official laboratories. 3. Official laboratories shall, upon request of the competent authorities, make available to the public the	*第 38 條* **官方實驗室之義務** 1. 若在對官方管制或其他官方活動期間取得的樣品所執行之分析、測試或診斷的結果顯示有對人類、動物或植物健康，或關於基因改造生物和植物保護產品，亦應考量對環境的風險，或指出不符合的可能性時，官方實驗室應立即通知委託他們進行分析、測試或診斷的權責機關，並且，相關時，亦應通知已受委託任務的受委任機構或自然人。然而，權責機關、受委託任務的受委任機構或自然人與官方實驗室之間的具體安排得指明不需要立即提供該資訊。 2. 應歐盟參考標準實驗室或國家參考標準實驗室的要求，官方實驗室應參加實驗室間比對測試或能力測試，這些比對測試或能力測試是為該等實驗室作為官方實驗室所執行的分析、測試或診斷之表現而籌劃的。 3. 官方實驗室須應權責機關的要求，向公眾提供在

names of the methods used for analyses, tests or diagnoses performed in the context of official controls and other official activities. 4. Official laboratories shall indicate, at the request of the competent authorities, together with the results, the method used for each analysis, testing or diagnosis, performed in the context of official controls and other official activities.	官方管制和其他官方活動中所執行的分析、測試或診斷時所用方法的名稱。 4. 官方實驗室應依權責機關的要求，將在官方管制和其他官方活動範圍內所執行之結果以及每種分析、測試或診斷所用的方法予以表明。
Article 39 **Audits of official laboratories** 1. The competent authorities shall organise audits of the official laboratories they have designated in accordance with Article 37(1) on a regular basis and any time they consider that an audit is necessary, unless they find such audits to be redundant considering the accreditation assessment referred to in point (e) of Article 37(4). 2. The competent authorities shall immediately withdraw the designation of an official laboratory, either completely or for certain tasks, where it fails to take appropriate and timely remedial action following the results of an audit provided for in paragraph 1 which disclose any of the following: (a) it no longer complies with the conditions provided for in Article 37(4) and (5); (b) it does not comply with the obligations provided for in Article 38; (c) it is underperforming at inter-laboratory comparative tests referred to in Article 38(2).	*第 39 條* **官方實驗室的稽核** 1. 權責機關應定期以及在他們認為必要時之任何時間，對他們根據第 37(1)條指定的官方實驗室進行稽核，除非他們發現在考量已執行第 37(4)條之(e)點所提及的認證評估後，此種稽核是多餘的。 2. 如果一官方實驗等於接受第 1 項中所述的稽核而該稽核揭露以下任何事項之後本能採取適當和及時的補正措施，權責機關應立即撤銷，可為全部或某些任務之撤銷，該官方實驗室的指定資格： (a)該實驗室不再符合第 37(4) 和(5)條的條件； (b)未符合第 38 條所規定的義務； (c)在第 38(2)條所提及之實驗室間的比較試驗中表現不佳。
Article 40 **Derogations from the condition for the mandatory accreditation for certain official laboratories** 1. By way of derogation from point (e) of Article 37(4), competent authorities may designate the following as official laboratories irrespective of whether they fulfil the condition provided for in that point: (a) laboratories: (i) whose sole activity is the detection of *Trichinella* in meat; (ii) that only use the methods of detection of Trichinella referred to in Article 6 of Commission	*第 40 條* **特定官方實驗室的強制認證條件之例外** 1. 作為第 37(4)條之(e)點規定之例外，權責機關可將下列情況之實驗室指定為官方實驗室，不論其是否符合該點規定的條件： (a)實驗室： (i)其唯一活動是檢測肉類中的旋毛蟲者； (ii)僅使用歐盟執委會實施規章(EU)2015/1375 第 6 條所提及之旋毛蟲偵測方法者； (iii)在權責機關或根據第 37(1)條所指定的官方

Implementing Regulation (EU) 2015/1375 [58]; (iii) that carry out the detection of Trichinella under the supervision of the competent authorities or of an official laboratory designated in accordance with Article 37(1) and accredited in accordance with the standard EN ISO/IEC 17025 for the use of the methods referred to in point (ii) of this point; and (iv)that participate regularly and have satisfactory performance in the inter-laboratory comparative tests or proficiency tests organised by the national reference laboratories for the methods they use for the detection of Trichinella; (b) laboratories which only carry out analyses, tests or diagnoses in the context of other official activities, provided that they: (i) only use the methods of laboratory analysis, test and diagnosis referred to in Article 34(1) and point (a) or (b) of Article 34(2); (ii) carry out the analyses, tests or diagnoses under the supervision of the competent authorities or of the national reference laboratories in relation to the methods they use; (iii) participate regularly and have satisfactory performance in the inter-laboratory comparative tests or proficiency tests organised by the national reference laboratories in relation to the methods they use; and (iv) have a quality assurance system in place to ensure sound and reliable results from the methods for laboratory analysis, test and diagnosis used. 2. Where the methods used by the laboratories referred to in point (b) of paragraph 1 of this Article require confirmation of the result of the laboratory analysis, test or diagnosis, the confirmatory laboratory analysis, test or diagnosis shall be carried out by an official laboratory which complies with the requirements set out in point (e) of Article 37(4). 3. The official laboratories designated in accordance with paragraph 1 shall be located in the Member States in whose territory the competent authorities which have designated them are located.	實驗室之監督下進行旋毛蟲的偵測，並為使用本(a)點之(ii)所提及之方法而經 EN ISO/IEC 17025 標準接受認證者；以及 (iv)定期參加由國家參考標準實驗室所籌劃之毛蟲偵測方法的實驗室間比對測試或能力測試，取得令人滿意的成績者； (b)僅在其他官方活動範圍內執行分析、測試或診斷的實驗室，若其符合下列條件： (i)只使用第 34(1)條及第 34(2)條的(a)或(b)點所提及的實驗室分析、測試或診斷方法者； (ii)在權責機關或國家參考標準實驗室的監督下，就其使用的方法進行分析、測試或診斷者； (iii)定期參加由國家參考標準實驗室籌劃之的關於其使用方法的實驗室間比對測試或能力測試取得令人滿意的成績者；及 (iv)已有一品質保證系統在運作，以確保所使用之實驗室分析、測試和診斷方法產出合理可靠的結果。 2. 如果本條第 1 項(b)點所提及之實驗室所使用的方法需要確認實驗室分析、測試或診斷的結果，則應由符合第 37(4)條之(e)點規定之要求的官方實驗室執行確認之實驗室分析、測試或診斷。 3. 按照第 1 項所指定的官方實驗室應設在指定該等實驗室之權責機關所在的會員國領土內。

58 Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for Trichinella in meat (OJ L 212, 11.8.2015, p. 7)./ 歐盟執委會 2015 年 8 月 10 日(EU)2015/1375 號制定關於肉類中旋毛蟲官方控制的具體規則之施行細則。

Article 41 **Powers to adopt derogations from the condition for the mandatory accreditation of all the methods of laboratory analysis, test and diagnosis used by official laboratories** The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the conditions under which, competent authorities may designate as official laboratories, in accordance with Article 37(1), laboratories which do not fulfil the conditions referred to in point (e) of Article 37(4) in relation to all the methods they use for official controls or other official activities, provided that such laboratories comply with the following conditions: (a) they operate and are accredited in accordance with the standard EN ISO/IEC 17025 for the use of one or more methods which are similar to and representative of the other methods they use; and (b) they make regular and significant use of the methods for which they have obtained the accreditation referred to in point (a) of this Article; except, as regards the area governed by the rules referred to in point (g) of Article 1(2), where a validated method for the detection of the particular pests of plants referred to in Article 34(1) and (2) does not exist.	*第 41 條* **對官方實驗室使用的所有實驗室分析、測試和診斷方法須進行強制認證的條件之例外情形的採用權力** 歐盟執委會應依據第 44 條採用授權法規，訂定實驗室不符合第 37(4)條之(e)點所提及關於該等實驗室於官方管制或其他官方活動中所使用的所有方法之條件，惟若該等實驗室符合下列條件，權責機關仍得依第 37(1)條將該等實驗室指定為官方實驗室之情形，以補充本規章： (a)該等實驗室就與其使用的其他方法相似並具有代表性之一種或多種方法而使用依據 EN ISO/IEC 17025 標準運作並經過認證；以及 (b)該等實驗室定期和主要的使用本條(a)點所提及經之認證的方法；惟於有關受第 1(2)條之(g)點所提及之規範所規定的領域，然第 34(1)條和(2)所提及之用於偵測植物之特殊害蟲之經確效的方法確實不存在時之情形除外。
Article 42 **Temporary derogations from the conditions of the mandatory accreditation for official laboratories** 1. By way of derogation from point (a) of Article 37(5), the competent authorities may temporarily designate an existing official laboratory as an official laboratory in accordance with Article 37(1) for the use of a method of laboratory analysis, test or diagnosis for which it has not obtained the accreditation referred to in point (e) of Article 37(4): (a) when the use of that method is newly required by Union rules; (b) when changes to a method in use require a new accreditation or an extension of the scope of the accreditation obtained by the official laboratory; or (c) in cases where the need for the use of the method results from an emergency situation or an emerging risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment. 2. The temporary designation referred to in paragraph 1 shall be subject to the following conditions:	*第 42 條* **官方實驗室強制認證的條件之暫時例外** 1. 作為第 37(5)條之(a)點規定之例外，權責機關可根據第 37(1)條暫時指定現有的官方實驗室作為官方實驗室，以使對未獲得第 37(4)條之(e)點所提及之認證之現有的官方實驗室可於以下情形使用實驗室分析、測試或診斷之方法。 (a)當歐盟規範對該方法之使用有新的要求時； (b)當使用中的方法的變更需要新的認證或擴大官方實驗室獲得的認證範圍時；或是 (c)如果所使用方法的需求是由於緊急情況或是對人類、動物或植物健康、動物福祉，或關於基因改造生物和植物保護產品，亦對環境造成的新興形成風險所產生時。 2. 第 1 項所提及之暫時指定應符合下列條件：

(a) the official laboratory is already accredited in accordance with the standard EN ISO/IEC 17025 for the use of a method which is similar to the one not included within the scope of its accreditation; (b) a quality assurance system is in place in the official laboratory to ensure sound and reliable results by using a method which is not included within the scope of the existing accreditation; (c) the analyses, tests or diagnoses are carried out under the supervision of the competent authorities or the national reference laboratory for that method. 3. The temporary designation provided for in paragraph 1 shall not exceed a period of one year. It may be renewed once for a further period of one year. 4. The official laboratories designated in accordance with paragraph 1 shall be located in the Member States in whose territory the competent authorities which have designated them are located.	(a)該官方實驗室已就與未包括在其認證範圍內的方法及相似方法之使用根據 EN ISO / IEC 17025 標準獲得認證； (b)該官方實驗室已運作一套品質保證系統，以確保所使用之不屬於現有認證範圍的方法仍能產出合理可靠的結果； (c)使用此種未受認證之方法執行分析、測試或診斷，應在權責機關或國家參考標準實驗室的監督下進行。 3. 第 1 項規定的暫時指定不得超過一年。其可更新一次，期間再延長一年。 4. 根據第 1 項**指定**的官方實驗室應設在指定該等實驗室的權責機關所在的會員國內。
CHAPTER V ***Official controls on animals and goods entering the Union***	*第 V 章* ***進入歐盟的動物和貨物之官方管制***
Article 43 **Official controls on animals and goods entering the Union** Official controls on animals and goods entering the Union shall be organised on a risk basis. In relation to animals and goods referred to in Articles 47 and 48, such official controls shall be performed in accordance with Articles 47 to 64.	*第 43 條* **進入歐盟的動物和貨物之官方管制** 進入歐盟的動物和貨物的官方管制應以風險為基礎進行籌劃。 關於第 47 和 48 條所提及之動物和貨物，此等官方管制應按照第 47 至 64 條進行。
Section I **Animals and goods other than those subject to official controls at border control posts under section II**	第 I 部分 **除依第 II 部分之要求於邊境管制站接受官方管制以外的動物和貨物**
Article 44 **Official controls on animals and goods other than those subject to official controls at border control posts under Section II** 1. To ascertain compliance with the rules referred to in Article 1(2), the competent authorities shall perform official controls regularly, on a risk basis and with appropriate frequency, on animals and goods entering the Union and to which Articles 47 and 48 do not apply. 2. On animals and goods referred to in paragraph 1 the appropriate frequency of the official controls shall be determined, taking into account:	*第 44 條* **關於除依第 II 部分要求於邊境管制站接受官方管制以外的動物和貨物所執行的官方管制** 1. 為了確實符合第 1(2)條所提及之規範，權責機關應在風險的基礎上並以適當的頻率，定期對進入歐盟以及不適用第 47 條和第 48 條的動物和貨物實施官方管制。 2. 關於第 1 項所提及之動物和貨物，應確定適當的官方管制頻率，並考慮到下列事項：

(a) the risks to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, associated with different types of animals and goods;

(b) any information indicating the likelihood that consumers might be misled, in particular as to the nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production of goods;

(c)the history of compliance with the requirements established by the rules referred to in Article 1(2) applicable to the animals or goods concerned:

(i) of the third country and establishment of origin or place of production, as appropriate;

(ii) of the exporter;

(iii) of the operator responsible for the consignment;

(d) the controls that have already been performed on the animals and goods concerned; and

(e) the guarantees that the competent authorities of the third country of origin have given with regard to compliance of the animals and goods with the requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto.

3. The official controls provided for in paragraph 1 shall be performed at an appropriate place within the customs territory of the Union, including:

(a) the point of entry into the Union;

(b) a border control post;

(c) the point of release for free circulation in the Union;

(d) the warehouses and the premises of the operator responsible for the consignment;

(e) the place of destination.

4. Notwithstanding paragraphs 1 and 3, the competent authorities at border control posts and other points of entry into the Union shall perform official controls on the following whenever they have reason to believe that their entry into the Union may pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment:

(a) means of transport, including where empty; and

(b) packaging, including pallets.

(a)與不同類型的動物和貨物有關之對人類、動物或植物健康、動物福祉，或關於基因改造生物和植物保護產品，亦對環境造成影響的風險；

(b)任何提出消費者可能有被誤導的可能性之資訊，特別是有關貨物的本質、身分、性質、成分、數量、耐用性、原產國或出產地，製造或生產方法的資訊；

(c)對下列對象對適用於所涉動物或貨物之依第1(2)條所提及之規範而訂定的要求之符合性的履歷：

(i)恰如其分之第三國和原產地或生產地之廠場的；

(ii)出口商的；

(iii)負責該批貨物之運營商的；

(d)已對所涉動物及貨物執行的管制； 和

(e)第三國原產國之權責機關就動物和貨物對第1(2)條所提及之規範之要求或與已確認至少為相當的要求之符合性所已提供的保證。

3. 第1項規定的官方管制措施應在歐盟關稅區內的適當地點進行，其中包括：

(a)進入歐盟的點；

(b)邊境管制站；

(c)歐盟自由流通的發貨點

(d)負責貨物的運營商的倉庫及處所；

(e)目的地

4. 儘管有第1和第3項的規定，在邊境管制站和其他進入歐盟的點之權責機關，只要有理由相信該等動物及貨物進入歐盟可能對人類、動物或植物健康、動物福祉，或關於基因改造生物和植物保護產品，以及環境構成危險，均應對例事項進行官方管制：

(a)運輸方式，包括未擺放物品的地方； 以及

(b)包裝，其中包括棧板。

5. The competent authorities may also perform official controls on goods that are placed under one of the customs procedures defined in point (16)(a), (b) and (c) of Article 5 of Regulation (EU) No 952/2013 and in a temporary storage defined in point (17) of Article 5 of that Regulation.	5. 權責機關亦得就根據(EU)952/2013 號規章第 5 條第(16)(a)、(b)和(c)點規定的海關程序之一所置放以及該法規第 5 條第(17)點規定的臨時儲存點之貨物實施官方管制。
Article 45 **Types of official controls on animals and goods other than those subject to official controls at border control posts under Section II** 1. Where official controls are performed in accordance with Article 44(1), they shall: (a) always include a documentary check; and (b) include identity checks and physical checks depending on the risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment. 2. The competent authorities shall carry out the physical checks referred to in point (b) of paragraph 1 under appropriate conditions allowing investigations to be conducted properly. 3. Where the documentary checks, identity checks or physical checks referred to in paragraph 1 of this Article show that animals and goods do not comply with the rules referred to in Article 1(2), Article 66(1), (3) and (5), Articles 67, 68, and 69, Article 71(1) and (2), Article 72(1) and (2), Articles 137 and 138 shall apply. 4. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where and the conditions under which competent authorities may request operators to notify the arrival of certain goods entering the Union.	*第 45 條* **除依第 II 部分規定在邊境管制站執行官方管制之外的動物和貨物之官方管制類型** 1. 如果按照第 44(1)條執行官方管制，則應： (a)必定包括文件檢查；以及 (b)包括根據對人類、動物或植物健康、動物福祉或關於基因改造生物和植物保護產品，以及對環境的風險所做的身分檢查和物性檢查。 2. 權責機關應在可妥適地執行調查之適當條件下進行第 1 項第(b)點所提及之物性檢查，以進行適當的調查。 3. 當本條第 1 項所提及之文件檢查、身分檢查或物性檢查指出動物和貨物不符合第 1(2)條、第 66(1)條、(3)和(5)， 第 67, 68 和 69 條，第 71(1)條和(2)，第 72(1)條和(2)所提及之規範時，則應適用第 137 和 138 條之規範。 4. 歐盟執委會有權根據本法第 144 條採用授權法規以補充本規章中關於權責機關可要求運營商應通知特定之進入歐盟的貨物已抵達歐盟的條件之情形。
Article 46 **Samples taken on animals and goods other than those subject to official controls at border control posts under Section II** 1. Where samples on animals and goods are taken, the competent authorities shall, without prejudice to Articles 34 to 42: (a) inform the operators concerned and, where appropriate, the customs authorities; and (b) decide whether the animals or goods need to be detained pending the results of the analysis, test or diagnosis carried out, or whether they can be released provided that the traceability of the animals or	*第 46 條* **對除依第 II 部分規定在邊境管制站執行官方管制之外的動物和貨物所作之取樣** 1. 如果動物和貨物樣本已取得，權責機關應在不影響第 34 至 42 條的情況下執行下列事宜： (a)通知所涉運營商，並在適當時通知海關；以及 (b)決定是否需要在所執行的分析、測試或診斷的結果出來之前留置該等動物或貨物，或者只要確保動物或貨物的可追溯性，它們就可以被放行。 2. 歐盟執委會應藉由施行細則：

goods is ensured. 2. The Commission shall, by means of implementing acts: (a) establish the procedures necessary to ensure the traceability of the animals or goods referred to in point (b) of paragraph 1; and (b) identify the documents that must accompany the animals or goods referred to in paragraph 1 when samples have been taken by the competent authorities. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	(a) 制定必要的程序，以確保第 1 項第(b)點所提及之動物或貨物的可追溯性;以及 (b)明訂在權責機關取樣時，必須隨同第 1 項所提及動物或貨物必須附帶的文件。 上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
Section II **Official controls at border control posts on animals and goods**	第 II 部分 **關於動物和貨物在邊境管制站所作之官方管制**
Article 47 **Animals and goods subject to official controls at border control posts** 1. To ascertain compliance with the rules referred to in Article 1(2), the competent authorities shall perform official controls, at the border control post of first arrival into the Union, on each consignment of the following categories of animals and goods entering the Union: (a) animals; (b) ►M1products of animal origin, germinal products and animal by-products; products of animal origin, germinal products, animal by-products, hay and straw and foodstuffs containing both products of plant origin and processed products of animal origin (“composite products”) ◄M1 (c) plants, plant products, and other objects as referred to in the lists established pursuant to Articles 72(1) and 74(1) of Regulation (EU) 2016/2031; (d) goods from certain third countries for which the Commission has decided, by means of implementing acts provided for in point (b) of paragraph 2 of this Article, that a measure requiring a temporary increase of official controls at their entry into the Union is necessary due to a known or emerging risk or because there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) might be taking place; (e) ►M3 animals and goods which are subject to an emergency measure provided for in acts adopted in	*第 47 條* **須接受邊境管制站所作之官方管制的動物和貨物** 1. 為了確保符合第 1(2)條所提及之規範，權責機關應對下列各類進入歐盟的每批動物和貨物首次抵達歐盟的邊境管制站進行官方管制： (a)動物； (b)動物源產品、胚種產品、動物副產品、乾草，稻草和含有植物源及經加工的動物源產品的食品（複合性產品）； (c)根據(EU)2016/2031 號規章第 72(1)條和 74(1)條訂定的清單中所提及的植物、植物產品和其他物品; (d)來自第三國的貨物，而該等貨物係歐盟執委會採用執行本條第 2 項之第(b)點所述之施行細則而決定，由於已知或新興的風險，或有證據表明可能即將發生普遍嚴重不符合第 1(2)條所述規範的情況故須在他們進入歐盟時需採取暫時增加官方管制的措施 ； (e)須接受根據(EC)178/2002 號規章第 53 條、(EC)2016/429 號規章第 261 條，或(EU)2016/2031 規章中第 28(1)條、第 30(1)條，40(3)條，41(3)

accordance with Article 53 of Regulation (EC) No 178/2002, Article 261 of Regulation (EU) 2016/429, or Articles 28(1), 30(1), 40(3), 41(3), 49(1), 53(3) and 54(3) of Regulation (EU) 2016/2031 requiring consignments of those animals or goods, identified by means of their codes from the Combined Nomenclature, to be subject to official controls at their entry into the Union; ◄M3	條，49(1)條，53(3)條和 54(3)條等條所採用之法案中所述的採取緊急措施之動物和貨物，該等法令要求採用依聯合命名法的代碼所識別出的動物或貨物之託運物，在進入歐盟時須受到官方管制；
(f) animals and goods in relation to whose entry into the Union conditions or measures have been established by acts adopted in accordance with Article 126 or 128 respectively, or with the rules referred to in Article 1(2), which require that compliance with those conditions or measures be ascertained at the entry of the animals or goods into the Union.	(f)與分別根據第 126 條或第 128 條，或第 1(2)條所提及之規章所採用之法案中所提及定進入歐盟之條件或措施相關的動物和貨物，該等法令要求這些條件或措施之符合性應在動物或貨物進入歐盟時予以確定。
2. The Commission shall, by means of implementing acts:	2. 歐盟執委會應藉由施行細則：
(a) establish lists which set out all the animals and goods referred to in points (a) and (b) of paragraph 1, indicating their codes from the Combined Nomenclature; and	(a)列出第 1 項之(a)及(b)點所提及的所有動物及貨物的清單，其中包括列明合併命名法中的代號；和
(b) establish the list of goods belonging to the category referred to in point (d) of paragraph 1, indicating their codes from the Combined Nomenclature, and update it as necessary in relation to the risks referred to in that point. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	(b)確定屬於第 1 項第(d)點所提及之類別的貨物清單，並採聯合命名法指出它們的代碼，並就與該點其中所提到的風險做必要的進行更新。 上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning amendments to the categories of consignments referred to in paragraph 1 of this Article, to include composite products, hay and straw, and other products strictly limited to products presenting a newly identified or a significantly increased risk to human, animal or plant health or, as regards GMOs and plant protection products, also to the environment.	3. 歐盟執委會有權根據第 144 條採用授權法規以修訂本規章中關於本條第 1 項所提及之託運物類別之修訂，包括複合性產品、乾草和稻草，以及嚴格限於對人類、動物或植物健康，或者關於基因改造生物和植物保護產品，以及對環境具有產生新辨識出的或顯著增加風險的其他產品。
4. Unless otherwise provided by the acts establishing the measures or conditions referred to in points (d), (e) and (f) of paragraph 1, this Article shall also apply to consignments of the categories of animals and goods referred to in points (a), (b) and (c) of paragraph 1 when they are of a non-commercial nature.	4. 除使用以制定第 1 項第(d)、(e)和(f)點所提及之措施或條件的法令另有規定外，本條亦應適用於第 1 項第(a)、(b)和(c)點所提及之非商業性質之動物和貨物類別的託運物。
5. Operators responsible for the consignment shall ensure that animals and goods of the categories referred to in paragraph 1 are presented for official controls at the border control post referred to	5. 負責託運物之運營商應確保第 1 項所提及之類別的動物和貨物在所提及之邊境管制站被提交以作官方管制。

therein.	
Article 48 **Animals and goods exempted from official controls at border control posts** The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules establishing the cases where, and the conditions under which, the following categories of animals and goods are exempted from Article 47, and when such exemption is justified: (a) goods sent as trade samples or as display items for exhibitions, which are not intended to be placed on the market; (b) animals and goods intended for scientific purposes; (c) goods on board means of transport operating internationally which are not unloaded and are intended for consumption by the crew and passengers; (d) goods which form part of passengers personal luggage and are intended for personal consumption or use; (e) small consignments of goods sent to natural persons which are not intended to be placed on the market; (f) pet animals as defined in point (11) of Article 4 of Regulation (EU) 2016/429; (g) goods which have undergone specific treatment and do not exceed quantities to be established in those delegated acts; (h) categories of animals or goods posing a low risk or no specific risk and for which controls at border control posts are therefore not necessary.	*第 48 條* **在邊境管制站豁免官方管制的動物和貨物** 歐盟執委會應根據第 144 條採用授權法規以補充本規章中有關制定以下類別的動物和貨物豁免於第 47 條的情況與條件之規範，以及何時此種豁免是合理的： (a)寄送作為貿易樣品或作為展覽展示物品，而不打算於市面上銷售的貨物； (b)用於科學目的的動物和貨物； (c)在國際間運輸工具上的貨物，而尚未卸下並且係供運輸工具上的服務人員和乘客消費之用； (d)貨物構成旅客個人行李的一部分並供個人消費或使用； (e)寄給自然人而不打算於市面上銷售小批貨物； (f)如(EU)2016/429 號規章第 4 條第(11)點所定義的寵物； (g)經過特殊處理且不超過該等授權法規中所提及數量的貨物； (h)具有低風險或無特定風險，故無需於邊境管制站執行管制的動物或貨物類別。
Article 49 **Official controls at border control posts** 1. To verify compliance with the applicable requirements laid down in the rules referred to in Article 1(2), the competent authorities shall perform official controls on the consignments of the categories of animals and goods referred to in Article 47(1) upon arrival of the consignment at the border control post. Those official controls shall include documentary checks, identity checks and physical checks. 2. Physical checks shall be performed where those checks concern:	*第 49 條* **邊境管制站的官方管制** 1. 為了查驗是否符合第 1(2)條所提及之規範的適用要求，權責機關應對第 47(1)條所提及之動物和託運物類別的貨物在一抵達邊境管制站時進行官方管制。 該等官方管制應包括文件檢查、身分檢查和物性檢查。 2. 當該等檢查涉及下例這些的情況等，應執行物性檢查：

(a) animals, except aquatic animals, or meat and edible meat offal, by an official veterinarian, who may be assisted by staff trained in accordance with the requirements established under paragraph 5 in veterinary matters and designated by the competent authorities for that purpose; (b) aquatic animals, products of animal origin other than the ones referred to in point (a) of this paragraph, germinal products or animal by-products, by an official veterinarian or by staff trained in accordance with the requirements established under paragraph 5 and designated by the competent authorities for that purpose; (c) plants, plant products and other objects, by an official plant health officer. 3. The competent authorities at border control posts shall systematically perform official controls on consignments of animals being transported and on means of transport to verify compliance with the animal welfare requirements laid down in the rules referred to in Article 1(2). Competent authorities shall put in place arrangements to give priority to official controls on animals being transported and to reduce delays on such controls. 4. The Commission may, by means of implementing acts, lay down rules on the practical arrangements for presentation of consignments of the categories of animals and goods referred to in Article 47(1), the transport units or sub-entities which can constitute an individual consignment and the maximum number of such transport units or sub-entities in each consignment, taking into account the need to ensure the rapid and efficient handling of the consignments and the official controls to be performed by the competent authorities and, where relevant, international standards. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). 5. The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules establishing specific training requirements for staff referred to in paragraph 2 of this Article for the performance of the physical checks at the border control posts.	(a)動物(除了水產動物，或肉類和食用碎肉以外)，應由官方獸醫執行，該獸醫可由在獸醫事務中根據第 5 項所制定規定的要求接受培訓並由權責機關為該目的指定的職員協助； (b)水產動物，除本項(a)點所提及之以外之動物源產品、胚種產品或動物副產品，應由官方獸醫執行或按照第 5 項所制訂規定的要求接受培訓並由權責機關為該目的指定之職員執行； (c)植物、植物產品和其他物品，由官方的植物衛生官員執行。 3. 邊境管制站的權責機關應系統性地對運輸的動物託運物和運輸工具實施官方管制，以查驗是否符合第 1(2)條所提及之規範的動物福祉要求。權責機關應制定相關安排，優先對正在運輸的動物執行官方管制作業，並減少此類管制作業的延誤。 4. 歐盟執委會可藉由施行細則，明訂對第 47(1)條所提及之動物和貨物類別的託運物的呈現方式之實際安排、構成一個個別託運批之運輸包裝單位或更小包裝單位以及每批託運物中此類運輸包裝單位或更小包裝單位最大數量，同時考慮到確保快速有效率的處理該等託運物的需求以及由權責機關和，相關時，國際標準所執行之官方管制的規範。 上開施行細則應按照第 145(2)條所提及之審查程序予以採用。 5. 歐盟執委會應根據第 144 條採用授權法規以補充本規章，關於制定為而對本條第 2 項所提及之職員規定具體培訓要求的，以利在邊境管制站進行物性檢查的規範。
Article 50 **Certificates and documents accompanying consignments and split consignments** 1. The original official certificates or documents, or electronic equivalents, which are required by the rules referred to in Article 1(2) to accompany consignments of the categories of animals and goods	*第 50 條* **貨物和分拆貨物之附隨的證書與文件** 1. 第 1(2)條所提及之規範所要求須隨附於第 47(1)條條所提及之動物與貨物的類別之託運物的原始正式證書或文件，或電子等同文件，除非

referred in Article 47(1) shall be presented to, and kept by, the competent authorities of the border control post unless otherwise provided for in the rules referred to in Article 1(2). 2. The competent authorities of the border control post shall issue the operator responsible for the consignment with an authenticated paper or electronic copy of the official certificates or documents referred to in paragraph 1 or, if the consignment is split, with individually authenticated paper or electronic copies of such certificates or documents. 3. Consignments shall not be split until official controls have been performed and the Common Health Entry Document (CHED) referred to in Article 56 has been finalised in accordance with Article 56(5) and Article 57. 4. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules establishing the cases where, and the conditions under which, the CHED is required to accompany consignments of the categories of animals and goods referred to in Article 47(1) to the place of destination.	第 1(2)條所提及之規範另有要求外，提交予邊境管制站之權責機關保管。 2. 邊境管制站的權責機關應向負責該批託運物的運營商核發第 1 項所提及之正式證書或文件之紙質的或電子的正本，如果貨物被拆分，則應經個別核發此等證書或文件之紙質的或電子的正本。 3. 在官方管制已執行完成並且第 56 條所提及之共同衛生報單文件(CHED)已根據第 56(5)條和第 57 條最終確定之前，不得拆分託運物。 4. 歐盟執委會有權根據第 144 條採用授權法規以補充本規章中關於制定案件的規範，以及在何種情況下 CHED 必須與第 47(1)條所提及之動物和貨物之類別的託運物一起送達目的地。
Article 51 **Specific rules for official controls at border control posts** 1. The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules to supplement this Regulation concerning rules toestablish: (a) the cases where, and the conditions under which, the competent authorities of a border control post may authorise the onward transportation of consignments of the categories of animals and goods referred to in Article 47(1) to the place of final destination pending the availability of the results of physical checks, where such checks are required; (b) the time limits and arrangements for carrying out documentary checks and, where necessary, identity checks and physical checks on categories of animals and goods subject to the official controls provided for in Article 47(1) which enter the Union by sea or by air transport from a third country, when those animals or goods are moved from a vessel or aircraft and are transported under customs supervision to another vessel or aircraft in the same port or airport in preparation for onward travel ('transhipped consignments');	*第 51 條* **邊境管制站官方管制的具體規範** 1. 歐盟執委會應根據第 144 條採用授權法規，以補充本規章有關下列事宜須制定之規範： (a)在物性檢查係必須而在物性檢查結果尚未取得前，在何種情況下，以及何種條件下，邊境管制站之權責機關可授權將第 47(1)條所提及之動物和貨物類別的託運物繼續運送至最終目的地; (b)對經由海運或空運之來自第三國之受第 47(1)條規定的官方管制的動物和貨物類別進行識別檢查和物性檢查，該等動物和貨物採用海運或採用來自第三國的航空運輸，當該等動物或貨物從船隻或飛機上移出並在海關監管下運往同一港口或機場的另一艘船隻或飛機以準備繼續運送時(「轉運貨物」）進行文件檢查的時限和安排，必要時，對該等動物及貨物執行身分檢查及物性檢查; (c)轉運貨物以及逕由空運或海運抵達並繼續停留

(c) the cases where, and the conditions under which, identity checks and physical checks of transhipped consignments and of animals arriving by air or sea and staying on the same means of transport for onward travel may be performed at a border control post other than the one of first arrival into the Union; (d) the cases where, and the conditions under which, the transit of consignments of the categories of animals and goods referred to in Article 47(1) may be authorised and certain official controls to be performed at border control posts on such consignments, including the cases and conditions for the storage of goods in specially approved customs warehouses or in free zones; (e) the cases where, and the conditions under which, derogations from the rules on identity checks and physical checks shall apply as regards transhipped consignments and transit of consignments of the goods referred to in point (c) of Article 47(1). 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules to establish the cases where, and the conditions under which, derogations from the rules on documentary checks shall apply as regards transhipped consignments and transit of consignments of the goods referred to in point (c) of Article 47(1).	在同一運輸工具以備繼續下一級旅程的動物，在何種情況下，以及何種條件下，該等轉運貨物或動物第一次抵達歐盟時之邊境站以外之邊境管制站可執行之身分檢查及物性檢查； (d)在何種情況下，以及何種條件下，可以批准第47(1)條所述動物和貨物類別的託運物之過境，以及對該等貨物在邊境管制站執行某些官方管制，其中包括在特別批准的海關倉庫或自由區內儲存之貨物的情況和條件； (e)在何種情況下，以及何種條件下，可不適用第47(1)條第(c)點所提及應適用於轉運貨物和貨物過境方面之身分檢查和物性檢查等規範。 2. 歐盟執委會有權根據第 144 條採用授權法規，以補充本規章關於制定在第 47(1)條第(c)點所提及之轉運貨物和貨物過境時之文件查驗規範可不適用之情況與條件的規範。
Article 52 **Details of documentary checks, identity checks and physical checks** For the purposes of ensuring the uniform implementation of Articles 49, 50 and 51, the Commission shall, by means of implementing acts, lay down detailed rules on the operations to be carried out during and after the documentary checks, identity checks and physical checks referred to in those Articles to ensure the efficient performance of those official controls. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	*第 52 條* **文件檢查、身分檢查和物性檢查的細節** 為確保第 49、50 和 51 條之執行一致性，歐盟執委會應藉由施行細則，對該等條文所提及之文件檢查、身分檢查和物性檢查期間和之後執行的業制定細節規範。以確保該等官方管制之有效率的執行。上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
Article 53 **Official controls not performed at border control posts** 1. The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules establishing the cases where and the conditions under which: (a) identity checks and physical checks on consignments of the categories of animals and goods referred	*第 53 條* **未於邊境管制站執行之官方管制** 1. 歐盟執委會應根據第 144 條採用授權法規，以補充本規章中關於制定下列情形所依循的規範和條件： (a)對第 47(1)條所提及之動物和貨物類別的託運物

to in Article 47(1) may be performed by competent authorities at control points other than border control posts provided that those control points comply with the requirements provided for in Article 64(3) and in the implementing acts adopted in accordance with Article 64(4);	所執行之識別檢查和物性檢查，可由權責機關在提供的邊境管制站以外的管制點進行，若該等管制點符合第 64(3)條和根據第 64(4)條訂的施行細則的要求；
(b) physical checks on consignments which have undergone documentary checks and identity checks at a border control post of first arrival into the Union may be performed at another border control post in a different Member State;	(b)對在託運物首次抵達歐盟之邊境管制站已進行過文件檢查和身分檢查者，可在一個不同的會員國之另一個邊境管制站進行物性檢查；
(c) identity checks and physical checks on consignments which have undergone documentary checks at a border control post of first arrival into the Union may be performed at another border control post in a different Member State;	(c)對託運物在首次抵達歐盟之邊境管制站已進行過文件檢查者，可在另一個會員國的另一個邊境管制站進行身份和物性檢查；
(d)specific control tasks may be performed by customs authorities or other public authorities, insofar as those tasks are not already falling under the responsibility of those authorities, on:	(d)海關或其他公家機關可以執行關於下列事項之具體的管制任務，該等任務目前尚未由這些機關負責，即：
(i) consignments referred to in Article 65(2);	(i)第 65(2)條所提及之託運物；
(ii) passengers' personal luggage;	(ii)旅客的私人行李；
(iii) goods ordered by sales through distance contracts, including by telephone or via the internet;	(iii)透過遠程契約銷售訂購的貨物，其中包括透過電話或網路；
(iv) pet animals which meet the conditions laid down in Article 5 of Regulation (EU) No 576/2013 of the European Parliament and of the Council[59];	(iv)符合歐洲議會和歐盟理事會(EU)576/2013 號規章第 5 條所規定條件的寵物動物；
(e) documentary checks on consignments of plant, plant products and other objects referred to in point (c) of Article 47(1) may be performed at distance from a border control post.	(e)對 47(1)條(c)點所提及之之植物、植物產品和其他物品的託運物所進行的文件檢查，可在離邊境管制站的一段距離處進行。
2. Point (b) of Article 56(3), point (a) of Article 57(2), Article 59(1), points (a) and (d) of Article 60(1) and Articles 62 and 63 shall also apply to the control points referred to in point (a) of paragraph 1 of this Article.	2. 第 56(3)條第(b)點、第 57(2)條第(a)點，第 59(1)條，第 60(1)條第(a)和(d)點以及第 62 和 63 條也應適用於本條第 1 項之(a)點所提及之管制點。
Article 54 **Frequency of documentary checks, identity checks and physical checks**	*第 54 條* **文件檢查、身分檢查和物性檢查的頻率**
1. All consignments of the categories of animals and goods referred to in Article 47(1) shall be subject to	1. 第 47(1)條所提及之訂之所有動物和貨物類別的託運物均應接受文件檢查。

59 Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1)./ 歐洲議會和歐盟理事會於 2013 年 6 月 12 日頒佈了(EU) 576/2013 號規章，規定了寵物動物的非商業性流動，並廢除第(EC) 998/2003 號規章。

documentary checks.	
2. Identity checks and physical checks shall be performed on consignments of the categories of animals and goods referred to in Article 47(1) at a frequency dependent on the risk posed by each animal, good or category of animals or goods to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.	2. 應對第 47(1)條所提及之動物和貨物類別的託運物進行身分檢查和物性檢查，其頻率取決於每種動物、貨物或是動物或貨物類別的託運物對人類、動物 或植物健康、動物福祉，或關於基因改造生物和植物保護產品，以及對環境所造成的風險。
3. The Commission shall, by means of implementing acts, lay down rules for the uniform application of the appropriate frequency rate referred to in paragraph 2. Those rules shall ensure that those frequencies are higher than a zero frequency and shall establish:	3. 歐盟執委會應透過施行細則，制定統一的適用第 2 項所提及的適當頻率的規範。該當規範應確保這些頻率高於零頻率，並應制定下列事宜：
(a) the criteria and the procedures for determining and modifying the frequency rates of identity checks and physical checks to be performed on consignments of the categories of animals and goods referred to in points (a), (b) and (c) of Article 47(1) and to adjust them to the level of risk associated with those categories, having regard to:	(a)確定和修改對在第 47(1)條條的(a)，(b)和(c)點中所提及之動物和貨物類別的託運物執行身分檢查和物性檢查的頻率的標準和程序，，並考慮到以下因素將其調整到與該等類別有關的風險等級：
(i) information collected by the Commission in accordance with Article 125(1);	(i)歐盟執委會根據第 125(1)條所收集的資訊；
(ii) the outcome of controls performed by Commission experts in accordance with Article 120(1);	(ii)歐盟執委會專家根據第 120(1)條執行管制的結果；
(iii) operators' past record as regards compliance with the rules referred to in Article 1(2);	(iii)運營商以往關於符合第 1(2)條所提及之規範的紀錄；
(iv) data and information collected via the information management system for official controls (IMSOC) referred to in Article 131;	(iv)透過第 131 條所提及之“官方管制資訊管理系統(IMSOC)”所收集的數據和資訊；
(v) available scientific assessments; and	(v)可用的科學評估；及
(vi) any other information regarding the risk associated to the categories of animals and goods;	(vi)任何其他有關動物和貨物類別之相關風險的資訊；
(b) the conditions under which Member States may increase the frequency rates of identity checks and physical checks established in accordance with point (a) so as to take account of local risk factors;	(b)會員國可以依據(a)點所提及內容增加身分檢查和物性檢查的頻率之條件，以便考慮到當地的風險因素；
(c) the procedures for ensuring that the frequency rates of identity checks and physical checks established in accordance with point (a) are applied in a timely and uniform manner.	(c)確保按照(a)點所提及的身分檢查和物性檢查的頻率以及時和統一的方式應用的程序。
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
4. The Commission shall, by means of implementing acts, lay down rules on:	4. 歐盟執委會應，藉由施行細則，制訂關於以下事宜之規範：
(a) the frequency of identity checks and physical checks for the categories of goods referred to in point	(a)第 47(1)條(d)點所提及之貨物種類的身分檢查

(d) of Article 47(1); and (b) the frequency of identity checks and physical checks for the categories of animals and goods referred to in points (e) and (f) of Article 47(1) as long as this is not already provided for in the acts referred to therein. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	和物性檢查的頻率;及 (b)第 47(1)條(e)和(f)點所提及之動物和貨物種類的識別檢查和物性檢查的頻率，只要其中所提及之行為尚未規定者。 上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
Article 55 **Decisions on consignments** 1. A decision shall be taken by the competent authorities on each consignment of the categories of animals and goods referred to in Article 47(1) following the performance of official controls including documentary and, where necessary, identity checks and physical checks, indicating whether the consignment is in compliance with the rules referred to in Article 1(2) and, where relevant, the applicable customs procedure. 2. Decisions on consignments shall be taken by: (a) an official veterinarian where they concern animals, products of animal origin, germinal products or animal by-products; or (b) an official plant health officer where they concern plants, plant products and other objects. 3. By way of derogation from point (a) of paragraph 2, competent authorities may decide that the decision on consignments of fishery products, live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption, be taken by appropriately trained staff who have been specifically designated by competent authorities for that purpose.	*第 55 條* **關於託運物的決定** 1. 權責機關應在執行官方管制，其中包括文件及必要時，包括身分檢查和物性檢查後，對第 47(1)條所提及之之動物和貨物類別的每批託運物作出決定，以指出該批託運物是否符合第 1(2)條所提及之規範，並在相關時，符合適用的海關程序。 2. 託運物的決定應由下列方式為之： (a)涉及動物、動物源產品、胚種產品或動物副產品，由官方獸醫為之；或 (b)涉及植物、植物產品和其他物品，由官方植物衛生官員為之。 3. 作為第 2 項第(a)點規定的例外，權責機關得決定就關於供人類食用的漁產品、活雙枚貝類、活棘皮動物、活被囊動物和活海洋腹足動物等託運物所為之決定。為此目的，可由權責機關指定經過適當培訓的職員為之。
Article 56 **Use of the Common Health Entry Document (CHED) by the operator and by the competent authorities** 1. For each consignment of the categories of animals and goods referred to in Article 47(1) the operator responsible for the consignment shall complete the relevant part of the CHED, providing the information necessary for the immediate and complete identification of the consignment and its destination.	*第 56 條* **運營商和權責機關對共同衛生報單文件(CHED)之使用** 1. 對於第 47(1)條所提及之每批動物和貨物類別的託運物，負責該託運物的運營商應填寫 CHED 的有關部分，提供立即和完整識別該託運物所需的資訊及其目的地。

2. References in this Regulation to the CHED include a reference to its electronic equivalent. 3. The CHED shall be used by: (a) the operators responsible for consignments of the categories of animals and goods referred to in Article 47(1) in order to give prior notification to the competent authorities of the border control post of arrival of those consignments; and (b) the competent authorities of the border control post, in order to: (i) record the outcome of the official controls performed and any decisions taken on that basis, including the decision to reject a consignment; (ii) communicate the information referred to in point (i) through the IMSOC. 4. Operators responsible for the consignment shall give prior notification in accordance with point (a) of paragraph 3 by completing and submitting the relevant part of the CHED into the IMSOC for transmission to the competent authorities of the border control post prior to the physical arrival of the consignment into the Union. 5. The competent authorities of the border control post shall finalise the CHED as soon as: (a) all official controls required by Article 49(1) have been performed; (b) the results from physical checks, where such checks are required, are available; and (c) a decision on the consignment has been taken in accordance with Article 55 and recorded on the CHED.	2. 本規章中對 CHED 的引用包括對其電子等同文件的引用。 3. CHED 應由以下人員使用： (a)負責第 47(1)條所提及之動物和貨物類別之託運物的運營商，以便事先通知這些託運物到達的邊境管制站之權責機關；及 (b)邊境管制站的權責機關，以便： (i)記錄所執行的官方管制的結果以及在該基礎上作出的任何決定，其中包括拒絕該批託運物的決定； (ii)透過官方管制資訊管理系統(IMSOC)傳達第(i)點所指之資訊。 4. 負責託運物的運營商應按照第 3 項第(a)點的規定在進入歐盟之託運物實質到達前，以填寫並將 CHED 的有關部分提交 IMSOC 之方式做事先通知，俾利轉給邊境管制站之權責機關。 5. 邊境管制站之權責機關應在下列事宜一經竣事，即應完成 CHED，當： (a)第 49(1)條所要求的所有官方管制措施均已執行時； (b)在須執行物性檢查，而該檢查結果已取得時；及 (c)已根據第 55 條作出關於該託運物的決定並記錄在 CHED 上時。
Article 57 **Use of the CHED by customs authorities** 1. The placing and handling of consignments of the categories of animals and goods referred to in Article 47(1) under a customs procedure, including the entry or handling in customs warehouses or free zones, shall be subject to the presentation of the CHED by the operator responsible for the consignment to the custom authorities, without prejudice to the exemptions referred to in Article 48 and the rules referred to in Articles 53 and 54. At this stage, the CHED shall have been duly finalised in the IMSOC by the competent authorities of the border control post. 2. Customs authorities shall:	*第 57 條* **海關對 CHED 之使用** 1. 根據海關程序對第 47(1)條所提及之動物和貨物類別的託運物之放置與處理，其中包括進入或在海關倉庫或自由區內之處理，應在不影響第 48 條所提及之豁免以及第 53 條和第 54 條所提及之規範情形下，由負責該批託運物的運營商受到提交 CHED 給海關之約束。在本階段，CHED 應已由邊境管制站之權責機關在 IMSOC 中予以正式定稿完成。 2. 海關應：

(a) not allow the placing of the consignment under a customs procedure different from the one indicated by the competent authorities of the border control post; and (b) without prejudice to the exemptions referred to in Article 48 and the rules referred to in Articles 53 and 54, only allow the release for free circulation of a consignment upon presentation of a duly finalised CHED which confirms that the consignment is in compliance with the applicable rules referred to in Article 1(2). 3. Where a customs declaration is made for a consignment of the categories of animals or goods referred to in Article 47(1) and the CHED is not presented, the customs authorities shall detain the consignment and immediately notify the competent authorities of the border control post. The competent authorities shall take the necessary measures in accordance with Article 66(6).	(a)不允許該託運物之放置，若該項放置所依據之海關程序與邊境管制站之權責機關所示者不同時；以及 (b)在不違反第 48 條所提及之豁免和第 53 條和第 54 條所提及之規範的情況下，只允許提交妥適確定稿完成的 CHED，以確認符合第 1(2)條所提及之適用規範之託運物可以採用自由流通。 3. 當已就第 47(1)條所提及之動物或貨物類別的託運物向海關作申報，然未提交 CHED 時，海關應當扣留託運物，並立即通知邊境管制站之權責機關。 權責機關應根據第 66(6)條採取必要措施。
Article 58 **Format, time requirements and specific rules for the use of the CHED** The Commission shall, by means of implementing acts, lay down rules on: (a) the format of the CHED and the instructions for its presentation and use, taking into account relevant international standards; and (b) the minimum time requirements for prior notification of consignments by operators responsible for the consignment as provided for in point (a) of Article 56(3) in order to enable the competent authorities of the border control post to perform official controls in a timely and effective manner. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	*第 58 條* **使用 CHED 的格式、時間要求和具體規範** 歐盟執委會應藉由藉由施行細則，制訂關於以下事宜之規範： (a)CHED 的格式及其提交和使用之說明，同時考慮到相關的國際標準； 以及 (b)為了使邊境管制站的權責機關能夠及時有效地執行官方管制，如第 56(3)條第(a)點所規定之負責託運物的運營商事先通知貨物已到達的最短時間要求。 上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
Article 59 **Designation of border control posts** 1. Member States shall designate border control posts for the purpose of performing official controls on one or more of the categories of animals and goods referred to in Article 47(1). 2. Member States shall notify the Commission before designating a border control post. That notification shall include all the information necessary for the Commission to verify that the proposed border control post complies with the minimum requirements laid down in Article 64.	*第 59 條* **邊境管制站之指定** 1. 會員國應指定邊境管制站，以便對第 47 條之 1 所提及之一類或多類動物和貨物類別實施官方管制。 2. 會員國在指定邊境管制站之前應通知歐盟執委會。 該通知應包括歐盟執委會查驗被推薦的邊境管制站是否符合第 64 條規定的最低要求所需的所有資料。

3. Within three months of receiving the notification referred to in paragraph 2, the Commission shall inform the Member State: (a) whether the designation of the proposed border control post is dependent upon the favourable outcome of a control performed by Commission experts in accordance with Article 116 in order to verify compliance with the minimum requirements laid down in Article 64; and (b) of the date of such a control, which is not to be later than six months from the notification. 4. In cases where the Commission has informed a Member State, in accordance with paragraph 3, that a control is not necessary, the Member State may proceed with the designation. 5. The Member State shall delay designating the border control post until the favourable outcome of the control has been communicated to it by the Commission. The Commission shall communicate the outcome of its control as referred to in point (a) of paragraph 3 at the latest within three months from the date of that control.	3. 在收到第 2 項所提及之 6 通知後三個月內，歐盟執委會應通知會員國以下事實： (a)邊境管制站的指定是否取決於歐盟執委會專家根據第 116 條所執行的管制之有利結果，以利查驗是否符合第 64 條所規定的最低要求；以及 (b)該項管制日期，不得遲於通知後六個月。 4. 如果歐盟執委會，根據第 3 項，通知會員國前述由執委會專家所執行之管制是不需要的，則會員國可以繼續進行指定。 5. 會員國應遲延指定邊境管制站，直至歐盟執委會向其通報前述由執委會專家所執行之管制的有利結果為止。歐盟執委會應至遲在該項管制之日起三個月內將第 3 項第(a)點所提及之管制結果通知會員國。
Article 60 **Listing of border control posts** 1. Each Member State shall make available on the internet up-to-date lists of border control posts on its territory, providing the following information for each border control post: (a) its contact details; (b) its opening hours; (c) its exact location and whether it is a port, airport, rail or road entry point; and (d) the categories of animals and goods referred to in Article 47(1) which are included in the scope of its designation. 2. The Commission shall, by means of implementing acts, lay down rules on the format, categories, abbreviations for designations and other information to be used by Member States in the lists of border control posts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	*第 60 條* **邊境管制站之表列** 1. 每個會員國應在網路上提供其領土上最新的邊境管制站名單，為每個邊境管制站提供以下資料： (a)其聯絡細節； (b)其開放時間； (c)其確切位置，及其是否為港口，機場，鐵路或道路入口處；和 (d)第 47 條之 1 所提及之那些動物和貨物類別是包括在其被指定範圍之內。 2. 歐盟執委會應，藉由施行細則，對會員國在指定之邊境管制站名單中使用的格式、類別、指定項目之縮寫和其他信息作出規範。上開施行細則應按照第 145 條之 2 所提及之審查程序予以採用。
Article 61 **Withdrawal of approvals for, and re-designation of, existing border control entities**	*第 61 條* **對現有邊境管制單位的許可之撤銷以及重新指定**

1. The approval of border inspection posts in accordance with Article 6 of Directive 97/78/EC and Article 6 of Directive 91/496/EEC, the designation of points of entry in accordance with Article 5 of Regulation (EC) No 669/2009 and with Article 13c(4) of Directive 2000/29/EC and the designation of first points of introduction in accordance with Article 5 of Commission Regulation (EU) No 284/2011[60] shall be withdrawn. 2. Member States may re-designate border inspection posts, designated points of entry, points of entry and first points of introduction referred to in paragraph 1 of this Article as border control posts in accordance with Article 59(1) provided that the minimum requirements referred to in Article 64 are complied with. 3. Article 59(2), (3) and (5) shall not apply to the re-designation referred to in paragraph 2 of this Article.	1. 根據第 97/78/EC 號指令第 6 條和第 91/496/EEC 號指令第 6 條辦理之邊境檢查站許可、根據(EC)66/2009 號規章第 5 條和第 2000/29/EC 號指令第 13c(4)條所作之入境點指定，以及根據歐盟執委會(EU) 284/2011 號規章第 5 條所作之第一次引入點的指定應予撤銷。 2. 會員國可根據第 59(1)將第 1 項所提及之邊境檢查站、指定入境點、入境點和第一次引入點重新指定為邊境管制站，若其符合第 64 條所提及之最低要求。 3. 第 59 條之 2，之 3 和之 5 條不適用於本條第 2 項所提及之重新指定。
Article 62 **Withdrawal of the designation of border control posts** 1. Where border control posts cease to comply with the requirements referred to in Article 64, the Member States shall: (a) withdraw the designation provided for in Article 59(1) for all or for certain categories of animals and goods for which the designation was made; and (b) remove those border control posts from the lists referred to in Article 60(1), for the categories of animals and goods for which the designation is withdrawn. 2. Member States shall inform the Commission and the other Member States of the withdrawal of the designation of a border control post as provided for in paragraph 1 and of the reasons for such withdrawal. 3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the procedures by which, border control posts for which the designation has only been partially withdrawn in accordance with point (a) of paragraph 1	*第 62 條* **邊境管制站之指定資格的撤銷** 1. 如果邊境管制站不再符合第 64 條所提及之要求，會員國應： (a)撤銷第 59 條之 1 規定的所有或某些動物和貨物類別之邊境管制站的指定資格；和 (b)從第 60 條之 1 所提及之邊境管制站名單中就被撤銷指定資格的動物和貨物類別予以移除。 2. 各會員國應通知歐盟執委會和其他會員國有關撤銷第 1 項所規定的邊境管制站的指定資格以及撤銷原因。 3. 歐盟執委會有權根據第 144 條採用授權法規，以補充本規章關於根據本條第 1 項第(a)點僅被部分撤銷指定資格的邊境管制站可以例外不適用第 59 條的方式予以重新指定之情況和所依循之

60 Commission Regulation (EU) No 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China (OJ L 77, 23.3.2011, p. 25)./ 歐盟執委會 2011 年 3 月 22 日(EU) 284/2011 號規定進口源自中華人民共和國和香港特別行政區的聚酰胺和三聚氰胺塑料廚具的具體條件和詳細程序規章。

of this Article may be re-designated by way of derogation from Article 59. 4. This Article shall be without prejudice to Member States' competence to decide on the withdrawal of designation of border control posts for reasons other than those referred to in this Regulation.	程序。 4. 本條之規定應不妨礙會員國根據本規章所提及之原因以外之理由決定就邊境管制站的指定資格予以撤銷之權限。
Article 63 **Suspension of the designation of border control posts** 1. A Member State shall suspend the designation of a border control post and order its activities to be stopped, for all or for certain categories of animals and goods for which the designation was made, in cases where such activities may result in a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment. In the case of a serious risk, the suspension shall be with immediate effect. 2. Member States shall immediately inform the Commission and the other Member States of any suspension of the designation of a border control post and the reasons for such a suspension. 3. Member States shall indicate the suspension of the designation of a border control post in the lists referred to in Article 60(1). 4. Member States shall remove the suspension provided for in paragraph 1 as soon as: (a) the competent authorities are satisfied that the risk referred to in paragraph 1 no longer exists; and (b) they have communicated to the Commission and to the other Member States the information on the basis of which the suspension is removed. 5. This Article shall be without prejudice to Member States' competence to decide on the suspension of designation of border control posts for reasons other than those referred to in this Regulation.	*第 63 條* **邊境管制站之指定資格的暫停** 1. 會員國應就已取得所有或某些類別的動物和貨物活動指定邊境管制站予以暫停其指定資格，並命令停止其活動，若此筆活動可能導致對人類、動物或植物健康、動物福祉，或關於基因改造生物和植物保護產品，以及對環境之風險。但如果會導致嚴重風險者，則該項暫停應立即生效。 2. 會員國應立即將任何暫停邊境管制站之指定資格的情況以及此種暫停情況的原因通知歐盟執委會和其他會員國。 3. 會員國應在第 60 條之 1 所提及之清單中表明某邊境管制站之指定資格的情形。 4. 會員國應在有下列事實時盡快取消第 1 項所規定的指定資格之暫停： (a)權責機關對第 1 項所提及之風險已不復存在之情形感到滿意；和 (b)其已向歐盟執委會和其他會員國通報了取消該項暫停指定資格所依據的資訊。 5. 本條之規定應不妨礙會員國根據本規章所提及之原因以外之理由決定就暫停邊境管制站之指定資格的權限。
Article 64 **Minimum requirements for border control posts** 1. Border control posts shall be located in the immediate vicinity of the point of entry into the Union and either in a place which is designated by the customs authorities in accordance with Article 135(1) and (2) of Regulation (EU) No 952/2013 or in a free zone. 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where and conditions under which a border control post may be	*第 64 條* **邊境管制站的最低要求** 1. 邊境管制站應位於進入歐盟的緊鄰地點，並且不是位於海關根據(EU)952/2013 號規章第 135 條之 1 和之 2 條指定的地點，就是位在自由區。 2. 歐盟執委會有權根據第 144 條採用授權法規，以補充本規章關於在特定地理限制的情況下，邊境管制站除了在進入歐盟的緊鄰地點外，可能位於

situated at a distance other than in the immediate vicinity of the point of entry into the Union in cases of specific geographical constraints.

3. Border control posts shall have:

(a) a sufficient number of suitably qualified staff;

(b) premises or other facilities appropriate to the nature and volume of the categories of animals and goods handled;

(c) equipment and premises or other facilities to allow the performance of official controls for each of the categories of animals and goods for which the border control post has been designated;

(d) arrangements in place to ensure, as appropriate, access to any other equipment, premise and service necessary to apply the measures taken in accordance with Articles 65, 66 and 67 in cases of suspicion of non-compliance, non-compliant consignments or consignments presenting a risk;

(e) contingency arrangements to ensure the smooth operation of official controls and the effective application of the measures taken in accordance with Articles 65, 66 and 67 in cases of unforeseeable and unexpected conditions or events;

(f) the technology and equipment necessary for the efficient operation of the IMSOC and, as appropriate, of other computerised information management systems necessary for the handling and exchange of data and information;

(g) access to the services of official laboratories capable of providing analytical, testing and diagnostic results within appropriate deadlines and equipped with the information technology tools necessary to ensure the introduction of the results of analyses, tests or diagnoses carried out into the IMSOC as appropriate;

(h) appropriate arrangements for the proper handling of different categories of animals and goods and to prevent risks which may result from cross-contamination; and

(i) arrangements to comply with relevant biosecurity standards in order to prevent the spread of diseases into the Union.

4. The Commission may, by means of implementing acts, lay down detailed rules on the requirements under paragraph 3 of this Article to take into account specific features and logistic needs related to

遠處的地點之情況和條件。

3. 邊境管制站應具有：

(a)足夠的適切符合資格的人員；

(b)適用於所處理的動物和貨物類別的性質和數量的處所或其他設施；

(c)設備和處所或其他設施，以利對該邊境管制站受指定的每種動物和貨物類別之官方管制的執行；

(d)具備各項安排以確保在懷疑有不符合情事、不符規定的託運物或託運物出現風險的情況下，能妥適地採用必要的任何其他設備、處所及服務以利應用根據第 65、66 和 67 條採取的措施；

(e)應急安排，以確保在不可預見和意外情況或事件發生時，官方管制的順利運作以及根據第 65、66 和 67 條所採取之措施的有效應用；

(f)所需的技術和設備以有效率運作官方管制資訊管理系統(IMSOC)以及適當的必要之其他電子化資訊管理系統以處理和交換數據及資訊；

(g)獲取能夠在適當的期限內提供分析、測試和診斷結果，並配備必要的資訊技術工具之官方實驗室的服務，以確保能將所執行的分析、測試或診斷結果適切的導入 IMSOC；

(h)為妥善處理不同類別的動物和貨物，及防止因交叉污染可能造成的風險之適當安排；以及

(i)符合相關的生物安全標準，以防止疾病傳播到歐盟內之各種安排。

4. 歐盟執委會藉由施行細則，對本條第 3 項所列的要求制定詳細規範，以考慮到與官方管制之執行及根據第 66 條之 3 和之 6 以及第 67 條關於第

the performance of official controls and to the application of the measures taken in accordance with Article 66(3) and (6) and Article 67 in relation to the different categories of animals and goods referred to in Article 47(1). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	47 條之 1 所提及之不同類別的動物和貨物所採取之措施的應用有關的具體特點和後勤需要。上開施行細則應按照第 145 條之 2 所提及之審查程序予以採用。
5. The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases and **conditions** under which border control posts designated for the imports of unprocessed logs and sawn and chipped wood may be exempted from one or more of the obligations referred to in paragraph 3 of this Article to take into account the needs of competent authorities in charge of official controls operating under specific geographical constraints, while ensuring the proper performance of the controls.	5. 歐盟執委會應根據第 144 條採用授權法規，以補充本規章有關受指定執行進口未加工原木和鋸碎木，可免除本條第 3 項所提及之一項或多項義務的情況和條件，以考慮主管在特定地理限制下運作的官方管制之權責機關的需要，同時確保官方管制的適當執行。
Section III **Action in the event of suspicion of Non-compliance and of Non-compliance of animals and goods entering the union**	第 III 部分 **疑似有不符合規定之情事以及進入歐盟的動物和貨物不符合規定的情況時之行動**
Article 65 **Suspicion of non-compliance and intensified official controls**	*第 65 條* **疑似不符合情事及強化的官方管制**
1. In the event of suspicion of non-compliance of consignments of the categories of animals and goods referred to in Articles 44(1) and 47(1) with the rules referred to in Article 1(2), the competent authorities shall perform official controls in order to confirm or to eliminate that suspicion.	1. 於懷疑第 44 條之 1 和第 47 條之 1 所提及之動物和貨物類別的託運物有不符合第 1 條之 2 所提及之規範的情事時，權責機關應執行官方管制以確認或消除該項懷疑。
2. Consignments of animals and goods which are not declared by operators to consist of the categories of animals and goods referred to in Article 47(1), shall be subject to official controls by the competent authorities where there is reason to believe that such categories of animals or goods are present in the consignment.	2. 運營商未聲明係由第 47 條之 1 所提及之動物和貨物類別所組成之動物和貨物的託運物，當有理由相信此等類別的動物或貨物係在該批託運物內的情況時，應由權責機關進行官方管制。
3. The competent authorities shall place the consignments referred to in paragraphs 1 and 2 under official detention pending the outcome of the official controls provided for in those paragraphs. Where appropriate, those consignments shall be isolated or quarantined and animals shall be sheltered, fed, watered and as necessary treated, pending the outcome of the official controls.	3. 權責機關應將第 1 項和第 2 項所提及之貨物予以正式扣留，以等待該等節次之條文所款規定的官方管制的結果。 適當時，應對這些託運物進行隔離或檢疫，並在官方管制結果出來之前的等待期間對該等動物進行庇護、餵養、供水和受到必要的照顧。
4. Where the competent authorities have reasons to suspect fraudulent or deceptive practices by an	4. 如果權責機關有理由懷疑負責託運物的運營商

operator responsible for the consignment or the official controls give grounds to believe that the rules referred to in Article 1(2) have been seriously or repeatedly infringed, they shall, where appropriate, and in addition to the measures provided for in Article 66(3), intensify as appropriate official controls on consignments with the same origin or use.

5. The competent authorities shall notify the Commission and the Member States through the IMSOC of their decision to perform intensified official controls, as provided for in paragraph 4 of this Article, indicating the reasons for their decision.

6. The Commission shall, by means of implementing acts, lay down rules on the procedures for the coordinated performance by competent authorities of the intensified official controls referred to in paragraphs 4 and 5 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

有詐欺或欺騙行為，或官方管制讓權責機關有理由相信第 1 條之 2 所提及之規範已被嚴重或反覆地違反，則權責機關應在適當時，且除了第 66 條之 3 規定的措施外，還應適當地強化對具有相同來源或用途的托運物之官方管制。

5. 權責機關透過“方管制資訊管理系統(IMSOC)向歐盟執委會和會員國通報其根據本條第 4 項規定執行強化官方管制的決定，闡明其決定的理由。

6. 歐盟執委會應，藉由施行細則，制定關於由各權責機關經協調過的執行本條第 4 項和第 5 節所提及之強化官方管制作業之程序的規範。該等施行細則應按照第 145 條之 2 所提及之審查程序予以採用。

Article 66

Measures to be taken in cases of non-compliant consignments entering the Union

1. The competent authorities shall place under official detention any consignment of animals or goods entering the Union which does not comply with the rules referred to in Article 1(2) and shall refuse its entry into the Union.

   The competent authorities shall isolate or quarantine, as appropriate, any such consignment and the animals belonging to it shall be kept, cared for or treated under appropriate conditions pending any further decision. If possible, the competent authorities shall also take into account the interest of providing special care in respect of certain types of goods.

2. The Commission shall, by means of implementing acts, lay down rules on the practical arrangements for the isolation and quarantine provided for in the second subparagraph of paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3. The competent authority shall, as regards the consignment referred to in paragraph 1 order, without delay, the operator responsible for the consignment to:

(a) destroy the consignment;

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不符合規範的託運物進入歐盟之情況時應採取的措施

1. 權責機關應將任何進入歐盟之不符合第 1 條之 2 所提及的規範之動物或貨物的託運物予以正式扣留，並應拒絕其進入歐盟。

   在有進一步的任何決定之前，權責機關應將任何此類託運物予以適切的隔離或檢疫，而屬於該批託運物之動物應在適當的條件下進行餵養、照顧或對待。如有可能，權責機關還應考慮到針對某些類型的貨物提供特殊照顧的權益。

2. 歐盟執委會應，藉由施行細則，制定關於本條第 1 項第 2 款所規定的隔離和檢疫的實際安排之規範。上開施行細則應按照第 145(2)條所提及之審查程序予以採用。

3. 就第 1 項所提及之託運物，權責機關應立即命令負責的該託運物的運營商採取下列作為：

(a)銷毀該託運物；

(b) re-dispatch the consignment outside the Union in accordance with Article 72(1) and (2); or

(c) subject the consignment to special treatment in accordance with Article 71(1) and (2) or to any other measure necessary to ensure compliance with the rules referred to in Article 1(2), and, where appropriate, allocate the consignment for purposes other than those for which it was originally intended.

Any action referred to in points (a), (b) and (c) of the first subparagraph shall be performed in compliance with the rules referred to in Article 1(2), including in particular, as regards consignments of live animals, those intended to spare animals any avoidable pain, distress or suffering.

When the consignment consists of plants, plant products or other objects, points (a), (b) and (c) of the first subparagraph shall be applied either to the consignment or to lots thereof.

Before ordering the operator to take action in accordance with (a), (b) and (c) of the first subparagraph, the competent authority shall hear the operator concerned, unless immediate action is necessary in order to respond to a risk to human, animal or plant health, animal welfare or, as regards the GMOs and plant protection products, also to the environment.

4. Where the competent authority orders the operator to take one or more of the actions laid down in point (a), (b) or (c) of the first subparagraph of paragraph 3, that competent authority may exceptionally authorise the action to be taken in respect of a part of the consignment only, provided that the partial destruction, re-dispatch, special treatment, or other measure:

(a) is such as to ensure compliance;

(b) does not pose a risk to human, animal or plant health or to animal welfare or, as regards GMOs and plant protection products, also to the environment; and

(c) does not disrupt official control operations.

5. The competent authorities shall immediately notify any decision to refuse entry of a consignment as provided for in paragraph 1 of this Article, and any order issued in accordance with paragraphs 3 and 6 of this Article and with Article 67 to:

(a) the Commission;

(b)根據第 72 條之 1 和之 2 之規定在歐盟之外重新發運託運物；或是

(c)根據第 71 條之 1 和之 2 對託運物進行特殊處理，或採取任何其他必要措施，以確保符合第 1 條之 2 所提及之規範，並在適當時，分配該託運物用於除最初用途之外的目的。

第 1 款之(a)、(b)和(c) 點所提及之任何行動均應遵照第 1 條之 2 所提及之規範執行，特別是其中包括關於活體動物的託運物，旨在使動物不遭受任何可避免的痛苦、壓抑或折磨。

當託運物係由植物、植物產品或其他物品組成時，第 1 款的(a)、(b)和(c)點應不是適用於該託運物就是適用於其批次。

在命令運營商根據第 1 款(a)，(b)和(c)點採取行動之前，權責機關應聽取所涉運營商的意見，除非立即採取行動係有必要以因應對人類、動物或植物健康、動物福祉，或關於基因改造生物和植物保護產品，以及對環境的風險。

4. 如果權責機關命令運營商採取第 3 項第 1 款之(a)、(b)或(c)點規定的一項或多項行動時，權責機關可例外地授權該行動為僅針對該批託運物的一部分，若該部分之銷毀、重新發運、特殊處理或其他處置措施能符合下列要求：

(a)係已達可確保符合性的程度；

(b)不會對人類、動物或植物健康或動物福祉，或關於基因改造生物和植物保護產品及環境產生危險；以及

(c)不會擾亂官方管制行動。

5. 權責機關應立即將根據本條第 1 項規定拒絕所涉託運物進入歐盟的任何決定，以及根據本條第 3 和第 6 項以及第 67 條發布的任何命令通知下列之對象：

(a) 歐盟執委會；

(b) 其他會員國的權責機關；

(b) the competent authorities of the other Member States; (c) the customs authorities; (d) the competent authorities of the third country of origin; and (e) the operator responsible for the consignment. That notification shall be performed via the IMSOC. 6. If a consignment of the categories of animals or goods referred to in Article 47(1) is not presented for the official controls referred to therein, or is not presented in accordance with the requirements laid down in Articles 50(1) and (3), 56(1), (3) and (4), or with the rules adopted under Article 48, Article 49(4), Article 51, Article 53(1) and Article 58, the competent authorities shall order that such consignment be retained or recalled, and placed under official detention without delay. Paragraphs 1, 3 and 5 of this Article shall apply to such consignments. 7. The measures referred to in this Article shall be applied at the expense of the operator responsible for the consignment.	(c) 海關； (d) 第三來源國的權責機關；以及 (e) 負責該託運物的運營商。 該通知應透過官方管制資訊管理系統(IMSOC)執行。 6. 如果第 47(1)條所提及之動物或貨物類別的託運物沒有提交以執行該條所提到的官方管制，或者沒有按照第 50(1)及(3)條、第 56(1)、(3)及(4)條，或根據第 48 條、第 49(4)條、第 51 條、第 53(1)條和第 58 條所用的規範所明定之要求提交託運物，則權責機關應命令該託運物須予保留或召回貨物，並立即將其予以官方扣留。 本條第 1、第 3 和第 5 項適用於此等託運物。 7. 本條所提及之措施的實施應由負責該託運物的運營商支付費用。
Article 67 **Measures to be taken on animals or goods entering the Union from third countries presenting a risk** Where official controls indicate that a consignment of animals or goods presents a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, such consignment shall be isolated or quarantined and the animals belonging to it shall be kept, cared for or treated under appropriate conditions pending any further decision. The competent authorities shall retain the consignment concerned under official detention and shall, without delay, order the operator responsible for that consignment to: (a) destroy the consignment in compliance with the rules referred to in Article 1(2), taking all the measures necessary to protect human, animal or plant health, animal welfare or the environment, and as regards live animals including in particular the rules on the sparing of any avoidable pain, distress or suffering; or (b) subject the consignment to special treatment in accordance with Article 71(1) and (2). The measures referred to in this Article shall be applied at the expense of the operator responsible for the	*第 67 條* **對從第三國進入歐盟之存在風險的動物或貨物應採取的措施** 如果官方管制指明一批動物或貨物對人類、動物或植物健康、動物福祉或基因改造生物和植物保護產品，以及環境構成危險，則應隔離或檢疫此類託運物，該託運物中的動物在有任何進一步的決定之前，應在適當的條件下予以餵養、照顧或對待。 權責機關應保留在官方扣留下的所涉託運物，並應立即命令負責該託運物的運營商採取下列事宜： (a)按照第 1 條之 2 所提及之規範銷毀貨物，並採取一切必要措施以保護人類、動物或植物健康、動物福祉或環境；而關於活體動物，其中特別須符合使其免受可避免的痛苦、壓抑或折磨的規範；或 (b)根據第 71 條之 1 和之 2 對託運物進行特殊處理。 本條所提及之措施的實施應由負責該託運物的運營商支付費用。

consignment.	
Article 68 **Follow-up of decisions taken in relation to non-compliant consignments entering the Union from third countries** 1. The competent authorities shall: (a) invalidate the official certificates and as appropriate other relevant documents accompanying consignments which have been subject to measures pursuant to Article 66(3) and (6) and Article 67; and (b) cooperate in accordance with Articles 102 to 108 to take any further measures necessary to ensure that it is not possible to reintroduce consignments into the Union which have been refused entry in accordance with Article 66(1). 2. The competent authorities in the Member State where the official controls were performed shall supervise the application of the measures ordered in accordance with Article 66(3) and (6) and Article 67 to ensure that the consignment does not give rise to adverse effects on human, animal or plant health, animal welfare, or the environment, during or pending the application of those measures. Where appropriate, such application shall be completed under the supervision of the competent authorities of another Member State.	*第 68 條* **對從第三國進入歐盟之未符合規定的託運物所作出的相關決定之後續追蹤** 1. 權責機關應： (a)在適當的情形下，使附隨於受到 3 第 66 條之 3 和之 6 以及第 67 條之措施約束的託運物之官方證書及其他適切的相關文件無效；以及 (b)根據第 102 至 108 條進行合作，採取必要的進一步措施，以確保根據第 66 條之 1 被拒絕入境的託運物不可能被重新引入歐盟。 2. 進行官方管制的會員國之權責機關應監督根據第 66 條之 3 和之 6 以及第 67 條下達命令措施的執行情況，以確保託運物在這些處置措施的執行期間或等待該等處置措施執行之前，對人類、動物或植物健康、動物福祉或環境不會產生不利影響。 在適當情況下，此類措施之執行應在另一會員國權責機關的監督下完成。
Article 69 **Failure by the operator to apply the measures ordered by the competent authorities** 1. The operator responsible for the consignment shall carry out all the measures ordered by the competent authorities in accordance with Article 66(3) and (6) and Article 67 without delay and, at the latest, within 60 days from the day on which the competent authorities notified the operator concerned of their decision in accordance with Article 66(5). The competent authorities may specify a shorter period than the period of 60 days. 2. If, after the expiry of the period referred to in paragraph 1, no action has been taken by the operator concerned, the competent authorities shall order: (a) that the consignment be destroyed or subject to any other appropriate measure;	*第 69 條* **運營商未能採取權責機關命令其應執行的處置措施** 1. 負責所涉託運物的運營商應當，立即執行權責機關按照第 66 條第(3)款和第(6)款以及第 67 條的規定命令其執行的一切措施，最遲應自權責機關將其決定根據第 66 條之 5 通知所涉運營商當天起 60 天內執行。權責機關可特別指定短於 60 天的期間。 2. 如果在第 1 項所提及之期限屆滿後所涉運營商未採取任何行動，權責機關應命令下列作為： (a)該託運物應被銷毀或採取任何其他適當措施之處置； (b)在第 67 條所提及之情況下，託運物在盡可能靠

(b) in the cases referred to in Article 67, that the consignment be destroyed in suitable facilities located as close as possible to the border control post, taking all measures necessary to protect human, animal or plant health, animal welfare or the environment. 3. The competent authorities may extend the period referred to in paragraphs 1 and 2 of this Article for the time necessary to obtain the results of the second expert opinion referred to in Article 35, provided that this is without adverse effects to human, animal and plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment. 4. The measures referred to in this Article shall be applied at the expense of the operator responsible for the consignment.	近邊境管制站的適當設施中予以銷毀，並採取一切必要措施以保護人類、動植物健康、動物福祉或環境。 3. 權責機關可將本條第 1 和第 2 項所提及之期限延長以考量獲得第 35 條所提及之第二方專家意見結果所需的時間，若該項延長對人類、動物及植物健康、動物福祉、或關於基因改造生物和植物保護產品，以及對環境不會產生不利影響。 4. 本條所提及之措施的實施費用應由負責該託運物的運營商支付費用。
Article 70 **Consistency of application of Articles 66, 67 and 68** The Commission shall, by means of implementing acts, lay down rules to ensure consistency across all border control posts referred to in Article 59(1), and control points referred to in point (a) of Article 53(1), of decisions and measures taken and orders issued by the competent authorities in accordance with Articles 66, 67 and 68 which are to be followed by the competent authorities when responding to common or recurring situations of non-compliance or risk. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	*第 70 條* **第 66、67 和 68 條應用的一致性** 歐盟執委會應，藉由施行細則，制定規範以確保在第 59 條之 1 所提及之所有邊境管制站和第 53 條之 1 第(a)點所提及的管制點，就權責機關根據第 66、67 和 68 條所採取的決定、措施和命令能有執行之一致性；而 66、67 和 68 條為權責機關在應對常見或經常發生之不符合規定的情況或風險發生時須遵循的部分，保持其一致性。上開施行細則應按照第 145 條之 2 所提及之審查程序予以採用。
Article 71 **Special treatment of consignments** 1. The special treatment of consignments provided for in point (c) of Article 66(3) and point (b) of Article 67 may, as appropriate, include: (a) treatment or processing, including decontamination, where appropriate, but excluding dilution, so that the consignment complies with the requirements of the rules referred to in Article 1(2), or with the requirements of a third country of re-dispatch; or (b) treatment in any other manner suitable for safe animal or human consumption or for purposes other than animal or human consumption. 2. The special treatment provided for in paragraph 1 shall:	*第 71 條* **託運物的特殊處理** 1. 第 66(3)條第(c)點和第 67 條第(b)點所規定的託運物的特殊處理，可適當地，包括： (a)處理或加工，適當時，包括去污但不包括稀釋，以使託運物符合第 1(2)條所提及之規範要求，或符合重新發運的第三國之要求；或 (b)以適合作為安全的動物或人類消費，或為了動物或人類消費以外的其他目的的任何方式進行處理。 2. 第 1 項所規定的特殊處理應： (a)被有效地執行並確保消除對人類、動物或植物健康、動物福祉或關於基因改造生物和植物保護產

(a) be carried out effectively and ensure the elimination of any risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment; (b) be documented and carried out under the control of the competent authorities or, where appropriate, under the control of the competent authorities of another Member State by mutual agreement; and (c) comply with the requirements laid down in the rules referred to in Article 1(2). 3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the requirements and the conditions in accordance with which the special treatment provided for in paragraph 1 of this Article is to take place. In the absence of rules adopted by delegated acts, such special treatment shall take place in accordance with national law.	品，以及環境產生的任何風險； (b)在權責機關的管制下予以記錄和執行，或在適當時，由另一會員國在雙方同意的情況下權責機關執行管制；以及 (c)符合第 1(2)條所提及之規範要求。 3. 歐盟執委會有權根據第 144 條採用授權法規，以補充本規章關於依據本條第 1 項的特殊處理之規定若發生時的要求和條件。 在欠缺由授權法規採用規範的情況下，此種特殊處理應根據各國國內法律為之。
Article 72 **Re-dispatch of consignments** 1. The competent authorities shall allow the re-dispatch of consignments subject to compliance with the following conditions: (a) the destination has been agreed with the operator responsible for the consignment; (b) the operator responsible for the consignment has informed the competent authorities of the Member State in writing that the competent authorities of the third country of origin or, if different, the third country of destination have been informed of the reasons and circumstances for the refusal of the entry into the Union of the consignment of animals or goods concerned; (c) where the third country of destination is not the third country of origin, the operator has obtained the agreement of the competent authorities of that third country of destination and those competent authorities have notified the competent authorities of the Member State that they are prepared to accept the consignment; and (d) in the case of consignments of animals, the re-dispatch is in compliance with animal welfare requirements. 2. The conditions set out in points (b) and (c) of paragraph 1 of this Article shall not apply to consignments of the categories of goods referred to in point (c) of Article 47(1).	*第 72 條* **託運物的重新發運** 1. 權責機關應允許託運物之重新發運，但須符合下列條件： (a)負責該託運物的運營商已同意該目的地； (b)負責該託運物的運營商已向該會員國之權責機關為書面通知，通知內容為來源地第三國的權責機關、或，如果不同的話，為目的地第三國的權責機關已被告知所涉託運物之動物或貨物被拒絕進入歐盟之理由和情況； (c)如果目的地第三國不是來源地第三國時，則運營商須已獲得該目的地第三國之權責機關的同意，並且該等第三國之權責機關已通知該會員國之權責機關他們準備接受該託運物之發運；以及 (d)若為動物之託運物，則重新發運應符合動物福祉之要求。 2. 本條第 1 項第(b)和(c)點所規定的條件不適用於第 47(1)條第(c)點所提及之貨物種類的託運物。

Section IV **Approval of the pre-export controls**	第 IV 部分 **出口前管制的核准**
Article 73 **Approval of pre-export controls performed by third countries**	*第 73 條* **第三國所執行的出口前管制的核准**
1. The Commission may, by means of implementing acts, approve, upon request of a third country, specific pre-export controls that that third country carries out on consignments of animals and goods prior to export to the Union with a view to verifying that the exported consignments satisfy the requirements of the rules referred to in Article 1(2). Such approval shall only apply to consignments originating in the third country concerned and may be granted for one or more categories of animals or goods. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	1. 歐盟執委會得，藉由施行細則，應第三國的請求，核准該第三國在出口到歐盟之前對動物和貨物的託運物執行的具體出口前管制，以利查驗該出口貨物符合第 1 條之 2 所提及之規範的要求。此類核准應僅適用於源自所涉第三國的託運物，並可准許一類或多類的動物或貨物。上開施行細則應按照第 145 條之 2 所提及之審查程序予以採用。
2. The approval provided for in paragraph 1 shall specify: (a) the maximum frequency of official controls to be performed by the competent authorities of Member States at the entry of the consignments into the Union, where there is no reason to suspect non-compliance with the rules referred to in Article 1(2) or fraudulent or deceptive practices; (b) the official certificates that must accompany consignments entering the Union; (c) a model for the certificates referred to in point (b); (d) the competent authorities of the third country under the responsibility of which pre-export controls must be performed; and (e) where appropriate, any delegated body to which those competent authorities may delegate certain tasks. Such delegation may only be approved if it meets the criteria set out in Articles 28 to 33 or equivalent conditions.	2. 第 1 項所規定的核准應具體說明下列內容： (a)會員國權責機關在託運物入境時所執行的官方管制的最大頻率，此時沒有理由懷疑不符合第 1 條之 2 所提及之規範，或有詐欺或欺騙行為； (b)進入歐盟的貨物必須隨附的官方證書； (c)於(b)點所提及之官方證書的樣本； (d)負責執行出口前管制的第三國權責機關；以及 (e)適當時，該等權責機關可委以特定任務之任何受託機構。 只有符合第 28 至 33 條或同等條件規定的標準，才能核准此類委託予該受託機構。
3. The approval provided for in paragraph 1 of this Article may only be granted to a third country if the evidence available and, where appropriate, a Commission control performed in accordance with Article 120, demonstrate that the system of official controls in that third country is able to ensure that: (a) the consignments of the animals or goods exported to the Union meet the requirements of the rules referred to in Article 1(2), or equivalent requirements; and	3. 本條第 1 項所規定的核准，僅能在現有可得到之證據及適當時，歐盟執委會根據第 120 條所執行的管制，證明該第三國的官方管制系統能夠保證下列事項，方可授予該第三國(執行出口前管制)： (a)出口到歐盟的動物或貨物的託運物符合第 1 條之 2 所提及之規範的要求或是同等效力的要求；以

(b) the controls performed in the third country prior to dispatch to the Union are sufficiently effective to replace or reduce the frequency of the documentary, identity checks and physical checks laid down in the rules referred to in Article 1(2). 4. The competent authorities or a delegated body specified in the approval shall: (a) be responsible for contacts with the Union; and (b) ensure that the official certificates referred to in point (b) of paragraph 2 accompany each consignment that is controlled. 5. The Commission shall, by means of implementing acts, lay down detailed rules and criteria for approving pre-export controls performed by third countries in accordance with paragraph 1 of this Article and for official controls performed by the competent authorities of the Member States on animals and goods subject to the approval referred in that paragraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	及 (b)在發運到歐盟之前在第三國所執行的管制足以有效地取代或減少第 1 條之 2 所提及之規範中規定的紀錄影片、身分檢查和物性檢查的頻率。 4. 核准書中所指出的權責機關或受託機構應： (a)負責與歐盟間的聯繫；及 (b)確保第 2 項第(b)點所提及之官方證書確實隨附於每一批受管制的託運物上。 5. 歐盟執委會應藉由施行細則，制定詳細的規範和標準，以核准第三國根據本條第 1 項執行的出口前管制以及由會員國權責機關對受該節所述之核准的動物和貨物所執行的官方管制。上開施行細則應按照第 145 條之 2 所提及之審查程序予以採用。
Article 74 **Non-compliance with, and withdrawal of, the approval of pre-export controls performed by third countries** 1. When official controls on consignments of categories of animal and goods in respect of which specific pre-export controls have been approved in accordance with Article 73(1) reveal serious and recurrent non-compliance with the rules referred to in Article 1(2), Member States shall immediately: (a) notify the Commission and the other Member States and operators concerned via the IMSOC in addition to seeking administrative assistance in accordance with the procedures established in Articles 102 to 108; and (b) increase the number of official controls on consignments from the relevant third country and, where necessary to allow a proper analytical examination of the situation, keep an appropriate number of samples under appropriate storage conditions. 2. The Commission may, by means of implementing acts, withdraw the approval provided for in Article 73(1) where, following the official controls referred to in paragraph 1 of this Article, there are indications that the requirements laid down in Article 73(3) and (4) are no longer being met. Those implementing acts shall be adopted in accordance with the examination procedure referred to in	*第 74 條* **第三國對出口前管制批准的不符合情形及批准的撤銷** 1. 當已根據第 73 條之 1 所核准之對特定出口前管制動物和貨物類別的託運物所執行之官方管制顯示對第 1 條之 2 所提及之規範有嚴重地及一再出現的不符合情事時，則會員國應立即採取下列作為： (a)除了根據第 102 至 108 條規定的程序尋求行政協助外，應透過官方管制資訊管理系統(IMSOC)通知歐盟執委會、其他有關會員國與所涉之運營商；以及 (b)增加從相關第三國對託運物的官方管制次數，並在必要時，對該情況進行適當的分析檢查，及在適當的儲存條件下保留適當數量的樣品。 2. 歐盟執委會可，藉由施行細則，以利當在本條第 1 項所提及之官方管制之後，有跡象顯示依第 73 條之 1 規定所作之核准案，已不再符合第 73 條之 3 和之 4 規定的要求之情況下，將該項核准予以撤銷。上開施行細則應按照第 145 條之 2 所提

Article 145(2).	及之審查程序予以採用。
Section V **Cooperation between authorities in relation to consignments from third countries**	第 V 部分 **相關機關間就來自第三國託運物所進行的合作**
Article 75 **Cooperation between authorities in relation to consignments entering the Union from third countries** 1. Competent authorities, customs authorities and other authorities of the Member States dealing with animals and goods entering the Union shall cooperate closely to ensure that the official controls on consignments of animals and goods entering the Union are performed in accordance with the requirements of this Regulation. For that purpose, competent authorities, customs authorities and other authorities shall: (a) ensure reciprocal access to information which is necessary for the organisation and conduct of their respective activities in relation to animals and goods entering the Union; and (b) ensure the timely exchange of such information, including via electronic means. 2. The Commission shall, by means of implementing acts, lay down rules on uniform cooperation arrangements that competent authorities, customs authorities and other authorities referred to in paragraph 1 are required to put in place to ensure: (a) access by competent authorities to the information necessary for the immediate and complete identification of the consignments of animals and goods entering the Union that are subject to official controls at a border control post in accordance with Article 47(1); (b) the reciprocal update, through exchanges of information or synchronisation of relevant data sets, of information gathered by competent authorities, customs authorities and other authorities on consignments of animals and goods entering the Union; and (c) the swift communication of decisions taken by such authorities on the basis of the information referred to in points (a) and (b). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	*第 75 條* **相關機關間就從第三國進入歐盟的託運物所進行的合作** 1. 處理進入歐盟的動物和貨物的會員國之權責機關、海關和其他機關應密切合作，以確保對進入歐盟的動物和貨物之託運物的官方管制是確實按照本規章的要求執行的。 為此目的，權責機關，海關和其他機關應： (a)確保相互獲取為籌劃和開展與進入歐盟的動物和貨物有關的該等機關之各別活動所必需的資訊;及 (b)確保及時交換此類資訊，其中包括透過電子方法。 2. 歐盟執委會應藉由施行細則，制定有關一致的合作安排之規範，以利要求和第 1 項所提及權責機關、海關之其他機關付諸實施以確保： (a)由權責機關獲得立即和完整的識別進入歐盟之須依第 47(1)條條接受邊境管制的官方管制之動物和貨物的託運物所需的資訊; (b)透過資訊交換或相關數據集之同步，相互更新由權責機關、海關和其他機關收集之關於進入歐盟的動物和貨物的託運務之資訊;及 (c)迅速通報該等機關所根據(a)及(b)點所提及之資訊作出的決定。 上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
Article 76	*第 76 條*

Cooperation between authorities in relation to consignments not subject to specific controls at borders	機關間關於不受特定邊境管制的託運物方面的合作
1. Paragraphs 2, 3, and 4 of this Article shall apply in the case of consignments of animals and goods other than those subject to controls at entry into the Union as required by Article 47(1) of this Regulation and for which a customs declaration for release for free circulation has been made in accordance with point 12 of Article 5 of Regulation (EU) No 952/2013 and Articles 158 to 202 of that Regulation.	1. 本條第 2、3 和 4 節適用於本規章第 47(1)條所要求之進入歐盟的須受管制(範圍)以外的動物和貨物的託運物之情況，以及已根據(EU)第 952/2013 號規章第 5 條第 12 點和該規章第 158 至 202 條，由海關申報以利放行於歐盟自由流通之該等動物和貨物的託運務之情形。
2. Customs authorities shall suspend release for free circulation when they have reason to believe that the consignment may present a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, and immediately notify the competent authorities of such suspension.	2. 當海關有理由相信前述須受管制範圍以外的動物和貨物之託運物可能對人類、動物或植物健康、動物福祉，或關於基因改造生物和植物保護產品，以及對環境造成風險時，應立即暫停放行以供自由流通，並將此類暫停事宜立即通知權責機關。
3. A consignment whose release for free circulation has been suspended pursuant to paragraph 2 shall be released if, within three working days of the suspension of release, the competent authorities have not requested customs authorities to continue the suspension or have informed customs authorities that no risk is present.	3. 在前述該類似放行以供自由流通的託運物被依第 2 項暫停放行(以供自由流通)後三個工作日內，如果權責機關未要求海關繼續該項暫停或已通知海關該託運物並沒有風險存在，則應予以放行。
4. Where the competent authorities consider that a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, is present;	4. 當權責機關認為對人類、動物或植物健康、動物福祉，或關於基因改造生物和植物保護產品，以及對環境的風險存在時，應採取以下作為；
(a) they shall request the customs authorities not to release the consignment for free circulation and to include the following statement on the commercial invoice accompanying the consignment and on any other relevant accompanying document or the relevant electronic equivalents: 'Product presents a risk — release for free circulation not authorised — Regulation (EU) 2017/625';	(a)他們應要求海關不要放行該託運物使其自由流通，並在該託運物隨附的商業發票和任何其他相關隨附文件或相關電子等同文件加入以下陳述：「產品存在風險— 未經允許放行以供自由流通— (EU)2017/625 規章」；
(b) no other customs procedure shall be permitted without the consent of the competent authorities; and	(b)未經權責機關同意，不得允許其進行其他海關程序；以及
(c) Article 66(1), (3), (5) and (6), Articles 67, 68 and 69, Article 71(1) and (2) and Article 72(1) and (2) shall apply.	(c)第 66(1)、(3)、(5)和(6)條，第 67、68 和 69 條，第 71(1)和(2)條以及第 72(1)和(2)條將適用此種情況。
5. In the case of consignments of animals and goods other than those subject to controls at entry into the Union as required by Article 47(1) and for which no customs declaration for release for free circulation has been made, customs authorities, where they have reason to believe that the consignment may present a risk to human, animal or plant health, animal welfare or, as regards	5. 如果動物和貨物的託運物不是如第 47(1)條所要求於進入歐盟時受到管制者，並且未向海關申報以利(於歐盟)自由流通時，當海關有理由相信該託運物可能對人類、動物或植物健康、動物福祉或基因改造生物和植物保護產品，以及對環境構

GMOs and plant protection products, also to the environment, shall transmit all relevant information to the customs authorities in the Member States of final destination.	成風險時，應將所有相關資訊傳遞給最終目的地會員國的海關。
Section VI **Specific measures**	第 VI 部分 **特定措施**
Article 77 **Rules for specific official controls and for measures to be taken following the performance of such controls**	*第 77 條* **特定官方管制以及實施此等管制措施後應採取的措施之規範**
1. The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules for the performance of specific official controls and on measures in cases of non-compliance, to account for the specificities of the following categories of animals and goods or the arrangements for, and means of, their transport:	1. 歐盟執委會應根據第 144 條採用授權法規，以補充本規章關於執行具體官方管制和遇有不符合情事時的措施之規範，以說明下列動物和貨物之類別與對其之安排的獨特性，以及運輸的安排和方式：
(a) consignments of fresh fishery products directly landed in ports designated by Member States in accordance with Article 5(1) of Council Regulation (EC) No 1005/2008 [61] from a fishing vessel flying a third country flag;	(a)從懸掛第三國國旗的漁船直接卸貨在會員國根據歐盟理事會(EC)第 1005/2008 號規章第 5(1)條所指定的港口之新鮮漁業產品的託運物；
(b) consignments of unskinned, furred wild game;	(b)未剝皮、帶有皮毛的野生獵物的託運物者；
(c) consignments of the categories of goods referred to in point (b) of Article 47(1) which are delivered, with or without storage in a specially approved customs warehouses or in free zones, to vessels leaving the Union and intended for ship supply or consumption by the crew and passengers;	(c)第 47(1)條第(b)點所提及之貨物類別的託運物，其無論是否存放在特別核准的海關倉庫或自由區內，將被交付給離開歐盟的船舶，並作為船員和乘客的船舶供應品或消費者之用；
(d) wood packaging material;	(d)木質包裝材料者；
(e) feed accompanying animals and intended for the feeding of those animals;	(e)餵養陪伴動物並用於餵養該等動物者；
(f) animals and goods ordered by sales through distance contracts and delivered from a third country to an address in the Union, and the notification requirements necessary to allow the proper performance of official controls;	(f)由辦理部門透過長途契約訂購並從第三國交付到在歐盟範圍內的地址的動物和貨物，且要求須作通知以利官方管制適當執行之；

61 Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999 (OJ L 286, 29.10.2008, p. 1)./ 歐盟理事會 2008 年 9 月 29 日第(EC)1005/2008 號建立歐洲共同體系統，以預防、制止和消除非法、未報告和無管制的捕撈，並修訂第(EEC)2847/93、(EC)1936/2001 和(EC)601/2004 等號規章並廢除第(EC)1093/94 和(EC)1447/1999 等號規章。

(g) plant products which, on account of their subsequent destination, may give rise to the risk of spreading infectious or contagious animal diseases; (h) consignments of the categories of animals and goods referred to in points (a), (b) and (c) of Article 47(1) originating from, and returning to, the Union following a refusal of entry by a third country; (i) goods entering the Union in bulk from a third country, irrespective of whether they all originate from that third country; (j) consignments of goods referred to in Article 47(1) coming from the territory of Croatia and transiting through the territory of Bosnia and Herzegovina at Neum ('Neum corridor') before re-entering the territory of Croatia via the points of entry at Klek or Zaton Doli; (k) animals and goods exempted from Article 47 in accordance with Article 48. 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the conditions for monitoring the transport and arrival of consignments of certain animals and goods, from the border control post of arrival to the establishment at the place of destination in the Union, to the border control post at the place of destination or to the border control post of exit. 3. The Commission may, by means of implementing acts, lay down rules on: (a) model official certificates and rules for the issuance of such certificates; and (b) the format of documents that must accompany the categories of animals or goods referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	(g)植物產品，其由於其跟催目的地之效，可能會引起感染性或傳染性動物疾病的風險者； (h)第 47(1)條第(a)、(b)和(c)點所提及之源自歐盟內的動物和貨物種類的託運物，在第三國被拒絕入境後，運回歐盟者； (i)從第三國大量進入歐盟的貨物，不論它們是否均以該第三國為原產地者； (j)第 47(1)條所提及之貨物的託運物，其來自克羅埃西亞境內並經波斯尼亞和黑塞哥維那聯邦領土的 Neum(內烏姆走廊)轉運，然後採用 Klek 或 Zaton Doli 入境點重新進入克羅埃西亞領土者； (k)根據第 48 條豁免邊境管制的第 47 條所述的動物和貨物者。 2. 歐盟執委會有權根據第 144 條採用授權法規，以補充本規則關於監控某些動物和貨物的運輸和到達的條件，從抵達的邊境管制站到位於歐盟內之目的地處所的廠場、到目的地處所的邊境管制站或到出境歐盟管制站。 3. 歐盟執委會，藉由可以採用施行細則，制定關於以下事宜之規範： (a)官方證書樣本和為頒發此類證書之規範；及 (b)必須隨附於第 1 項所提及之動物或貨物類別的文件之格式。 上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
CHAPTER VI ***Financing of official controls and of other official activities***	*第 VI 章* ***官方管制和其他官方活動的財政***
Article 78 **General rules** 1. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to perform official controls and other official	*第 78 條* **一般規則** 1. 會員國應確保有足夠的財政資源，俾為權責機關提供必要的職員和其他資源，以便進行官方管制和其他官方活動。

activities. 2. This Chapter also applies in the case of delegation of certain official control tasks and other official activities in accordance with Articles 28 and 31.	2. 本章也適用於根據第 28 條和第 31 條作特定官方管制任務和其他官方活動之授權的情況。
Article 79 **Mandatory fees or charges** 1. The competent authorities shall collect fees or charges for the official controls performed in relation to the activities referred to in Chapter II of Annex IV and on animals and goods referred to in points (a), (b) and (c) of Article 47(1), at border control posts or at control points referred to in point (a) of Article 53(1), either; (a) at the level of the cost calculated in accordance with Article 82(1); or (b) at the amounts provided for in Annex IV. 2. The competent authorities shall collect fees or charges to recover the costs they incur in relation to: (a) official controls performed on animals and goods referred to in points (d), (e) and (f) of Article 47(1); (b) official controls performed at the request of the operator, to obtain the approval provided for in Article 10 of Regulation (EC) No 183/2005; (c) official controls which were not originally planned, and which; (i) have become necessary following the detection of a case of non-compliance by the same operator, during an official control performed in accordance with this Regulation; and (ii) are performed to assess the extent and the impact of the case of non-compliance or to verify that the non-compliance has been remedied. 3. Notwithstanding paragraphs 1 and 2, Member States may, in relation to the activities referred to in Chapter II of Annex IV, on an objective and non-discriminatory basis, reduce the amount of the fees or charges, taking into account: (a) the interests of operators with a low throughput; (b) the traditional methods used for production, processing and distribution; (c) the needs of operators located in regions subject to specific geographical constraints; and (d) the operators' record of compliance with the relevant rules referred to in Article 1(2) as ascertained	*第 79 條* **強制性的費用** 1. 權責機關應於邊境管制站或於第 53(1)條第(a)點所提及之管制點，收取與附件 IV 第 2 章所提及之活動有關以及關於第 47(1)條第(a)、(b)和(c)點所提及之動物和貨物的官方管制的費用。不是(下列之)； (a)按照第 82(1)條計算的成本水準；就是(下列之) (b)按附件 IV 規定的數額。 2. 權責機關應收取費用或收費，以彌補其因下列相關事項產生的費用： (a)對第 47(1)條之第(d)、(e)和(f)點所提及之動物和貨物執行的官方管制； (b)應運營商的要求所執行的官方管制，以獲得(EC)183/2005 號規章第 10 條所述的核准； (c)原先未規劃以及有下列情況時的官方管制； (i)在根據本規章執行的官方管制期間，於查到同一運營商所為之不符合情事之情況後變得有執行的必要；及 (ii)用以評估未符合法規情況的程度和影響，或核實不符合法規情況是否已得到改正。 3. 儘管有第 1 項和第 2 項的規定，會員國可在客觀和非歧視性的基礎上就與附件 IV 第 II 章所提及之活動相關者，考慮到下列事宜，減少其收費標準： (a)低營運量的運營商之利益； (b)用於生產、加工和分銷的傳統方法； (c)位於受特定地域限制的地區的運營商的需求；及 (d)透過官方管制所確定的運營商符合第 1(2)條所提及之相關規範的紀錄。

through official controls. 4. Member States may decide that fees and charges calculated in accordance with point (b) of Article 82(1) shall not be collected below the amount at which, taking into account the cost of collection and the overall income expected from the fees and charges, the collection of that fee or charge would be uneconomical. 5. This Article shall not apply to official controls performed to verify compliance with the rules referred to in points (i) and (j) of Article 1(2).	4. 會員國可以決定，根據第 82(1)條第(b)點所計算的費額若較經考量到收取之成本和預期的總收入的數額後，收取該等費額將是不經濟的，(底限金額)為低時，則在不予收取該等費額。 5. 本條不適用於為查驗是否符合第 1 條第(2)款第(i)和(j)點所提及之規範而執行的官方管制。
Article 80 **Other fees or charges** Member States may collect fees or charges to cover the costs of official controls and other official activities other than those fees or charges referred to in Article 79, unless prohibited by the legislative provisions applicable in the areas governed by the rules referred to in Article 1(2).	*第 80 條* **其他費用** 否則除非適用於第 1(2)條所提及之規範所轄管領域的法令規定予以禁止之情況，會員國可收取費用，以支付第 79 條所提及之費用以外的官方管制和其他官方活動的成本。
Article 81 **Costs** The fees or charges to be collected in accordance with point (a) of Article 79(1) and with Article 79(2) shall be determined on the basis of the following costs, insofar as these result from the official controls concerned : (a) the salaries of the staff, including support and administrative staff, involved in the performance of official controls, their social security, pension and insurance costs; (b) the cost of facilities and equipment, including maintenance and insurance costs and other associated costs; (c) the cost of consumables and tools; (d) the cost of services charged to the competent authorities by delegated bodies for official controls delegated to these delegated bodies; (e) the cost of training of the staff referred to in point (a), with the exclusion of the training necessary to obtain the qualification necessary to be employed by the competent authorities; (f) the cost of travel of the staff referred to in point (a), and associated subsistence costs;	*第 81 條* **成本** 根據第 79(1)條第(a)點和第 79(2)條收取的費用，應依以下之成本為基礎作決定，只要該等費用係有所涉的官方管制所產生： (a)參與執行官方管制之職責(其中包括協助和行政職員)的薪資其社會保險、養老金和保險費用； (b)設施和設備的成本，其中包括維修和保險費用以及其他相關費用； (c)消耗品和工具的費用； (d)受委託機構向權責機關收取的授予該等受委託機構執行的官方管制服務費用； (e)於(a)點所提及之職員的培訓費用，但不包括獲得權責機關所錄用需資格的訓練費用； (f)於(a)點所提及之職員的旅費和相關的基本生活費； (g)官方實驗室為這些任務所收取的取樣和實驗室分析、測試和診斷的費用。

(g) the cost of sampling and of laboratory analysis, testing and diagnosis charged by official laboratories for those tasks.	
Article 82 **Calculation of fees or charges** 1. Fees or charges collected in accordance with point (a) of Article 79(1) and with Article 79(2) shall be established in accordance with one of the following methods of calculation or a combination of them: (a) at a flat-rate on the basis of the overall costs of official controls borne by the competent authorities over a given period of time, and applied to all operators irrespective of whether any official control is performed during the reference period in relation to each operator charged; in establishing the level of the fees to be charged for each sector, activity and category of operators, the competent authorities shall take into consideration the impact that the type and the size of the activity concerned, and the relevant risk factors, have on the distribution of the overall costs of those official controls; or (b) on the basis of the calculation of the actual costs of each individual official control, and applied to the operators subject to such official control. 2. Travel costs as referred to in point (f) of Article 81 shall be considered for the calculation of the fees or charges referred to in point (a) of Article 79(1) and in Article 79(2) in a manner that does not discriminate between operators on the basis of the distance of their premises from the location of the competent authorities. 3. Where fees or charges are calculated in accordance with point (a) of paragraph 1, the fees or charges collected by competent authorities shall not exceed the overall costs incurred for the official controls performed over the period of time referred to therein. 4. Where fees or charges are calculated in accordance with point (b) of paragraph 1, they shall not exceed the actual cost of the official control performed.	*第 82 條* **費用之計算** 1. 根據第 79(1)條第(a)點和第 79(2)條收取的費用，應按照下列計算方法之一或其組合訂定： (a)以權責機關在一段時間內承擔的官方管制的總成本為基礎按統一費率計算，並適用於所有運營商，不論在參考期間是否有對每個被收費的運營商執行任何官方管制；在制定對運營商的每個行業活動和類別的收費標準時，權責機關應考慮到所涉活動的類型和規模，以及相關風險因素對於該等官方管制總成本分配上的影響；或 (b)以每個個別官方管制的實際成本之計算為基礎，並適用於受該官方管制的運營商。 2. 第 81 條第(f)點所提及之差旅費，於計算第 79(1)條第(a)點和第 79(2)條所提及之費用應以不依據運營商處所與權責機關所在地之間的距離而對運營商有差別待遇之方式加以考量。 3. 如果費用是按照第 1 項第(a)點計算的，權責機關收取的費用不得超過在該條文中提及的時間內執行的官方管制所產生的總成本。 4. 如果費用係按照第 1 項第(b)點計算時，則不得超過所執行的官方管制的實際成本。
Article 83 **Collection and application of fees or charges** 1. An operator shall only be charged with a fee or charge for an official control and for another official activity performed on the basis of a complaint if that control leads to the confirmation of	*第 83 條* **費用之收取與適用** 1. 運營商只應被收取官方管制以及基於其顧客抱怨所執行的其他官方活動所衍生的費用，如果經該項管制確認有不符合情事時。

non-compliance. 2. Fees or charges collected in accordance with Articles 79 and 80 shall not be directly or indirectly refunded, unless unduly collected. 3. Member States may decide that fees or charges shall be collected by authorities other than the competent authorities or by delegated bodies.	2. 除非是不適當的收取，否則不得直接或間接退還根據第 79 條和第 80 條所收取的費用。 3. 會員國可決定由權責機關以外之機關或由受委任機構收取費用。
Article 84 **Payment of fees or charges** 1. The competent authorities shall ensure that the operators receive, upon request, proof of payment of fees or charges in the event that the operators do not otherwise have access to such proof. 2. Fees or charges collected in accordance with Article 79(1) shall be paid by the operator responsible for the consignment or its representative.	*第 84 條* **費用之支付** 1. 權責機關應確保運營商在其無法以其他方式取的付費制明知情況下，應其要求，使其可收到該項證明。 2. 根據第 79(1)條收取的費用應由負責貨物的運營商或其代表支付。
Article 85 **Transparency** 1. 1. Member States shall ensure a high level of transparency on: (a) the fees or charges provided for in point (a) of Article 79(1), Article 79(2) and Article 80, namely on: (i) the method and data used to establish these fees or charges; (ii) the amount of the fees or charges, applied to each category of operators and for each category of official controls or other official activities; (iii) the breakdown of the costs, as referred to in Article 81; (b) the identity of the authorities or bodies responsible for the collection of the fees or charges. 2. Each competent authority shall make available to the public the information referred to in paragraph 1 of this Article for each reference period and the costs to the competent authority for which a fee or charge is due in accordance with point (a) of Article 79(1), Article 79(2) and Article 80. 3. Member States shall consult relevant stakeholders on the general methods used to calculate the fees or charges provided for in point (a) of Article 79(1), Article 79(2) and Article 80.	*第 85 條* **透明性** 1. 會員國應確保關於以下事宜之高度透明性： (a)第 79(1)條第(a)項、第 79(2)條和第 80 條規定的費用，即關於下列事項： (i)用以訂定這些費用的方法和數據; (ii)適用於每類運營商以及每類官方管制或其他官方活動的費額； (iii)第 81 條所提及之成本明細; (b)負責收取費用或規費的機關或機構的身分。 2. 各權責機關應向大眾公開本條第 1 項所提及之資訊，該等資訊係關於權責機關根據第 79(1)條第(a)點、第 79(2)條和第 80 條所收取的費用為適當之相關參考期間與成本之說明。 3. 會員國應就用來計算第 79(1)條第(a)點、第 79(2)條和第 80 條所規定的費用的一般方法與相關利害關係者商量。
CHAPTER VII ***Official certification***	*第 VII 章* ***官方驗證***

Article 86 **General requirements concerning official certification** 1. Official certification shall result in the issuance of: (a) official certificates; or (b) official attestations in the cases provided for in the rules referred to in Article 1(2). 2. Where the competent authorities delegate certain tasks related to the issuance of official certificates or official attestations, or to the official supervision referred to in Article 91(1), such delegation shall comply with Articles 28 to 33.	*第 86 條* **官方驗證的一般要求** 1. 官方認證將產生下列事項之發布： (a)官方證書；或 (b)第 1 條第(2)款所執行之規範中之情況的官方證明。 2. 如果權責機關將與發放官方證書或官方證明有關或與第 91(1)條所提及之官方監督予以授權，則該授權應符合第 28 至 33 條的規定。
Article 87 **Official certificates** Articles 88, 89 and 90 shall apply: (a) when the rules referred to in Article 1(2) require the issuance of an official certificate; and (b) to official certificates which are necessary for the purposes of exporting consignments of animals and goods to third countries or which are requested from the competent authority of a Member State of dispatch by the competent authority of a Member State of destination in respect of consignments of animals and goods which are to be exported to third countries.	第 87 條 **官方證書** 第 88、89 及 90 條將適用以下情形： (a)當第 1 條第(2)款所提及之規範要求頒發官方證書時；以及 (b)為向第三國出口動物和貨物之託運物所必需的官方證書，或由目的地會員國之權責機關向發運擬出口到第三國的動物和貨物的託運物之會員國權責機關要求發出的官方證書。
Article 88 **Signature and issuance of official certificates** 1. Official certificates shall be issued by the competent authorities. 2. Competent authorities shall designate the certifying officers who are authorised to sign official certificates and shall ensure that these officers: (a) are impartial, free from any conflict of interest, and in particular are not in a situation which may, directly or indirectly, affect the impartiality of their professional conduct in relation to what is being certified; and (b) have received appropriate training on the rules with which compliance is certified by an official certificate and on the technical assessment of compliance with those rules as well as with the relevant rules laid down in this Regulation.	*第 88 條* **官方證書之簽署與簽發** 1. 官方證書應由權責機關簽發。 2. 權責機關應指定有權簽署官方證書的驗證官員，並應確保該等官員如下事宜： (a)是公正的、不存在任何利益衝突，特別是不會有可能，直接或間接地影響將被驗證的專業行為之公正性；及 (b)已接受關於用來使符合性得由官方證書加以驗證之規範以及關於對(前述)該等規範與本規所提及之相關規範的符合性之技術評鑑的之適當培訓。

3. Official certificates shall be signed by the certifying officer and issued on one of the following grounds: (a) direct knowledge by the certifying officer of up-to-date facts and data relevant for the certification that is obtained through: (i) an official control; or (ii) the acquisition of another official certificate issued by the competent authorities; (b) facts and data relevant for the certification, knowledge of which was ascertained by another person authorised for that purpose by, and acting under the control of, the competent authorities, provided that the certifying officer can verify the accuracy of such facts and data; (c) facts and data relevant for the certification which were obtained from the operators' own control systems, complemented and confirmed by results from regular official controls, where the certifying officer is thus satisfied that the conditions for issuing the official certificate are met. 4. Official certificates shall be signed by the certifying officer and issued only on the basis of point (a) of paragraph 3 of this Article when rules referred to in Article 1(2) so require.	3. 官方證書應由驗證官員簽署，並以下列理由之一簽發： (a)由驗證官員直接了解透過以下方式獲得之與驗證相關的最新事實和數據： (i)官方管制;或 (ii)獲得由權責機關簽發的另一份官方證書; (b)與驗證有關的事實和數據，其對該等事實和數據之了解係由另一個由權責機關為此目的授權並由權責機關管制的人所確定，但前提是驗證官員可以查驗此類事實和數據的準確性; (c)從運營商自己的管制系統獲得的與驗證相關的事實和數據，並由定期官方管制的結果加以補充和確認，故驗證官員對該發官方證書的條件能夠符合性將是滿意的。 4. 官方證書應由認證官員簽署，並且只有在第1(2)條所提及之規範要求時，才能基於本條第3項第(a)點加以核發。
Article 89 **Guarantees of reliability for official certificates** 1. Official certificates shall: (a) bear a unique code; (b) not be signed by the certifying officer where they are blank or incomplete; (c) be drawn up in one or more of the official languages of the institutions of the Union understood by the certifying officer and, where relevant, in one of the official languages of the Member State of destination; (d) be authentic and accurate; (e) allow for the identification of the person who signed them and the date of issue; and (f) allow the easy verification of the links between the certificate, the issuing authority and the consignment, lot or individual animal or good covered by the certificate. 2. The competent authorities shall take all appropriate measures to prevent the issuance of false or	*第89條* **官方證書信賴度之保證** 1. 官方證書應： (a)具有唯一的代碼; (b)如證書空白或不完整，則驗證官員不得簽署; (c)以驗證官員所能了解的歐盟制度下的一種或多種正式語文擬具，相關時，並可以目的地會員國的一種正式語文擬具; (d)要真實且正確; (e)可識別簽署官方證書的人和簽發日期; 和 (f)允許簡易查驗證書、發證機關以及證書所涵蓋的託運物、批次或個別動物或貨物之間的聯結。 2. 權責機關應採取一切適當措施，以防止核發虛假

misleading official certificates or the abuse of official certificates.	的或誤導性的官方證書或濫用官方證書。
Article 90 **Implementing powers concerning official certificates** The Commission may, by means of implementing acts, lay down rules for the uniform application of Articles 88 and 89 concerning: (a) model official certificates and rules for the issuance of such certificates, where requirements are not laid down in the rules referred to in Article 1(2); (b) the mechanisms and technical arrangements to ensure the issuance of accurate and reliable official certificates, and prevent risk of fraud; (c) the procedures to be followed in the case of withdrawals of official certificates and for the issuance of replacement certificates; (d) rules for the production of certified copies of official certificates; (e) the format of documents that must accompany animals and goods after official controls have been performed; (f) rules for the issuance of electronic certificates and for the use of electronic signatures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	*第 90 條* **關於官方證書的執行權力** 歐盟執委會可，藉由施行細則，制訂關於下列事項之一致性應用第 88 和 89 條的規範： (a)官方證書樣本及核發此等證書之規範，此處之要求並未明訂於第 1(2)條所提及之規範中； (b)確保核發正確可靠的官方證書並防止欺詐風險的機制和技術安排； (c)撤銷官方證書和核發替代證書時應遵循的程序； (d)製作經驗證的官方證書副本的規範； (e)在執行官方管制後，必須附隨於動物和貨物文件格式； (f)頒發電子證書和使用電子簽名的規範。 上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
Article 91 **Official attestations** 1. When this Regulation or the rules referred to in Article 1(2) require the issuance of official attestations by the operators under the official supervision of the competent authorities, or by the competent authorities themselves, paragraphs 2, 3 and 4 of this Article shall apply. 2. Official attestations shall: (a) be authentic and accurate; (b) be drawn up in one or more of the official languages of the institutions of the Union and, where relevant, in one of the official languages of the Member State of destination; and (c) where they relate to a consignment or a lot, allow the verification of the link between the official	*第 91 條* **官方證明** 1. 當本規章或第 1(2)條條所提及之規範要求運營商在權責機關的官方監督下或權責機關自己核發官方證明時，適用本條第 2、3 和 4 節。 2. 官方證明應： (a)要真實且正確； (b)以歐盟各制度下的一種或多種官方語言擬具，相關時，並以目的地會員國的一種官方語言擬具；及 (c)如果該等官方證明與託運物或批次有關，則允許查驗該官方證明與該批託運物或批次之間的聯繫。

attestation and that consignment or lot. 3. Competent authorities shall ensure that the staff performing official controls to supervise the issuance of official attestations or, where the official attestations are issued by the competent authorities, the staff involved in the issuance of those official attestations: (a) are impartial, free from any conflict of interest, and in particular are not in a situation which may, directly or indirectly, affect the impartiality of their professional conduct in relation to what is being certified by the official attestations; and (b) have received appropriate training on: (i) the rules with which compliance is certified by the official attestations and on the technical assessment of compliance with those rules; (ii) the relevant rules laid down in this Regulation. 4. Competent authorities shall perform regular official controls to verify that: (a) the operators issuing the attestations comply with the conditions laid down in the rules referred to in Article 1(2); and (b)the attestation is issued on the basis of relevant, correct and verifiable facts and data.	3. 權責機關應確保執行官方管制的職員監督官方證明的核發，或在權責機關核發官方證明的情況下，參與核方該等官方證明之職員應符合下列要求： (a)公正、不存在任何利益衝突，特別是不會有可能，直接或間接地，影響將被官方驗證所證明的專業行為的公正性；及 (b)接受過關於下列事項之適當的培訓： (i)用來使符合性得以由官方證明加以驗證的規範以及對(前述)該等規範的符合性之技術評鑑； (ii)本規章所載的有關規範。 4. 權責機關應定期執行官方管制，以查驗下列事項： (a)核發證明的運營商符合第 1(2)條所提及之規範中明訂的條件；以及 (b)該證明是根據相關的、正確的、和可查驗的事實和數據核發的。
TITLE III **REFERENCE LABORATORIES AND REFERENCE CENTRES**	第 III 編 **參考實驗室和參考中心**
Article 92 **Decision to establish a European Union reference laboratory** 1. In the areas governed by the rules referred to in Article 1(2), a European Union reference laboratory shall be established where the effectiveness of official controls and other official activities also depends on the quality, uniformity and reliability of: (a) the methods of analysis, test or diagnosis employed by the official laboratories designated in accordance with Article 37(1); and (b) the results of the analyses, tests and diagnoses performed by those official laboratories. 2. A European Union reference laboratory shall be established where there is a recognised need to promote uniform practices in relation to the development or use of the methods referred to in point (a)	*第 92 條* **建立歐盟參考實驗室之決定** 1. 在受第 1(2)條所提及之規範管轄的領域，在官方管制和其他官方活動的有效性還取決於以下方面的品質、一致性和可靠性時，應建立歐盟參考實驗室： (a)根據第 37(1)條指定的官方實驗室所採用的分析、測試或診斷方法；及 (b)該等官方實驗室所執行的分析、測試和診斷的結果。 2. 如果有公認的需求以促進與第 1 項第(a)點所提及方法之開發或使用相關的一致性做法時，則應建立歐盟參考實驗室。

of paragraph 1. 3. The Commission shall review regularly the mandate and operation of the European Union reference laboratories. 4. The Commission shall supplement this Regulation by adopting the decision to establish a European Union reference laboratory by means of a delegated act in accordance with Article 144.	3. 歐盟執委會應定期審查歐盟參考實驗室的受委任的任務和運作情況。 4. 歐盟執委會應根據第 144 條以採用藉由授權法規建立歐盟參考實驗室的決定之方式來補充本規章。
Article 93 **Designation of European Union reference laboratories** 1. The Commission shall, by means of implementing acts, designate European Union reference laboratories in the cases where a decision has been taken to establish such a laboratory in accordance with Article 92. 2. The designations provided for in paragraph 1 shall: (a) follow a public selection process; and (b) be limited in time and with a minimum period of five years, or reviewed regularly. 3. European Union reference laboratories shall: (a) operate in accordance with standard EN ISO/IEC 17025 and be accredited in accordance with that standard by a national accreditation body, operating in accordance with Regulation (EC) No 765/2008. The scope of that accreditation: (i) shall include all the methods of laboratory analysis, test or diagnosis required to be used by the laboratory when it operates as a European Union reference laboratory; (ii) may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods; (iii) may be defined in a flexible manner, so as to allow the scope of the accreditation to include modified versions of the methods used by the European Union reference laboratory when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratory's own validations without a specific assessment, prior to the use of those modified or new methods, by the national accreditation body of the Member State where the European Union reference laboratory is located;	*第 93 條* **歐盟參考實驗室的指定** 1. 歐盟執委會應藉由施行細則，在根據第 92 條作出決定以建立此一實驗室的情況下，已指定歐盟參考實驗室。 2. 第 1 項所述的指定應： (a) 遵循公眾的甄選程序；及 (b) 在時間上有限制，最短期限為五年，或定期審查。 3. 歐盟參考實驗室應： (a)按照 EN ISO/IEC 17025 標準運作，並由按照(EC)第 765/2008 號規章運作之國家認證機構按照該標準進行認證。該項認證範圍如下： (i)應包括實驗室作為歐盟參考實驗室運作時所需的所有實驗室分析、測試或診斷方法； (ii)可包括一種或多種實驗室分析，測試或診斷方法或方法組； (iii)可以彈性方式定義，以便使認證的範圍包括歐盟參考實驗室在獲得認證時使用的方法的修改版本，或者除了該等方法之外的新方法。這些經過修改的方法或新的方法在使用之前，未經在歐盟參考實驗室所在地的會員國的國家認證機構具體評估，而係以實驗室自己的確效作為基礎； (b)保持公正，不受任何利益衝突的影響，特別是在可能，直接或間接地，影響其作為歐盟參考實驗室的任務的履行之專業行為的公正性的情況下； (c)擁有或可依契約獲得適當地認可合格的職，該等

(b) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as European Union reference laboratories;	職員應具備在其職權領域內所應用之適當的分析、測試和診斷技術訓練，並可妥適地之支援職員；
(c) have, or have contractual access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques applied in their area of competence, and support staff as appropriate;	(d)擁有或可獲得執行分配給他們的任務所需的基礎設施、設備和產品；
(d) possess, or have access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;	(e)確保其職員和任何契約聘用的人員對國際標準和做法有充分的了解，並確保在其工作中考慮到國家、歐盟和國際級的研究的最新發展；
(e) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;	(f) 配備或有權使用在緊急情況下執行其任務之必要的設備；以及
(f) be equipped, or have access to, the necessary equipment to perform their tasks in emergency situations; and	(g)有相關時，應配備符合相關生物安全標準的設備。
(g) where relevant, be equipped to comply with relevant biosecurity standards.	
4. By way of derogation from point (a) of paragraph 3 of this Article, for the area governed by the rules referred to in point (g) of Article 1(2), the Commission may designate official laboratories, designated as such by the competent authorities on the basis of a derogation adopted pursuant to Article 41, as European Union reference laboratories irrespective of whether they fulfil the conditions provided for in point (a) of paragraph 3 of this Article.	4. 作為本條第 3 項第(a)點規定的例外，對於受第 1(2)條第(g)點所提及之規範所管理的領域，歐盟執委會得指定權責機關基於不適用第 41 條的例外情形所指定之官方實驗室作為歐盟參考實驗室，不論其是否滿足本條第 3 項第(a)點所規定的條件。
5. By way of derogation from paragraphs 1 and 2 of this Article, the laboratories referred to in the first paragraph of Article 32 of Regulation (EC) No 1829/2003 and the first paragraph of the Article 21 of Regulation (EC) No 1831/2003 shall be the European Union reference laboratories having the responsibilities and performing the tasks referred to in Article 94 of this Regulation in the areas respectively of:	5. 作為本條第 1 項和第 2 項規定的例外，(EC)1829/2003 號規章第 32 條第 1 項和(EC)1831/2003 號規章第 21 節第 1 款所提及之實驗室應為歐盟參考實驗室，該等試驗室分別在以下領域負有其職責和執行本規章第 94 條所提及之任務：
(a) GMOs and genetically modified food and feed; and	(a)基因改造生物和轉基因改造食品和飼料；以及
(b) feed additives.	(b)飼料添加劑。
6. The confidentiality obligations of staff, referred to in Article 8, shall apply mutatis mutandis to staff of	6. 第 8 條所提及之職員的保密義務應比照適用於歐盟參考實驗室的職員。

the European Union reference laboratories.	
Article 94 **Responsibilities and tasks of European Union reference laboratories**	*第 94 條* **歐盟參考實驗室的職責和任務**
1. European Union reference laboratories shall contribute to the improvement and harmonisation of methods of analysis, test or diagnosis to be used by official laboratories designated in accordance with Article 37(1) and of the analytical, testing and diagnostic data generated by them.	1. 歐盟參考實驗室應協助改進和調和根據第 37(1)條指定的官方實驗室使用的分析、測試或診斷方法以及由它們產生的分析、測試和診斷之數據。
2. European Union reference laboratories designated in accordance with Article 93(1) shall be responsible for the following tasks insofar as they are included in the reference laboratories' annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014:	2. 根據第 93(1)條指定的歐盟參考實驗室應負責下列任務，只要它們被包括在按照為與歐盟執委會根據(EU)第 652/2014 號規章第 36 條採用的相關工作計畫目標和優先事項相符所制訂的參考實驗室年度或多年工作方案中：
(a) providing national reference laboratories with details and guidance on the methods of laboratory analysis, testing or diagnosis, including reference methods;	(a)向各國家參考實驗室提供關於實驗室分析、測試或診斷方法的細節和指引，其中包括參考方法；
(b) providing reference materials to national reference laboratories;	(b)向各國家參考實驗室提供參考標準物質；
(c) coordinating the application by the national reference laboratories and, if necessary, by other official laboratories of the methods referred to in point (a), in particular, by organising regular inter-laboratory comparative testing or proficiency tests and by ensuring appropriate follow-up of such comparative testing or proficiency tests in accordance, where available, with internationally accepted protocols, and informing the Commission and the Member States of the results and follow-up to the inter-laboratory comparative testing or proficiency tests;	(c)協調由各國家參考實驗室以及若有必要時，由其他官方實驗室所提出關於第(a)點所提及方法的申請，特別是，可藉由籌劃定期的實驗室間比較測試或能力檢驗，並藉由根據，在可取得時，國際間所接受的議定書確保此類比較測試或能力檢驗結果適當跟催(加以協調之)，並向歐盟執委會和各會員國通報實驗室間比較測試或能力檢驗的結果和後續之跟催；
(d) coordinating practical arrangements necessary to apply new methods of laboratory analysis, testing or diagnosis, and informing national reference laboratories of advances in this field;	(d)協調實施新的實驗室分析、測試或診斷方法所需的實際安排，並向各國家參考實驗室通報該領域的進展；
(e) conducting training courses for staff from national reference laboratories and, if needed, from other official laboratories, as well as of experts from third countries;	(e)為來自各國家參考實驗室的職員及，若有需要時，來自其他官方實驗室的職員以及來自第三國的專家舉辦培訓班；
(f) providing scientific and technical assistance to the Commission within the scope of their mission;	(f)在其任務範圍內向歐盟執委會提供科學和技術的協助；
(g) providing information on relevant national, Union and international research activities to national reference laboratories;	(g)向各國家參考實驗室提供有關國家、歐盟和國際

(h) collaborating within the scope of their mission with laboratories in third countries and with the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC); (i) assisting actively in the diagnosis of outbreaks in Member States of foodborne, zoonotic or animal diseases, or of pests of plants, by carrying out confirmatory diagnosis, characterisation and taxonomic or epizootic studies on pathogen isolates or pest specimens; (j) coordinating or performing tests for the verification of the quality of reagents and lots of reagents used for the diagnosis of foodborne, zoonotic or animal diseases and pests of plants; (k) where relevant for their area of competence, establishing and maintaining: (i) reference collections of pests of plants and/or reference strains of pathogenic agents; (ii) reference collections of materials intended to come into contact with food used to calibrate analytical equipment and provide samples thereof to national reference laboratories; (iii) up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents; and (l) where relevant for their area of competence, cooperate among themselves and with the Commission, as appropriate, to develop methods of analysis, testing or diagnosis of high standards. As regards point (i) of point (k), the European Union reference laboratory may establish and maintain those reference collections and reference strains by contractual outsourcing to other official laboratories and to scientific organisations. 3. European Union reference laboratories shall publish the list of the national reference laboratories designated by the Member States in accordance with Article 100(1).	研究活動的訊息； (h)在其任務範圍內與第三國的實驗室以及與歐洲食品安全局(EFSA)、歐洲藥品管理局(EMA)和歐洲疾病預防和管制中心(ECDC)合作； (i)藉由對病原體分離株或害蟲標本執行確認診斷、特性鑑定和分類學或動物流行病學的研究，主動協助會員國於食源性、人畜共通傳染病或動物疾病，或植物害蟲的爆發(原因之)診斷； (j)協調或執行測試，以查驗用於診斷食源性、人畜共通傳染病或動物疾病和植物害蟲的試劑和許多試劑批次的品質； (k)在與其職權領域有官時，建立和維持下列事宜： (i)參考植物害蟲和/或病原體參考株之蒐集； (ii)擬與用於校正分析設備的食品接觸的參考物質的蒐集，並將其樣品提供給各國家參考實驗室； (iii)可獲得的參考物質和試劑以及此類物質和試劑的製造商和供應商的最新清單；及 (l)在與其領域相關的情況下，彼此相互合作，並與歐盟執委會妥為合作，以開發高標準的分析、測試或診斷方法。 關於(k)點中(i)點部分，歐盟參考實驗室可藉由契約外包給其他官方實驗室和科學組織來建立和維護該等參考蒐集品及參考株。 3. 歐盟參考實驗室應公佈各會員國根據第100(1)條指定的國家參考實驗室清單。
Article 95 **Designation of European Union reference centres for animal welfare**	*第95條* **歐盟動物福祉參考中心之指定**
1. The Commission shall, by means of implementing acts, designate European Union reference centres for animal welfare that shall support the activities of the Commission and of the Member States in relation to the application of the rules referred to in point (f) of Article 1(2).	1. 歐盟執委會應，藉由施行細則，指定歐盟動物福祉參考中心，以支持執委會和會員國有關第1(2)條(f)點所提及之規範之應用的活動。
2. The designations provided for in paragraph 1 shall:	2. 第1項所述的指定應：

(a) follow a public selection process; and (b) be limited in time or reviewed regularly. 3. European Union reference centres for animal welfare shall: (a) act impartially as regards the exercise of their tasks as European Union reference centres; (b) possess a high level of scientific and technical expertise in human-animal relationship, animal behaviour, animal physiology, animal genetics, animal health and nutrition related to animal welfare, and animal welfare aspects related to the commercial and scientific use of animals; (c) have suitably qualified staff with adequate training in the areas referred to in point (b) and in ethical issues related to animals and support staff as appropriate; (d) possess, or have access to, the infrastructure, the equipment and products necessary to carry out the tasks assigned to them; and (e) ensure that their staff have good knowledge of international standards and practices in the areas referred to in point (b) and that the latest developments in research at national, Union and international level, including studies performed and actions undertaken by other European Union reference centres for animal welfare, in those areas are taken into account in their work.	(a)遵循公眾的甄選程序;及 (b)有時間限制或作定期檢討。 3. 歐盟動物福祉參考中心應： (a)公正地履行其作為歐盟參考中心的任務; (b)在與動物福祉有關的人 – 動物關係、動物行為、動物生理學、動物遺傳學、動物健康和營養，以及與動物的商業和科學用途有關的動物福祉方面向擁有高水準的科學和技術的專門知識; (c)有適當地認可合格並在第(b)點所提及之領域以及與動物有關的道德問題上具有充分訓練的職員，並能妥適地支持職員; (d)擁有或可獲得執行分配給他們的任務所需的基礎設施、設備和產品; 以及 (e)確保其職員充分了解(b)點所提及領域的國際標準和做法，以及確保在該等領域於他們的工作中已考量國家、歐盟和國際層級研究的最新進展，其中包括其他歐盟之動物福祉參考中心所開展的研究和採取的行動。
Article 96 **Responsibilities and tasks of European Union reference centres for animal welfare** The European Union reference centres for animal welfare shall be responsible for the following supporting tasks insofar as they are included in the reference centres' annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014: (a) providing scientific and technical expertise within the scope of their mission including, where appropriate in the form of coordinated assistance, to relevant national support networks and bodies in the area governed by the rules referred to in point (f) of Article 1(2); (b) providing scientific and technical expertise for the development and application of the animal welfare indicators referred to in point (e) of Article 21(8);	*第 96 條* **歐盟動物福祉參考中心的職責和任務** 歐盟動物福祉參考中心應負責下列的支持性任務，只要它們被包括在按照為與歐盟執委會根據(EU)652/2014 號規章第 36 條採用的相關工作計畫之目標和優先事項相符所制定的年度或多年度工作計畫中。： (a)對在第 1(2)條第(f)點所提及之規範所管理的領域內之相關的國家支援網絡和機構，提供在其任務範圍內之科學和技術的專門知識，其中包括，適當時，以經協調的協助的形式； (b)為第 21(8)條第(e)點所提及之動物福祉指標的發展和應用提供科學和技術的專業知識; (c)制定或協調制定評估動物福祉水準的方法以及改善動物福祉的方法;

(c) developing or coordinating the development of methods for the assessment of the level of welfare of animals and of methods for the improvement of the welfare of animals; (d) carrying out scientific and technical studies on the welfare of animals used for commercial or scientific purposes; (e) conducting training courses for staff of the national scientific support networks or bodies referred to in point (a), for staff of the competent authorities and for experts from third countries; and (f) disseminating research findings and technical innovations and collaborating with Union research bodies in the fields within the scope of their mission.	(d)對用於商業或科學目的之動物的福祉執行科學和技術的研究； (e)為第(a)點所提及之國家科學支援網絡或機構的職員，及為權責機關的職員和第三國的專家舉辦培訓班；以及 (f)傳播研究成果和技術創新，並在其任務範圍內與歐盟研究機構合作。
Article 97 **Designation of European Union reference centres for the authenticity and integrity of the agri-food chain** 1. The Commission may, by means of implementing acts, designate European Union reference centres that shall support the activities of the Commission and of the Member States to prevent, detect and combat violations of the rules referred to in Article 1(2) perpetrated through fraudulent or deceptive practices. 2. The designations provided for in paragraph 1 shall: (a) follow a public selection process; and (b) be limited in time or reviewed regularly. 3. European Union reference centres for the authenticity and integrity of the agri-food chain shall: (a) act impartially as regards the exercise of their tasks as European Union reference centres; (b) possess a high level of scientific and technical expertise in the areas governed by the rules referred to in Article 1(2) and in applied forensic science in those areas, in order to have the ability to carry out or coordinate research at the highest level on the authenticity and integrity of goods and to develop, apply and validate the methods to be used for the detection of violations of the rules referred to in Article 1(2) perpetrated through fraudulent or deceptive practices; (c) have suitably qualified staff with adequate training in the areas referred to in point (b) and the necessary support staff; (d) possess, or have access to, the infrastructure, the equipment and the products necessary to carry out	*第 97 條* **為歐盟農業食品供應鏈的真實性和完整性之歐盟參考中心指定** 1. 歐盟執委會，藉由施行細則，指定歐盟參考中心，該等參考中心應支持歐盟執委會和會員國的活動，以防止、發現和打擊透過欺詐或欺騙行為之違反第 1(2)條規範的情事。 2. 第 1 項所述的指定應： (a)遵循公眾的甄選程序；以及 (b)有期間限定或作定期檢討。 3. 歐盟農業食品供應鏈真實性和完整性參考中心應： (a)公正地履行其作為歐盟參考中心的任務； (b)在第 1(2)條所提及之規範管理的領域內和在該等領域的應用法醫科學方面擁有高水準之的科學和技術的專門知識，以便有能力就貨物的真實性和完整性以最高水準執行或協調其研究，並制訂、應用和確效用於偵測是採用欺詐或欺騙行為之違反第 1(2)條所提及之規範的方法； (c)有適當地認可合格之在第(b)點所提及的領域具有充分的訓練的職員，以及必要的支援職員； (d)擁有或可獲得執行分配給他們的任務所需的基礎設施、設備和產品；及

the tasks assigned to them; and (e) ensure that their staff have good knowledge of international standards and practices in the areas referred to in point (b) and that the latest research developments at national, Union and international level in those areas are taken into account in their work.	(e)確保其職員充分了解第(b)點所述領域的國際標準和做法，並確保在該等領域於其工作中已考慮到國家、歐盟和國際層級的最新研究進展。
Article 98 **Responsibilities and tasks of European Union reference centres for the authenticity and integrity of the agri-food chain** The European Union reference centres for the authenticity and integrity of the agri-food chain shall be responsible for the following supporting tasks insofar as they are included in the reference centres' annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014: (a) providing specialised knowledge in relation to the authenticity and integrity of the agri-food chain and to the methods for detecting violations of the rules referred to in Article 1(2) of this Regulation perpetrated through fraudulent or deceptive practices, in relation to the forensic science applied to the areas governed by these rules; (b) providing specific analyses designed to identify the segments of the agri-food chain that are potentially subject to violations of the rules referred to in Article 1(2) of this Regulation perpetrated through fraudulent or deceptive practices and helping to develop specific official control techniques and protocols; (c) where necessary, performing the tasks referred to in points (a) to (h) of Article 94(2) of this Regulation, thereby avoiding duplication with the tasks of European Union reference laboratories designated in accordance with Article 93 of this Regulation; (d) where necessary, establishing and maintaining collections or databases of authenticated reference materials, to be used to detect violations of the rules referred to in Article 1(2) of this Regulation perpetrated through fraudulent or deceptive practices; and (e) disseminating research findings and technical innovations in the fields within the scope of their	*第 98 條* **歐盟參考中心對農業食品供應鏈的真實性和完整性的責任和任務** 歐盟農業食品供應鏈真實性和完整性參考中心應負責以下列支持性任務，只要它們被包括在按照為與歐盟執委會根據(EU)第 652/2014 號規章第 36 條採用的相關工作計畫之目標和優先事項制訂的年度或多年度工作計畫中： (a)提供與農業食品供應鏈的真實性和完整性有關以及與用來偵測透過欺詐或欺騙行為之違反本規章第 1(2)條所提及之規範的方法有關的專業知識，而該等行為係與應用於此等規範所管理之領域的法醫科學相關； (b)提供被設計用來識別潛在地遭受到透過欺詐或欺騙行為之違反本規章第 1(2)條所提及之規範的農業食品供應鏈部分之具體分析，並有助於制訂具體的官方管制技術和協議； (c)在必要時，執行本規章第 94(2)條第(a)至(h)點所提及之任務，從而避免與根據本規章第 93 條指定的歐盟參考實驗室的任務重複； (d)在必要時，建立和維護經過證實為真的參考物質的蒐集或資料庫，以用於偵測透過欺詐或欺騙行為之違反本規章第 1(2)條所訂的情事；以及 (e)傳播在其任務範圍內之研究成果和技術創新。

mission.	
Article 99 **Obligations of the Commission**	*第 99 條* **歐盟執委會的義務**
1. The Commission shall publish and update, whenever necessary, the list of: (a) European Union reference laboratories provided for in Article 93; (b) European Union reference centres for animal welfare provided for in Article 95; (c) European Union reference centres for the authenticity and integrity of the agri-food chain provided for in Article 97. 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the establishment of requirements, responsibilities and tasks for the European Union reference laboratories, the European Union reference centres for animal welfare and European Union reference centres for the authenticity and integrity of the agri-food chain in addition to those laid down in Article 93(3), Article 94, Article 95(3), Article 96, Article 97(3) and Article 98. Such delegated acts shall be limited to situations of new or emerging risks, new or emerging animal diseases or pests of plants or where new legal requirements so warrant. 3. European Union reference laboratories and European Union reference centres shall be subject to Commission controls to verify compliance with the requirements of Article 93(3), Article 94, and Articles 95(3) and 97(3). 4. If the Commission controls referred to in paragraph 3 of this Article show non-compliance with the requirements laid down in Article 93(3), Article 94, and Articles 95(3) and 97(3), the Commission shall, after having received the comments of the European Union reference laboratory or European Union reference centre: (a) by means of an implementing act, withdraw the designation of that laboratory or centre; or (b) take any other appropriate measure.	1. 歐盟執委會應在必要時公佈和更新以下清單： (a)第 93 條所述的歐盟參考實驗室； (b)第 95 條所述的歐盟動物福祉參考中心； (c)第 97 條所述的歐盟農業食品供應鏈真實性和完整性參考中心。 2. 歐盟執委會有權根據第 144 條採用授權法規以補充本規章關於對歐盟參考實驗室、歐盟動物福祉參考中心，以及歐盟農業食品供應鏈之真實性和完整性參考中心除第 93(3)條、第 94 條、第 95(3)條、第 96 條、第 97(3)條和第 98 條規定外之要求、責任和任務的制定。上開授權法規應限於新的或新興的風險、新的或新興的動物疾病或植物害蟲的情況，或新的法律要情如此做的情況。 3. 歐盟參考實驗室和歐盟參考中心應受歐盟執委會之管制，以查驗是否符合第 93(3)條、第 94 條，以及第 95(3)和 97(3)條的要求。 4. 如果本條第 3 項所提及之歐盟執委會之管制措施顯示有不符合第 93(3)條、第 94 條，以及第 95(3)和 97(3)條所訂要求，歐盟執委會應，在收到歐盟參考實驗室或歐盟參考中心的評論之後(做下列事宜)： (a)藉由施行細則，撤銷該實驗室或中心的指定資格；及 (b)採取任何其他適當措施。
Article 100 **Designation of national reference laboratories** 1. Member States shall designate one or more national reference laboratories for each European Union	*第 100 條* **國家參考實驗室的指定** 1. 會員國應為根據第 93(1)條指定的每個歐盟參考

reference laboratory designated in accordance with Article 93(1).

Member States may designate a national reference laboratory also in the cases where there is no corresponding European Union reference laboratory.

A Member State may designate a laboratory situated in another Member State or in a third country that is a Contracting Party to the Agreement on the European Economic Area.

A single laboratory may be designated as a national reference laboratory for more than one Member State.

2. The requirements provided for in point (e) of Article 37(4), Article 37(5), Article 39 and Article 42(1), points (a) and (b) of Article 42(2) and Article 42(3) shall apply to national reference laboratories.

By way of derogation from point (e) of Article 37(4), for the area governed by the rules referred to in point (g) of Article 1(2), competent authorities may designate official laboratories, designated as such by the competent authorities on the basis of a derogation adopted under Article 41, as national reference laboratories irrespective of whether they fulfil the condition provided for in point (e) of Article 37(4).

3. National reference laboratories shall:

(a) be impartial, free from any conflict of interests, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as national reference laboratories;

(b) have, or have contractual access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques in their area of competence, and support staff as appropriate;

(c) possess, or have access to, the infrastructure, equipment and products needed to carry out the tasks assigned to them;

(d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;

(e) be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations; and

實驗室指定一個或多個國家參考實驗室。

在沒有相應的歐盟參考實驗室的情況下，會員國亦得指定一個國家參考實驗室。

一個會員國得指定位於另一會員國的實驗室或位於歐洲經濟區協議締約方的第三國之家實驗室。

一個單一實驗室得被指定為一個以上之會員國的國家參考實驗室。

2. 第 37(4)條(e)點、第 37(5)條、第 39 條和第 42(1)、第 42(2)條(a)點和(b)點，以及第 42(3)條所述的規定應適用於國家參考實驗室。

做為第 37(4)第(e)點之規定的例外，對於受第 1(2)第(g)點所提及之規範管理的領域，權責機關得指定基於第 41 條所採用之例外情形所指定之官方實驗室，作為國家參考實驗室，不論該等實驗室是否滿足第 37(4)第(e)點所述之條件。

3. 國家參考實驗室應 ：

(a)秉持公正，不受任何利益衝突的影響，特別是不可在可能，直接或間接影響關於其作為國家參考實驗室之任務的履行之專業作為之公正性的狀況下；

(b)擁有，或因契約獲得，適當地認可合格具有在其職權範圍內接受充分的分析、測試和診斷技術培訓的職員，並妥為支援其職員。

(c)擁有或可獲得執行分配給他們的任務所需的基礎設施、設備和產品。

(d)確保其職員和任何契約聘用的職員，對國際標準和做法有充分的了解，並確保在其工作中已考慮到國家、歐盟和國際層級的研究之最新發展。

(e)已配備或可獲得在緊急情況下執行任務之必要的設備；以及

(f)在相關時，具有符合相關的生物安全標準之配備。

(f) where relevant, be equipped to comply with relevant biosecurity standards. 4. Member States shall: (a) communicate the name and address of each national reference laboratory to the Commission, the relevant European Union reference laboratory and other Member States; (b) make the information referred to in point (a) available to the public; and (c) update the information referred to in point (a) whenever necessary. 5. Member States that have more than one national reference laboratory for a European Union reference laboratory shall ensure that such laboratories work closely together, so as to ensure efficient coordination between them, with other national laboratories and with the European Union reference laboratory. 6. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the establishment of requirements for national reference laboratories in addition to those laid down in paragraphs 2 and 3 of this Article. Such delegated acts shall be limited to ensuring coherence with any additional requirements adopted in accordance with Article 99(2).	4. 會員國應: (a)將每個國家參考實驗室的名稱及地址通知歐盟執委會、相關的歐盟參考實驗室與其他會員國; (b)使第(a)點所提及的資訊公布於大眾;以及 (c)必要時更新第(a)點所提到的資訊。 5. 擁有可為歐盟一個參考實驗室提供服務之一個以上的國家參考實驗室的會員國,應確保該等實驗室可緊密合作,以確保它們之間與其他國家實驗室之間,和歐盟參考實驗室之間的有效率之合作。 6. 歐盟執委會有權根據第 144 條採用授權法規以補充本規章關於國家參考實驗室除本條第 2 和第 3 項所規定者以外之要求的制訂。上開授權法規應限於確保與根據第 99(2)條所採用的任何其他額外的要求之一致性。
Article 101 **Responsibilities and tasks of national reference laboratories** 1. National reference laboratories shall, in their area of competence: (a) collaborate with the European Union reference laboratories, and participate in training courses and in inter-laboratory comparative tests organised by these laboratories; (b) coordinate the activities of official laboratories designated in accordance with Article 37(1) with a view of harmonising and improving the methods of laboratory analysis, test or diagnosis and their use; (c) where appropriate, organise inter-laboratory comparative testing or proficiency tests between official laboratories, ensure an appropriate follow-up of such tests and inform the competent authorities of the results of such tests and follow-up; (d) ensure the dissemination to the competent authorities and official laboratories of information that the European Union reference laboratory supplies; (e) provide within the scope of their mission scientific and technical assistance to the competent	*第 101 條* **國家參考實驗室的職責與任務** 1. 國家參考實驗室應,在其職權領域內辦理下列事宜: (a)與歐盟參考實驗室合作,並參與由該等實驗室籌劃的培訓課程和實驗室間比對測試; (b)協調根據第 37(1)條指定的官方實驗室之活動,以調和及改進實驗室分析、測試或診斷及其使用方法; (c)適當時,在官方實驗室之間組織實驗室間比對測試或能力測試,確保對此類測試進行適當的跟催,並將此類測試和跟催的結果告知權責機關; (d)確保向權責機關和官方實驗室傳送歐盟參考實驗室提供的資訊; (e)在其任務範圍內向權責機關提供科學和技術協助,以實施第 109 條所提及之多年國家管制計畫 MANCP 和根據第 112 條所採用之經協調的管制計

authorities for the implementation of MANCPs referred to in Article 109 and of coordinated control programmes adopted in accordance with Article 112; (f) where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents; (g) where necessary, conduct training courses for the staff of official laboratories designated under Article 37(1); and (h) assist actively the Member State having designated them in the diagnosis of outbreaks of foodborne, zoonotic or animal diseases or of pests of plants and in case of non-compliance of consignments, by carrying out confirmatory diagnoses, characterisation and epizootic or taxonomic studies on pathogen isolates or pest specimens. 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the establishment of responsibilities and tasks for national reference laboratories in addition to those provided for in paragraph 1 of this Article. Such delegated acts shall be limited to ensuring coherence with any additional responsibilities and tasks adopted in accordance with Article 99(2).	畫； (f)相關時，將試劑和試劑批次做確效，建立和維護可用的參考物質和試劑以及此類物質和試劑的製造商和供應商的最新清單； (g)必要時，為第 37(1)條所指定的官方實驗室職員舉辦培訓課程；及 (h)藉由對病原體分離株或害蟲標本執行確認性診斷、特性鑑定和動物流行病學或分類學研究，積極協助以指定該等國家參考實驗室之會員國於食源性、人畜共通傳染病或動物疾病或植物害蟲的爆發以及託運物不符合情事時(原因)之診斷。 2. 歐盟執委會有權根據第 144 條採用授權法規以補充本規章關於對國家參考實驗室除了本條第 1 項規定者以外之責任和任務之判定。上開授權法規應限於確保與根據第 99(2)條採用的任何其他額外的責任和任務之一致性。
TITLE IV **ADMINISTRATIVE ASSISTANCE AND COOPERATION**	第 IV 編 **行政協助與合作**
Article 102 **General rules**	*第 102 條* **通則**
1. The competent authorities in the Member States concerned shall provide each other with administrative assistance in accordance with Articles 104 to 107, in order to ensure the correct application of the rules referred to in Article 1(2) in cases which have relevance in more than one Member State. 2. Administrative assistance shall include, where appropriate, and, by agreement between the competent authorities concerned, participation by the competent authorities of a Member State in on-the-spot official controls that the competent authorities of another Member State perform.	1. 為了確保在與一個以上會員國有相關之情事時能正確應用第 1(2)條所提及之規範，所涉會員國的權責機關應根據第 104 至 107 條相互提供行政協助。 2. 行政協助，適當時應包括，藉由所涉權責機關之間的協議，由某一會員國之權責機關參加另一會員國權責機關所執行的現場官方管制作業。

3. This Title shall be without prejudice to national law: (a) applicable to the release of documents and information that are the object of, or related to, judicial investigations and court proceedings, including criminal investigations; and (b) aimed at the protection of natural or legal persons' commercial interests. 4. Member States shall take measures to facilitate the transmission, from other law enforcement authorities, public prosecutors and judicial authorities, to the competent authorities, of information on possible non-compliance with the rules referred to in Article 1(2) which is relevant for the application of this Title and which may constitute: (a) a risk to human, animal or plant health, or to animal welfare, or, as regards GMOs and plant protection products, also to the environment; or (b) a possible violation of the rules referred to in Article 1(2) perpetrated through fraudulent or deceptive practices. 5. All communications between competent authorities in accordance with Articles 104 to 107 shall be in writing, on paper or in electronic form. 6. In order to streamline and simplify communication exchanges, the Commission shall, by means of implementing acts, establish a standard format for: (a) the requests for assistance provided for in Article 104(1); and (b) the communication of common and recurrent notifications and responses. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	3. 本編不得違背(下列事項的)國家法律: (a) 適用於與司法調查及法庭訴訟或其中包括刑事調查之標的或有關的文件和資訊者;以及 (b) 旨在保護自然人或法人的商業利益者。 4. 會員國應採取措施以促進從其他的法律執行機關、檢察官和司法當局項權責機關傳達關於可以不符合第 1(2)條所提及之規範而與本編之應用相關的資訊，該等資訊可能構成(下列問題): (a) 對人類、動物或植物健康或對動物福祉，或關於基因改造生物和植物保護產品，以及對環境造成風險者;或 (b) 透過詐欺或欺騙行為而可能違反第 1(2)條所提及之規範者。 5. 權責機關間根據第 104 至 107 條所作的所有溝通應採用書面，可以於紙上或以電子形式呈現。 6. 為了效率化和簡化溝通交流，歐盟執委會應藉由施行細則，為以下方面建立標準格式: (a) 請求第 104(1)條所述的協助；以及 (b) 一般的和反覆出現的通知和答覆的傳達。 上開施行細則應按照第 145(2)條所述的審查程序予以採用。
Article 103 **Liaison bodies**	*第 103 條* **聯絡機構**
1. Each Member State shall designate one or more liaison bodies acting as contact points responsible for facilitating the exchange of communications between competent authorities in accordance with Articles 104 to 107. 2. The designation of liaison bodies shall not preclude direct contacts, exchange of information or cooperation between the staff of competent authorities in different Member States.	1. 每個會員國應指定一個以上的聯絡機構作為聯絡點，也負責根據第 104 至 107 條促進權責機關之間的通訊交流。 2. 聯絡機構之指定不得排除不同會員國之權責機關的職員之間的直接接觸、資訊交流或合作。

3. Member States shall communicate to the Commission and other Member States the contact details of their liaison bodies designated in accordance with paragraph 1, and any subsequent modification of those details.	3. 會員國應向歐盟執委會和其他會員國通報其根據第 1 項所指定的聯絡機構之聯繫細節，以及之後對該等細節的任何修改。
4. The Commission shall publish and update on its website the list of liaison bodies communicated to it by the Member States in accordance with paragraph 3.	4. 歐盟執委會應在其網站上公佈並更新會員國根據第 3 項向其通報的聯絡機構名單。
5. All requests for assistance pursuant to Article 104(1), and notifications and communications pursuant to Articles 105, 106 and 107 shall be transmitted by a liaison body to its correspondent in the Member State to which the request or the notification is addressed.	5. 所有根據第 104(1)條提出的需予協助之請求，以及根據第 105、106 和 107 條提出的通知和通訊，均應由聯絡機構傳達給該項請求或通知所針對的會員國的對應聯繫人員。
6. The Commission shall, by means of implementing acts, establish the specifications of the technical tools and the procedures for communication between liaison bodies designated in accordance with paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	6. 歐盟執委會應，藉由施行細則，制定根據本條第 1 項指定的聯絡機構之間的通訊技術工具的規格和程序。上開施行細則應按照第 145(2)條所提及的審查程序予以採用。
Article 104 **Assistance on request**	*第 104 條* **應要求所提供之協助**
1. Where the competent authorities in a Member State consider that, for the performance of official controls or for the effective follow-up to such controls in their territory, they require data or information from the competent authorities of another Member State, they shall issue a reasoned request for administrative assistance to the competent authorities of that Member State. The requested competent authorities shall:	1. 若一個會員國權責機關認為，為了在其領土內實施官方管制或對此類管制的有效跟催，他們需要來自另一會員國權責機關的數據或資訊時，他們應向該會員國權責機關發出合理的請求提供行政協助。被請求的權責機關應：
(a) acknowledge receipt of the request without delay;	(a)確認無延誤地收到請求；
(b) where the requesting competent authority so specifies, indicate within ten working days from the date of receipt of the request, the estimated time necessary to provide an informed response to the request; and	(b)如果請求方之權責機關如此規定，則(受請求方)在收到請求之日起十個工作日內應指出對請求方作出瞭解情況的回覆之估計所需的時間;及
(c) perform official controls or investigations necessary to provide the requesting competent authorities without delay with all necessary information and documents to enable them to take informed decisions and verify compliance with Union rules within their jurisdiction.	(c)執行必要的官方管制或調查，以便立即向請求的權責機關提供所有必要的資訊和文件，使其能夠做出瞭解情況的決定並證實其管轄範圍內是否符合歐盟規範。
2. Documents may be transmitted in their original form or copies may be provided.	2. 文件可以正本傳送，亦可提供複本。

3. By agreement between the requesting competent authorities and the requested competent authorities, staff designated by the former may be present during the official controls and investigations referred to in point (c) of paragraph 1 performed by the requested competent authorities. In such cases the staff of the requesting competent authorities shall: (a) at all times be able to produce written authority stating their identity and their official capacity; (b) be granted access by the operator to the same premises and documents as the staff of the requested competent authorities, through their intermediary, and for the sole purpose of the administrative enquiry being carried out; and (c) not, on their own initiative, exercise the powers of enquiry conferred on officials of the requested competent authorities.	3. 經由請求的權責機關與被請求的權責機關間之協議，前者所指定的職員得在被請求的權責機關執行的第 1 項(c)點所提及的官方管制和調查期間時在場。 在此情況下，請求的權責機關的職員應： (a)在任何時候都能夠產生書面授權以述明他們的身份和官方角色； (b)透過調解人，可如同被請求的權責機關的職員一樣被運營商允許進入相同的處所與接觸到相同的文件，並且前述活動僅作為所執行之行政調查之目的；及 (c)並非出於主動，執行賦予被請求的權責機關之官員行使調查之權力。
Article 105 **Assistance without request in the event of non-compliance** 1. When the competent authorities in a Member State become aware of a case of non-compliance, and if such non-compliance may have implications for another Member State, they shall notify such information to the competent authorities of that other Member State without being requested to do so and without undue delay. 2. The competent authorities notified in accordance with paragraph 1 shall: (a) acknowledge receipt of the notification without undue delay; (b) where the notifying competent authority so specifies, indicate within ten working days from the date of receipt of the notification: (i) what investigations they intend to carry out; or (ii) the reasons why they consider that no investigations are necessary; and (c) where investigations referred to in point (b) are considered necessary, investigate the matter and inform the notifying competent authorities without delay of the results and, where appropriate, of any measures taken.	*第 105 條* **在有不符合的情事時非依請求(所提供)之協助** 1. 當某一會員國的權責機關覺察有不符合之情事，且如果此種不符合之情事可能涉及另一會員國時，則該等權責機關應將該訊息不經該會員國請求且無不當延誤地通知該另一會員國的權責機關。 2. 依據第 1 項被通知的權責機關應： (a)確認無不當延誤地收到通知； (b)如果通知方的權責機關如此規定，則(被通知方權責機關)在收到通知之日起十個工作日內指出(下列事宜)： (i)他們欲執行什麼調查；或 (ii)他們認為不需要進行調查的理由；及 (c)如果認為有必要進行第(b)點所提及的調查，則應立即調查此事並將該等結果告知該通知的權責機關，並且，適當時，所採取的任何措施亦作通知。
Article 106	*第 106 條*

Assistance in the event of non-compliance creating a risk or a repeated or potentially serious infringement	於不符合情事造成風險或重複的或潛在嚴重違反(規範)時的所提供的協助
1. Where, during official controls performed on animals or goods originating in another Member State, the competent authorities establish that such animals or goods do not comply with the rules referred to in Article 1(2) in such a way as to create a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, or to constitute a potentially serious infringement of those rules, they shall, without delay, notify the competent authorities of the Member State of dispatch and of any other concerned Member State in order to enable those competent authorities to undertake appropriate investigations.	1. 如果在對源自另一會員國的動物或貨物執行官方管制之期間，權責機關確定此類動物或貨物不符合第 1(2)條所提及之規範，從而對人類、動植物健康、動物福祉，或關於基因改造生物和植物保護產品，以及對環境產生風險，或構成對該等規範的潛在嚴重違反時，他們應立即通知發運之會員國的權責機關以及任何其他所涉及的會員國，以便使得該等權責機關能夠進行適當的調查。
2. The notified competent authorities shall without delay: (a) acknowledge receipt of the notification; (b) where the notifying competent authority so specifies, indicate what investigations they intend to carry out; and (c) investigate the matter, take all necessary measures and inform the notifying competent authorities of the nature of the investigations and official controls performed, of the decisions taken and of the reasons for such decisions.	2. 被通知的權責機關應立即： (a)確認收到通知； (b)若通知方的權責機關如此規定，則指明他們欲執行什麼調查；及 (c) 調查此事採取一切必要措施並將所執行的調查和官方管制的本質、所作出的決定以及作出此等決定的理由告知該通知方的權責機關。
3. If the notifying competent authorities have reason to believe that the investigations performed or the measures taken by the notified competent authorities do not adequately address the non-compliance established, they shall request the notified competent authorities to complement the official controls performed or the measures taken. In such cases the competent authorities from the two Member States shall: (a) seek an agreed approach with the aim of appropriately addressing the non-compliance, including through joint official controls and investigations performed in accordance with Article 104(3); and (b) inform the Commission without delay where they are not able to agree on appropriate measures.	3. 如果通知方的權責機關有理由相信由被通知的權責機關所執行的調查或所採取的措施未能適當地解決所確定的不符合情事時，則應要求被通知的權責機關補充其所執行的官方管制或所採取的措施。在此等情況下，此二會員國的權責機關應： (a)尋求一個彼此同意的方法，以便適當解決該不符合情事，其中包括透過依據第 104(3)條執行的聯合官方管制和調查；及 (b)在無法就適當措施達成協議的情況時，立即通知歐盟執委會。
4. When official controls performed on animals or goods originating in another Member State show repeated cases of non-compliance as referred to in paragraph 1, the competent authorities of the Member State of destination shall inform the Commission and the competent authorities of the other	4. 如果對源自另一會員國的動物或貨物所執行官方管制顯示第 1 項所提及的不符合情事一再發生時，則目的地國權責機關應立即通知歐盟執委會和其他會員國的權責機關。

Member States without delay.	
Article 107 **Assistance on the basis of information provided by third countries** 1. When competent authorities receive information from a third country indicating non-compliance with rules referred to in Article 1(2) or a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, they shall, without delay: (a) notify such information to the competent authorities in other concerned Member States; and (b) communicate such information to the Commission where it is or may be relevant at Union level. 2. Information obtained through official controls and investigations performed in accordance with this Regulation may be communicated to the third country referred to in paragraph 1, provided that: (a) the competent authorities which have provided the information consent to such communication; (b) the third country has undertaken to provide the assistance necessary to gather evidence of practices that are or appear to be non-compliant with Union rules or that pose a risk to humans, animals or plants or the environment; and (c) relevant Union and national rules applicable to the communication of personal data to third countries are complied with.	*第 107 條* **根據第三國提供的資訊所作的協助** 1. 當權責機關從第三國收到之資訊表明有不符合第 1(2)條所提及之規範或對人類、動植物健康、動物福祉或關於基因改造生物和植物保護產品，以及對環境造成風險之情事時，他們應立即： (a)將此類資訊通知其他有關會員國的權責機關；及 (b)在此類資訊是或可能是與歐盟層級相關時，將此類資訊傳達給歐盟執委會。 2. 透過官方管制以及依據本規章執行之調查獲得的資訊可以傳達給第 1 項所提及之第三國，但前提是： (a)提供該資訊的權責機關同意此種傳達； (b)第三國已著手提供必要的協助，以收集是或似乎是違反歐盟規範或對人類、動物或植物，或環境構成風險的做法之證據；及 (c)符合適用於向第三國傳遞個人數據的相關歐盟和國家之規範。
Article 108 **Coordinated assistance and follow-up by the Commission** 1. Where the competent authorities in the Member States concerned are unable to agree on appropriate action to address the non-compliance with the rules referred to in Article 1(2), the Commission shall coordinate without delay the measures and actions undertaken by competent authorities in accordance with this Title where information available to the Commission either: (a) reports activities that are, or appear to be, non-compliant with the rules referred to in Article 1(2), and such activities have, or might have, ramifications in more than one Member State; or (b) indicates that the same, or similar, activities that are, or appear to be, non-compliant with the rules referred to in Article 1(2) might be taking place in more than one Member State. 2. In the cases referred to in paragraph 1, the Commission may:	*第 108 條* **歐盟執委會之經協調的協助支援和跟催** 1. 如果有關的會員國的權責機關無法就解決不符合第 1(2)條所提及之規範的情事之適當行動方面達成協議，歐盟執委會應立即協調權責機關按照本編中執委會可得到的資訊採取的措施和行動。不是(採取)： (a)報告是或似乎是不符合第 1(2)條所提及之規範的活動，且此等活動在一個以上的會員國中會產生或可能產生影響;就是(採取) (b)指明可能在一個以上會員國內發生之是或似乎是不符合第 1(2)條所提及之規範的情事相同或類似的活動。 2. 在第 1 項所提及的情況下，歐盟執委會可以：

(a) in collaboration with the Member State concerned, send an inspection team to perform an on-the-spot official control; (b) request, by means of implementing acts, that the competent authorities in the Member State of dispatch and, where appropriate, in other Member States concerned, appropriately intensify official controls and report to it on the measures taken by them; (c) take any other appropriate measure in accordance with the rules referred to in Article 1(2). 3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by establishing rules for the rapid exchange of information in the cases referred to in paragraph 1.	(a)與有關會員國合作，派遣檢查隊以執行現場官方管制; (b)藉由施行細則，要求發運的會員國及，適當時，相關的其他會員國之權責機關適當地加強官方管制，並就他們所採取的措施向歐盟執委會報告; (c)依據第 1(2)條所提及之規範採取任何其他適當的措施。 3. 歐盟執委會有權依據第 144 條採用授權法規，以藉由制定於第 1 項所提及之情況時之迅速交換資訊的規範來補充本規章。
TITLE V **PLANNING AND REPORTING**	第 V 編 **計畫與報告**
Article 109 **Multi-annual national control plans (MANCP) and a single body for the MANCP** 1. Member States shall ensure that official controls governed by this Regulation are performed by the competent authorities on the basis of a MANCP, the preparation and implementation of which are coordinated across their territory. 2. Member States shall designate a single body tasked with: (a) coordinating the preparation of the MANCP across all competent authorities responsible for the official controls; (b) ensuring that the MANCP is coherent; (c) collecting the information on the implementation of the MANCP in view of submitting the annual reporting referred to in Article 113 and of its review and update as necessary in accordance with Article 111(2).	*第 109 條* **多年度國家管制計畫(MANCP)和 MANCP 的單一機構** 1. 會員國應確保本規章所管理的官方管制由權責機關依據多年度國家管制計畫 MANCP 執行，該計畫之準備和實施在其領土內進行協調。 2. 會員國應指定一個單一機構，其任務是： (a)協調負責官方管制的所有權責機關之關於 MANCP 的準備工作; (b)確保 MANCP 是一致的; (c)收集有關 MANCP 之實施情況的資訊，以便提交第 113 條所提及之年度報告及依據第 111(2)條所進行的審查和做必要的更新。
Article 110 **Content of the MANCPs** 1. MANCPs shall be prepared so as to ensure that official controls are planned in all the areas governed by the rules referred to in Article 1(2) and in accordance with the criteria laid down in Article 9 and	*第 110 條* **MANCP 的內容** 1. MANCP 應被準備以確保官方管制在第 1(2)條所提及之規範所管理的所有領域內以及依據第 9 條規定的標準和第 18 條至第 27 條規定的規範進

with the rules provided for in Articles 18 to 27. 2. MANCPs shall contain general information on the structure and organisation of the systems of official control in the Member State concerned in each of the areas covered, and shall contain information on at least the following: (a) the strategic objectives of the MANCP and on how the prioritisation of official controls and allocation of resources reflect these objectives; (b) the risk categorisation of the official controls; (c) the designation of competent authorities and their tasks at central, regional and local level, and on resources available to those authorities; (d) where appropriate, the delegation of tasks to delegated bodies; (e) the general organisation and management of official controls at national, regional and local level, including official controls in individual establishments; (f) control systems applied to different sectors and coordination between the different services of competent authorities responsible for official controls in those sectors; (g) procedures and arrangements in place to ensure compliance with the obligations of the competent authorities provided for in Article 5(1); (h) the training of staff of the competent authorities; (i) the documented procedures provided for in Article 12(1); (j) the general organisation and operation of contingency plans in accordance with the rules referred to in Article 1(2); and (k) the general organisation of cooperation and mutual assistance between competent authorities in the Member States.	行規劃。 2. MANCP 應包括有關所涵蓋的每個領域之有關會員國的官方管制系統之結構和組織的一般資訊，並應至少包括以下資訊： (a)MANCP 的戰略目標以及關於官方管制與資源分配的優先次序如何反映此等目標； (b)官方管制的風險分類； (c)在中央、區域和地方層級的權責機關之指定及其任務，及關於該等機關可取得的資源； (d)適當時，將任務委任給受託機構； (e)國家、區域和地方層級的官方管制之一般組織與管理，其中包括個別廠場的官方管制； (f)適用於不同產業別的管制系統，以及負責該等產業別之官方管制的權責機關之不同服務之間的協調； (g)確保符合第 5(1)條所述之權責機關的義務之以備妥的程序和安排； (h)權責機關職員的培訓； (i)第 12(1)條所述的文件化程序； (j)按照第 1(2)條所提及之規範的應急計畫之一般組織和運作；及 (k)會員國權責機關之間的一般合作和互助組織。
Article 111 **Preparation, update and review of MANCPs**	*第 111 條* **MANCP 的準備、更新和審查**
1. Member States shall ensure that the MANCP provided for in Article 109(1) is made available to the public, with the exception of those parts of the plan the disclosure of which could undermine the effectiveness of official controls.	1. 除該 MANCP 計畫之部分內容的公開可能會破壞官方管制的有效性以外，會員國應確保向大眾公布第 109(1)條所述的 MANCP。

2. The MANCP shall be regularly updated to adjust it to changes to the rules referred to in Article 1(2), and reviewed to take account at least of the following factors: (a) the emergence of new diseases, pests of plants or other risks to human, animal or plant health, animal welfare or, in the case of GMOs and plant protection products, also to the environment; (b) significant changes to the structure, management or operation of the competent authorities in the Member State; (c) the outcome of Member States' official controls; (d) the outcome of Commission controls performed in the Member State in accordance with Article 116(1); (e) scientific findings; and (f) the outcome of official controls performed by the competent authorities of a third country in a Member State. 3. Member States shall provide the Commission, upon request, with the latest up-to-date version of their respective MANCP.	2. MANCP 應定期更新，以因應第 1(2)條所提及之規範的改變而進行該計畫之調整，並進行審查，至少考慮以下因素： (a)新的疾病、植物害蟲的出現或其他對人類、動植物健康、動物福祉或，在基因改造生物和植物保護產品的情況時，亦對環境造成之風險的出現; (b)會員國權責機關的結構、管理或運作產生重大變化; (c)會員國官方管制的結果; (d)根據第 116(1)條之歐盟執委會對會員國所執行管制的結果; (e)科學發現;以及 (f)在某會員國內之第三國權責機關所執行的官方管制結果。 3. 會員國應應歐盟執委會之要求，提供其各自 MANCP 的最新版本。
Article 112 **Coordinated control programmes and information and data collection** With a view to conducting Union-wide targeted assessment of the state of application of the rules referred to in Article 1(2) or establishing the prevalence of certain hazards across the Union, the Commission may adopt implementing acts concerning: (a) the implementation of coordinated control programmes of limited duration in one of the areas governed by the rules referred to in Article 1(2); (b) the organisation, on an ad hoc basis, of the collection of data and information in relation to the application of a specific set of the rules referred to in Article 1(2) or regarding the prevalence of certain hazards. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	*第 112 條* **經協調的管制計畫以及資訊和數據的收集** 為了在全歐盟範圍內對第 1(2)條所提及之規範之適用狀況進行有針對性的評估，或確定整個歐盟中某些危害的普遍程度，歐盟執委會得採用關於下列事項之施行細則： (a)在受第 1(2)條所提及之規範所管理的其中一個領域內之限期的經協調之管制計畫的實施; (b)收集與適用第 1(2)條所提及之一套特定規範或與某些危害的普遍性有關的數據和資訊之專案性組織。 上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
Article 113	*第 113 條*

Annual reports by the Member States 1. By 31 August every year, each Member State shall submit to the Commission a report setting out: (a) any amendments made to its MANCP to take account of the factors referred to in Article 111(2); (b) the outcome of official controls performed in the previous year under its MANCP; (c) the type and number of cases of non-compliance with the rules referred to in Article 1(2), per area, detected in the previous year by the competent authorities; (d) the measures taken to ensure the effective operation of its MANCP, including enforcement action and the results of such measures, and (e) a link to the web page of the competent authority containing the public information on fees or charges referred to in Article 85(2). 2. In order to ensure the uniform presentation of the annual reports provided for in paragraph 1, the Commission shall, by means of implementing acts, adopt and update as necessary standard model forms for the submission of the information and data referred to in that paragraph. Those implementing acts shall, whenever possible, allow the use of the standard model forms adopted by the Commission for the submission of other reports on official controls that the competent authorities are required to submit to the Commission in accordance with the rules referred to in Article 1(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	**會員國的年度報告** 1. 每年 8 月 31 日，每個會員國應向歐盟執委會提交一份報告，其中應陳述下列事宜： (a)對其 MANCP 作出的任何修訂，以考慮到第 111(2)條所提及之因素； (b)根據其 MANCP 在上一年所執行的官方管制的結果； (c)權責機關在上一年發現到的每個領域不符合第 1(2)條所提及之規範的案件類型和數量； (d)為確保其 MANCP 的有效運作而採取的措施，其中包括制行之行動和此類措施的結果，以及 (e)權責機關網頁的鏈接，其中載有第 85(2)條所提及之費用的公開資訊。 2. 為確保第 1 項所述的年度報告呈現的一致性，歐盟執委會應，藉由施行細則，採用並作標準表格必要的更新以利該節所提及之資訊和數據的提送。 上開施行細則，應盡可能，允許使用歐盟執委會所採用之權責機關被要求根據第 1(2)條所提及之規範向歐盟執委會提交的關於官方管制的其他報告所用之標準示範表格。 上開施行細則應按照第 145(2)條所提及之審查程序予以採用。
Article 114 **Annual reports by the Commission** 1. By 31 January every year, the Commission shall make available to the public an annual report on the operation of official controls in the Member States, taking into account: (a) the annual reports submitted by the Member States in accordance with Article 113; and (b) the results of Commission controls performed in accordance with Article 116(1). 2. The annual report provided for in paragraph 1 may, where appropriate, include recommendations on possible improvements to official control systems in Member States and to certain official controls in certain areas.	*第 114 條* **歐盟執委會的年度報告** 1. 每年 1 月 31 日前，歐盟執委會應公開關於會員國官方管制運作情形的年度報告，同時應考量： (a)會員國依據第 113 條提交的年度報告；以及 (b)依據第 116(1)條所執行的歐盟執委會管制的結果。 2. 第 1 項所述的年度報告，適當時，可包括關於會員國官方管制系統和某些領域的官方管制之可能的改進之建議。

Article 115 **Contingency plans for food and feed**	*第 115 條* **食品和飼料的應變計畫**
1. For the application of the general plan for crisis management provided for in Article 55(1) of Regulation (EC) No 178/2002, Member States shall draw up contingency plans for food and feed setting out measures to be applied without delay when food or feed is found to pose a serious risk to human or animal health either directly or through the environment. 2. The contingency plans for food and feed provided for in paragraph 1 shall specify: (a) the competent authorities to be involved; (b) the powers and responsibilities of the authorities referred to in point (a); and (c) channels and procedures for sharing information between competent authorities and other parties concerned as appropriate. 3. Member States shall review regularly their contingency plans for food and feed to take into account changes in the organisation of the competent authorities and experience gained from implementing the plan and simulation exercises. 4. The Commission may adopt implementing acts concerning: (a) rules for the establishment of the contingency plans provided for in paragraph 1 of this Article to the extent necessary to ensure the consistent and effective use of the general plan for crisis management provided for in Article 55(1) of Regulation (EC) No 178/2002; and (b) the role of stakeholders in the establishment and operation of those contingency plans. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	1. 為於(EC)178/2002 號規章第 55(1)條所述的危機管理所作之總體計畫的應用之需，會員國應制定食品和飼料應變計畫，該計畫訂定於發現食品或飼料無論是直接或透過環境對人類或動物健康造成嚴重風險時，所應立即採取的措施。 2. 第 1 項所述的食品和飼料應變計畫應具體規定： (a)涉及的權責機關； (b)(a)點所提及的機關之權力和責任；以及 (c)權責機關與其他有關各方之間適當地分享資訊的管道和程序。 3. 會員國應定期審查其食品和飼料應變計畫，以將權責機關組織的變化以及從執行該計畫和模擬活動所獲得的經驗考慮在內。 4. 歐盟執委會可採用關於下列事宜之施行細則： (a)本條第 1 項所述的應變計畫的制定規範，以達到確保(EC)178/2002 號規章第 55(1)條所述的危機管理之總體計畫的一致和有效地使用；以及 (b)利害關係人在該等應變計畫之制訂和運作所扮演之角色。 上開施行細則應按照第 145(2)條所提及的審查程序予以採用。
TITLE VI **UNION ACTIVITIES** *CHAPTER I* ***Commission controls***	第 VI 編 **歐盟行動** *第 I 章* ***歐盟執委會的管制***
Article 116 **Commission controls in Member States**	*第 116 條* **歐盟執委會對會員國的管制**

1. Commission experts shall perform controls, including audits, in each Member State to: (a) verify the application of the rules referred to in Article 1(2) and those provided for in this Regulation; (b) verify the functioning of national control systems in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation, and of the competent authorities which operate them; (c) investigate and collect information: (i)on official controls and enforcement practices in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation; (ii)on important or recurring problems with the application or enforcement of the rules referred to in Article 1(2); (iii)in relation to emergency situations, emerging problems or new developments in the Member States in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation. 2. The controls provided for in paragraph 1 shall be organised in cooperation with the competent authorities of the Member States and shall be performed on a regular basis. 3. The controls provided for in paragraph 1 may include on-the-spot verifications. The Commission experts may accompany the staff of the competent authorities performing official controls. 4. Experts from the Member States may assist the Commission experts. National experts accompanying Commission experts shall be given the same rights of access as the Commission experts.	1. 歐盟執委會專家應對每個會員國執行管制，其中包括稽核，以便： (a)查核第 1(2)條所提及之規範以及本規章所述的規範的適用情況; (b)查核於第 1(2)條所提及之規範和本規章所述之規範所管理的領域內的國家管制系統以及運作該等管制系統之權責機關的運作情況; (c)調查和收集下列資訊： (i)關於受第1(2)條所提及之規範和本規章所述之規範所管理的領域內的官方管制和執行作法; (ii)關於第1(2)條所提及之規範的應用或執行的重要或經常性的問題; (iii)關於，會員國在第 1(2)條所提及之規範和本規章所述之規範所管理的領域之緊急情況、新興問題或新發展。 2. 第 1 項所述的管制措施應與會員國之權責機關合作加以籌劃，並應定期執行。 3. 第 1 項所述的管制措施可包括現場查核。歐盟執委會專家得陪同執行官方管制的權責機關的職員。 4. 來自會員國的專家可以協助歐盟執委會的專家。陪同歐盟執委會專家的國家專家應被給予和歐盟執委會專家同樣的進入廠場處所或取得相關文件的權利。
Article 117 **Reports by the Commission on controls in Member States** The Commission shall: (a) prepare a draft report on the findings and on recommendations addressing the shortcomings identified by its experts during controls performed in accordance with Article 116(1); (b) send to the Member State where those controls have been performed a copy of the draft report provided for in point (a) for its comments;	*第 117 條* **歐盟執委會所作關於會員國之管制的報告** 歐盟執委會應 ： (a)準備一份其專家在依據第 116(1)條執行管制期間關於所發現的事實以及關於解決所確認之缺點的建議之報告草案; (b)向被執行該等管制的會員國發送第(a)點所述的報告草案副本供該會員國評論; (c)在編寫關於執委會專家如第 116(1)條所述於會

(c) take the comments of the Member State referred to in point (b) into account in preparing the final report on the findings of the controls performed by its experts in the Member States as provided for in Article 116(1); and (d) make publicly available the final report referred to in point (c) and the comments of the Member State referred to in point (b).	員國所執行的管制結果所發現的事實之最終報告時，需將第(b)點中所提及之會員國評論意見納入考量;以及 (d)將第(c)點所提及之最終報告和第(b)點所提及之會員國評論意見予以公布。
Article 118 **Programme of the Commission controls in Member States** 1. The Commission shall, by means of implementing acts: (a) establish an annual or multiannual control programme for the controls to be performed by its experts in the Member States as provided for in Article 116(1); and (b) by the end of each year, communicate to the Member States the annual control programme or any update to the multiannual control programme for the following year. 2. The Commission may, by means of implementing acts, amend its control programme to take account of developments in the areas governed by the rules referred to in Article 1(2). Any such amendment shall be communicated without delay to the Member States.	*第 118 條* **歐盟執委會於會員國的管制計畫** 1. 歐盟執委會應藉由施行細則： (a)制定一個如第 116(1)條所述由會員國之專家執行的管制之年度或多年度管制計畫；及 (b)在每年年底前，向會員國通報年度管制計畫或下一年度之多年管制計畫的任何更新。 2. 歐盟執委會，藉由施行細則，修改其管制程序，以考慮到第 1(2)條所提及之規範所管理之領域的發展。任何此類修正案應立即通知會員國。
Article 119 **Obligations of the Member States as regards Commission controls** Member States shall: (a) take appropriate follow-up measures to remedy any specific or systemic shortcomings identified through the controls performed by the Commission experts in accordance with Article 116(1); (b) give the necessary technical assistance and provide the available documentation, including the results of the audits referred to in Article 6, upon justified request, and other technical support that Commission experts request to enable them to perform controls efficiently and effectively; and (c) give the necessary assistance to ensure that the Commission experts have access to all premises or parts of premises, animals and goods, and to information, including computing systems, relevant for the execution their duties.of	*第 119 條* **會員國關於歐盟執委會管制方面的義務** 會員國應： (a)採取適當的跟催措施以補救歐盟執委會專家透過根據第 116(1)條所執行的管制所確定的任何具體或系統性之缺陷; (b)提供必要的技術援助並提供可用的文件，其中，如應合理的要求時，包括第 6 條所提及之稽核結果，以及歐盟執委會專家要求的其他技術支持，以使該等專家能夠有效率及有效地執行管制;以及 (c)提供必要的協助，以確保歐盟執委會專家能夠進入所有(相關的)處所或部分處所、動物和貨物，以及接觸到該等專家職責之執行有關的資訊，其中包括計算機系統。

Article 120 **Commission controls in third countries**	*第 120 條* **歐盟執委會於第三國之管制**
1. Commission experts may perform controls in third countries in order to:	1. 歐盟執委會專家可以在第三國執行管制，以便：
(a) verify the compliance or equivalence of third-country legislation and systems, including official certification and the issuance of official certificates, official labels, official marks and other official attestations, with the requirements laid down in the rules referred to in Article 1(2);	(a)查驗第三國之立法和制度，其中包括官方驗證和官方證明書、官方標籤、官方標誌和其他官方證明之核發對第 1(2)條所提及之規範所訂要求之符合性與同等性；
(b) verify the capacity of the third country control system to ensure that consignments of animals and goods exported to the Union comply with relevant requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto;	(b)查驗第三國之管制系統的能力，以確保出口到歐盟的動物和貨物的託運物符合第 1(2)條所提及之規範的相關要求或符合經認可至少與其等同的要求；
(c) collect information and data to elucidate the causes of recurring or emerging problems in relation to exports of animals and goods from a third country.	(c)收集資訊和數據以闡明與來自第三國所出口動物和貨物有關之反覆發生的或新興問題的原因。
2. The controls provided for in paragraph 1 shall have particular regard to:	2. 第 1 項所述的管制措施應特別考慮到下列事宜：
(a) the legislation of the third country;	(a)第三國的立法；
(b) the organisation of the third country's competent authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively;	(b)第三國權責機關的組織、他們的權力和獨立性、以及他們所受的監督，以及他們所擁有之有效地執行適用法律的權力；
(c) the training of staff of the competent authority of the third country in the performance of official controls;	(c)第三國權責機關的職員於執行官方管制方面的訓練；
(d) the resources including analytical, testing and diagnostic facilities available to competent authorities;	(d)資源，其中包括提供給權責機關的分析、測試和診斷設施；
(e) the existence and operation of documented control procedures and control systems based on priorities;	(e)基於優先事項的文件化管制程序和管制系統的存在和運作；
(f) where applicable, the situation regarding animal health, animal welfare, zoonoses and plant health, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases and pests of plants;	(f)適用時，關於動物健康、動物福祉、人畜共通傳染病和植物健康的情況，以及通知歐盟執委會和有關國際機構關於動物疾病和植物害蟲之爆發的程序；
(g) the extent and operation of controls performed by the competent authority of the third country on animals, plants and their products arriving from other third countries; and	(g)第三國權責機關對來自其他第三國的動植物及其產品所執行的管制的程度和運作；以及
(h) the assurances which the third country can give regarding compliance with, or equivalence to, the	(h)第三國可以就符合或等同於第 1(2)條所提及之規範的要求所提供之保證。

requirements laid down in the rules referred to in Article 1(2). 3. In order to facilitate the efficiency and effectiveness of the controls provided for in paragraph 1, the Commission may, prior to performing such controls, request that the third country concerned provide: (a) the necessary information referred to in Article 125(1); and (b) where appropriate and necessary, the written records on the controls its competent authorities perform. 4. The Commission may appoint experts from Member States to assist its own experts during the controls provided for in paragraph 1.	3. 為了促進第 1 項所述的管制措施之效率和有效性，歐盟執委會可在實施此等管制之前，要求有關的第三國提供： (a)第 125(1)條所提及的必要資訊；以及 (b)在適當及必要時，其權責機關所執行的管制之書面紀錄。 4. 歐盟執委會可任命來自會員國專家在第 1 項所述的管制期間協助執委會之專家。
Article 121 **Frequency of Commission controls in third countries** The frequency of Commission controls in third countries referred to in Article 120 shall be determined on the basis of the following criteria: (a) a risk assessment of the animals and goods exported to the Union from the third country concerned; (b) the rules referred to in Article 1(2); (c) the volume and nature of animals and goods entering the Union from the third country concerned; (d) the outcome of controls already performed by the Commission experts or by other inspection bodies; (e) the outcome of official controls on animals and goods entering the Union from the third country concerned and of any other official controls that competent authorities of Member States have performed; (f) information received from the EFSA or similar bodies; (g) information received from internationally recognised bodies such as: (i) the World Health Organization; (ii) the Codex Alimentarius Commission; (iii) the World Organization for Animal Health (OIE); (iv) European and Mediterranean Plant Protection Organization and any other regional plant protection organisations established under the International Plant Protection Convention (IPPC); (v) the secretariat of the IPPC;	*第 121 條* **歐盟執委會於第三國之管制的頻率** 第 120 條所提及之歐盟執委會於第三國之管制的頻率應根據以下標準決定： (a)對從所涉第三國出口到歐盟的動物和貨物之風險評估； (b)第 1(2)條所提及之規範； (c)由所涉第三國進入歐盟的動物和貨物的數量和本質； (d)由歐盟執委會專家或由其他檢查機構已經執行完成的管制結果； (e)從所涉第三國進入歐盟的動物和貨物的官方管制結果以及會員國權責機關以執行的任何其他官方管制的結果； (f)從歐盟食品安全局(EFSA)或類似機構收到的資訊； (g)從如下列之國際公認機構收到的資訊： (i)世界衛生組織； (ii)食品法典委員會； (iii)世界動物衛生組織(OIE)； (iv)歐洲和地中海植物保護組織以及根據「國際植物保護公約」(IPPC)創立的任何其他之區域植物保護組織； (v)國際植物保護公約秘書處； (vi)經濟合作與發展組織；

(vi) Organisation for Economic Co-operation and Development; (vii) United Nations Economic Commission for Europe; (viii) the secretariat of the Cartagena Protocol on Biosafety to the Convention on Biological Biodiversity; (h) evidence of emerging disease situations or other circumstances that might result in animals and goods entering the Union from a third country presenting health or environmental risks or a risk of fraudulent or deceptive practices; (i) the need to investigate or respond to emergency situations in individual third countries.	(vii)聯合國歐洲經濟委員會; (viii)「生物多樣性公約」卡塔赫納生物安全議定書秘書處; (h)可能導致從第三國進入歐盟的動物和貨物之新興的疾病狀況或其他情況的證據，該等國家係存在著對健康或環境風險或存在著欺詐或欺騙行為的風險; (i)調查或應對個別第三國的緊急情況之需求。
Article 122 **Reports by the Commission on controls in third countries** The Commission shall report on the findings of each control performed in accordance with Articles 120 and 121. Its report shall, where appropriate, contain recommendations. The Commission shall make its reports publicly available.	*第 122 條* **歐盟執委會所作關於第三國之管制的報告** 歐盟執委會應報告根據第 120 條和第 121 條所執行的每項管制的結果。其報告，適當時，應包括建議。歐盟執委會應公佈其報告。
Article 123 **Programme of the Commission controls in third countries** The Commission shall communicate its programme of controls in third countries to Member States in advance and shall report on the results. The Commission may amend that programme to take account of developments in the areas governed by the rules referred to in Article 1(2). Any such amendment shall be communicated to the Member States in advance.	*第 123 條* **歐盟執委會於第三國的管制計畫** 歐盟執委會應事先將其第三國之管制計畫通知會員國，並報告該等結果。歐盟執委會可修訂該計畫，以考慮到第 1(2)條所提及之規範所管理之領域的發展。任何此類修正案應事先通知會員國。
Article 124 **Third-country controls in Member States** 1. Member States shall inform the Commission of planned controls in the areas governed by the rules referred to in Article 1(2) on their territory, by the competent authorities of third countries. 2. Commission experts may participate in the controls referred to in paragraph 1, at the request of the competent authorities of Member States where those controls are being performed. 3. The participation by Commission experts in the controls referred to in paragraph 1 shall serve in particular to: (a) provide advice on the rules referred to in Article 1(2);	*第 124 條* **第三國於會員國所作之管制** 1. 會員國應將在其領土上接受由第三國權責機關所執行對第 1(2)條所提及之規範管轄的領域的計畫性管制通報歐盟執委會。 2. 歐盟執委會專家可應被執行第 1 項所提及之管制的會員國之權責機關的請求，參加該等管制作業。 3. 由歐盟執委會專家參與的第 1 項所提及之管制應特別適用於下列情形： (a)就第 1(2)條所提及之規範提供意見;

(b) provide information and data available at Union level that may be useful for the control performed by the competent authorities of the third country; (c) facilitate consistency and uniformity with regard to controls performed by the competent authorities of third countries in different Member States.	(b)提供歐盟層級之可用的資訊和數據，該等資訊和數據可能對由第三國權責機關所執行的管制有用處； (c)促進關於第三國權責機關對不同會員國所執行之管制的一致性和統一性。
CHAPTER II ***Conditions for the entry into the Union of animals and goods***	*第 II 章* ***動物和貨物進入歐盟的條件***
Article 125 **Information on third countries' control systems** 1. The Commission shall request third countries which intend to export animals and goods to the Union to provide the following accurate and up-to-date information on the general organisation and management of sanitary and phytosanitary control systems in their territory: (a) any sanitary or phytosanitary rules adopted or proposed within their territory; (b) risk-assessment procedures and factors taken into consideration for the assessment of risks and for the determination of the appropriate level of sanitary or phytosanitary protection; (c) any control and inspection procedures and mechanisms, including, where relevant, on animals or goods arriving from other third countries; (d) official certification mechanisms; (e) where appropriate, any measures taken following re- commendations provided for in the first paragraph of Article 122; (f) where relevant, results of controls performed on animals and goods intended to be exported to the Union; and (g) where relevant, information on changes made to the structure and functioning of control systems adopted to meet Union sanitary or phytosanitary requirements or recommendations provided for in the first paragraph of Article 122. 2. The request for information referred to in paragraph 1 shall be proportionate, taking account of the nature of the animals and goods to be exported to the Union and of the specific situation in, and structure of, the third country.	*第 125 條* **關於第三國管制系統的資訊** 1. 歐盟執委會應要求有意向歐盟出口動物和貨物的第三國提供以下關於其領土之衛生和植物檢疫管制系統之總體組織和管理的正確和最新資訊： (a)在其領土內所採用或所提議的任何衛生或植物檢疫之規範； (b)風險評估程序以及為風險評估和決定適當的衛生或植物檢疫保護水準而考慮的因素； (c)任何管制與檢查程序和機制，其中，相關時，包括關於自其他第三國運抵的動物或貨物(之管制與檢查程序與機制)； (d)官方驗證機制； (e)適當時，按照第 122 條第 1 項所述的建議所採取的任何措施； (f)在相關時，對擬出口到歐盟的動物和貨物所執行的管制之結果；以及 (g)相關時，提供有關為滿足第 122 條第 1 項所述的歐盟衛生或植物檢疫要求或建議而採用的管制系統之結構和運作的變化之資訊。 2. 對第 1 項所提及之資訊(提供)之要求應考慮到擬出口到歐盟的動物和貨物的性質以及該第三國的具體情況和結構而具有相稱性(即符合比例原則)。

Article 126 **Establishment of additional conditions for entry into the Union of animals and goods** 1. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the conditions to be respected by animals and goods entering the Union from third countries which are necessary to ensure that the animals and goods comply with the relevant requirements established by the rules referred to in Article 1(2), with the exception of points (d), (e), (g) and (h) of Article 1(2), or with requirements recognised to be at least equivalent thereto. 2. The conditions laid down in the delegated acts referred to in paragraph 1 shall identify animals and goods by referring to their codes from the Combined Nomenclature and may include: (a) the requirement that certain animals and goods shall only enter the Union from a third country or region of a third country which appears on a list drawn up by the Commission for that purpose; (b) the requirement that consignments of certain animals and goods from third countries be dispatched from, and obtained or prepared in, establishments which comply with the relevant requirements referred to in paragraph 1 or with requirements recognised to be at least equivalent thereto; (c) the requirement that consignments of certain animals and goods be accompanied by an official certificate, an official attestation, or by any other evidence that the consignments comply with the relevant requirements referred to in paragraph 1 or with requirements recognised to be at least equivalent thereto, including the results of the analysis performed by an accredited laboratory; (d) the obligation to provide the evidence referred to in point (c) in accordance with a specific format; (e) any other requirement necessary to ensure that certain animals and goods offer a level of protection of health and, as regards GMOs, also of the environment, equivalent to that ensured by the requirements referred to in paragraph 1. 3. The Commission may, by means of implementing acts, lay down rules on the format and type of official certificates, official attestations, or evidence required in accordance with the rules provided for in point (c) of paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	*第 126 條* **為進入歐盟之動物和貨物之額外條件的制定** 1. 歐盟執委會有權根據第 144 條採用授權法規，以補充本規章關於從第三國進入歐盟的動物和貨物應符合的條件，這些條件是確保動物和貨物符合根據第 1(2)條(但第 1(2)條的第(d)、(e)、(g)和(h)點除外)所提及之規範所制定的相關要求(或者至少與被公認為等同的要求)。 2. 第 1 項所提及的授權法規中所訂的條件應藉由參照聯合命名法中的代碼來識別動物和貨物，並可包括下列事宜： (a)要求某些動物和貨物只能從歐盟執委會為此目的所制訂的清單上出現的第三國或第三國的地區進入歐盟； (b)要求從符合第 1 項所提及的相關要求或至少與被公認為等同的要求的廠場發運、獲得或準備來自第三國的某些動物和貨物的託運物； (c)要求某些動物和貨物的託運物附有官方證書、官方證明，或任何其他證據證明該等託運物符合第 1 項所提及的相關要求或至少與被公認為等同的要求，其中括由一個經認證的實驗室所執行的分析結果； (d)有義務按照特定格式提供第(c)點所提及之證據； (e)確保某些動物和貨物提供一定程度的健康保護以及關於基因改造生物，亦對環境所必需的任何其他要求，等同於第 1 項所提及的要求確保的程度。 3. 歐盟執委會可，藉由施行細則，對按照本條第 2 項(c)點所述的規範所要求之官方證書、官方證明，或證據的格式和類型訂定規範。上開施行細則應按照第 145(2)條所提及的審查程序予以採用。
Article 127	*第 127 條*

Inclusion in the list of third countries referred to in point (a) of Article 126(2)	列入於第 126(2)條第(a)點所提及之第三國名單中
1. The inclusion of a third country or region thereof in the list referred to in point (a) of Article 126(2) shall be made in accordance with paragraphs 2 and 3 of this Article.	1. 將某第三國或第三國之區域列入第 126(2)條第(a)點所提及之清單，應按照本條第 2 和第 3 項的規定進行。
2. The Commission shall approve, by means of implementing acts, the request transmitted to it for the purpose referred to in paragraph 1 of this Article by the third country concerned, accompanied by appropriate evidence and guarantees that the animals and goods concerned from that third country comply with the relevant requirements referred to in Article 126(1) or with requirements equivalent thereto. Those implementing acts shall be adopted and updated in accordance with the examination procedure referred to in Article 145(2).	2. 歐盟執委會應，藉由施行細則，核准由所涉第三國為本條第 1 項所提及之目的而呈送給執委會的請求，並附有適當的證據且保證來自該第三國之所涉的動物和貨物符合第 126(1)條所提及之相關要求或與其等同的要求。 上開施行細則應根據第 145(2)條所提及的審查程序予以採用和更新。
3. The Commission shall decide on the request referred to in paragraph 2 taking into account, as appropriate:	3. 歐盟執委會應對關於第 2 項所提及之請求作出決定，並適當地考慮下列事宜：
(a) the third country's legislation in the sector concerned;	(a)第三國在所涉產業領域法令；
(b) the structure and organisation of the competent authorities of the third country and its control services, the powers available to them, the guarantees that can be provided with regard to the application and enforcement of the legislation of the third country applicable to the sector concerned, and the reliability of the official certification procedures;	(b)第三國權責機關的架構和組織及其管制服務、其可用的權力、所可提供之關於可適用於所涉產業領域的第三國法令的適用和執行方面的保證，以及官方驗證程序的可靠性；
(c) the performance by the competent authorities of the third country of adequate official controls and other activities to assess the presence of hazards for human, animal or plant health, for animal welfare or, in relation to GMOs and plant protection products, also for the environment;	(c)由第三國權責機關所執行之適當的官方管制和其他活動，以評估是否存在對人類、動物或植物健康、動物福祉、或與基因改造生物和植物保護產品相關，亦對環境所造成的危害；
(d) the regularity and rapidity of information supplied by the third country on the presence of hazards for human, animal or plant health, for animal welfare or, in relation to GMOs and plant protection products, also for the environment;	(d)由第三國所提供的關於對人類、動物或植物健康、動物福祉或與基因改造生物和植物保護產品相關，亦對環境的危害之存在性的資訊的定期性和快速性；
(e) the guarantees given by the third country that:	(e)第三國提供的下列事宜之保證：
(i) conditions applied to the establishments from which animals or goods are exported to the Union comply with requirements that are equivalent to those referred to in Article 126(1);	(i)適用於動物或貨物從該處出口到歐盟之廠場能符合與第 126(1)條所提及之該等內容等同的要求之條件；
(ii) a list of the establishments referred to in point (i) is drawn up and kept up to date;	(ii)擬定第(i)點所提及之廠場名單，並保持更新；
(iii) the list of establishments referred to in point (i) and updates thereof are communicated to the	(iii)第(i)點所提及之廠場名單及其後之更新，應立即通知歐盟執委會；
	(iv)第(i)點所提及的廠場是由第三國權責機關

Commission without delay; (iv) the establishments referred to in point (i) are the subject of regular and effective controls by the competent authorities of the third country; (f) the findings of controls performed by the Commission in the third country in accordance with Article 120(1); (g) any other information or data on the capability of the third country to ensure that only animals or goods which provide the same or an equivalent level of protection as that afforded by the relevant requirements referred to in Article 126(1) enter the Union. 4. The Commission shall delete the reference to a third country or a region of a third country from the list referred to in point (a) of Article 126(2) where the conditions for inclusion on the list cease to be met. The procedure referred to in paragraph 2 of this Article shall apply.	所作之定期和有效管制的主體; (f)由歐盟執委會根據第 120(1)條在第三國所執行的管制之結果; (g)關於第三國之確保只能提供與第 126(1)條所提及之相關要求所提供之相同或同等的保護水準之動物或貨物能進入歐盟的能力的任何其他資訊或數據。 4. 歐盟執委會應將不再符合列入第 126(2)條第(a)點所提及的清單中之條件的第三國或第三國之地區，自該清單中予以刪除。本條第 2 項所提及之程序應適用之。
Article 128 **Special measures regarding the entry into the Union of certain animals and goods** 1. Where, in cases other than those referred to in Article 53 of Regulation (EC) No 178/2002 and Article 249 of Regulation (EU) 2016/429, there is evidence that the entry into the Union of certain animals or goods originating from a third country, a region thereof or a group of third countries, pose a risk to human, animal or plant health or, as regards GMOs, also to the environment, or where there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) of this Regulation is taking place, the Commission shall adopt, by means of implementing acts, the measures necessary to contain such risk or put an end to the identified non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2) of this Regulation. 2. The measures referred to in paragraph 1 shall identify animals and goods by referring to their codes from the Combined Nomenclature, and may include: (a) the prohibition of entry into the Union of the animals and goods referred to in paragraph 1 originating in or dispatched from the third countries concerned or regions thereof; (b) the requirement that the animals and goods referred to in paragraph 1 originating in or dispatched	*第 128 條* **關於某些動物和貨物進入歐盟的特別措施** 1. 如果在(EC)178/2002 號規章第 53 條和(EC)2016/429 號規章第 249 條所提及之情況以外的情況下，有證據顯示來自某第三國，該第三國之其中一個地區或一組的第三國之某些動物或貨物的進入歐盟，對人類、動物或植物健康、或對基因改造生物構成威脅，亦對環境造成風險;或者有證據顯示刻正發生嚴重不符合本規章第 1(2)條所提及之規範之情事時，歐盟執委會應，藉由施行細則，採取必要措施以遏制此類風險或終止已識別的不符合情事。上開施行細則應當按照本規章第 145(2)條所提及之審查程序予以採用。 2. 第 1 項所提及之措施應藉由參照聯合命名法中的代碼來識別動物和貨物，並可包括： (a)禁止第 1 項所提及的源自所涉所涉第三國或其地區或從該等國家或地區發運之動物和貨物進入歐盟; (b)要求第 1 項所提及的源自所涉所涉第三國或其地區或從該等國家或地區發運之動物和貨物，在發

from certain third countries or regions thereof be subject, prior to dispatch, to specific treatment or controls; (c) the requirement that the animals and goods referred to in paragraph 1 originating in or dispatched from certain third countries or regions thereof be subject, upon entry into the Union, to specific treatment or controls; (d) the requirement that consignments of the animals and goods referred to in paragraph 1 of this Article originating in or dispatched from certain third countries or regions thereof, be accompanied by an official certificate, an official attestation, or by any other evidence that the consignment complies with requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto; (e) the requirement that the evidence referred to in point (d) be provided in accordance with a specific format; (f) other measures necessary to contain the risk. 3. When adopting the measures referred to in paragraph 2, account shall be taken of (a) the information collected in accordance with Article 125; (b) any other information that the third countries concerned have provided; and (c) where necessary, the results of Commission controls provided for in Article 120(1). 4. On duly justified imperative grounds of urgency relating to human health and animal health or, as regards GMOs and plant protection products, also to the protection of the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 145(3).	運之前，須受特定的處理或管制； (c)要求第 1 項所提及的源自所涉所涉第三國或其地區或從該等國家或地區發運的動物和貨物在進入歐盟之時，應接受特定的處理或管制； (d)要求第 1 項所提及的源自所涉所涉第三國或其地區或從該等國家或地區發運的動物和貨物之託運物，應隨附官方證書、官方證明或任何其他證據證明該托運物符合第 1(2)條所提及之規範之要求或符合經公認至少與之等同的要求； (e)要求第(d)點所提及之證據，須依特定格式提供； (f)其他的遏制風險之必要措施。 3. 當採用第 2 項所提之措施時，應考慮到： (a)根據第 125 條所收集的資訊； (b)所涉第三國已提供的任何其他資訊；以及 (c)必要時，第 120(1)條所述的歐盟執委會之管制的結果。 4. 基於與人類健康和動物健康、或關於基因改造生物和植物保護產品，以及對保護環境之緊急情事的合理迫切的立場，歐盟執委會應立即根據第 145(3)條所提及的審查程序採用適用的施行細則。
Article 129 **Equivalence** 1. In the areas governed by the rules referred to in Article 1(2), with the exclusion of points (d), (e), (g), and (h) of Article 1(2), the Commission may, by means of implementing acts, recognise that measures applied in a third country, or regions thereof, are equivalent to the requirements laid down in those rules, on the basis of:	*第 129 條* **等同性** 1. 在受第 1(2)條(除第 1(2)條第(d)、(e)、(g)和(h)點外)所提及規範所管理的領域，歐盟執委會可藉由施行細則，確認在第三國或其地區所使用的措施等同於該等規範中規定的要求，其依據如下：

(a) a thorough examination of information and data provided by the third country concerned pursuant to Article 125(1); and (b) where appropriate, the satisfactory outcome of a control performed in accordance with Article 120(1). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). 2. The implementing acts referred to in paragraph 1 shall set out the practical arrangements for the entry of animals and goods into the Union from the third country concerned, or regions thereof, and may include: (a) the nature and content of the official certificates or attestations that have to accompany the animals or goods; (b) specific requirements applicable to the entry into the Union of the animals or goods and the official controls to be performed at entry into the Union; (c) where necessary, procedures for drawing up and amending lists of regions or establishments in the third country concerned from which the entry of animals and goods into the Union is permitted. 3. The Commission shall, by means of implementing acts, repeal without delay the implementing acts provided for in paragraph 1 of this Article where any of the conditions for the recognition of equivalence cease to be fulfilled. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	(a)對所涉第三國根據第 125(1)條提供的資訊和數據資料徹底審查；及 (b)適當時，根據第 120(1)條所執行之管制的令人滿意的結果。 上開施行細則應按照第 145(2)條所提及的審查程序予以採用。 2. 第 1 項所提及之施行細則係規範從有關的第三國或地區進入歐盟的動物和貨物之實際安排，其中包括： (a)動物或貨物必須附有的官方證書或證明； (b)動物或貨物進入聯盟的具體要求以，及在進入歐盟時應實行的官方管制； (c)在必要時，制定和修訂有關動物和貨物進入歐盟之第三國或其地區的廠場名單程序。 3. 歐盟執委會應，當任何條件未獲履行時，藉由施行細則，毫不延誤地廢止本條第 1 項所述的措施。上開施行細則均應按照第 145（2）條所提及之審查程序予以採用。
CHAPTER III ***Training of staff of the competent authorities and of other authorities***	*第 III 章* ***權責機關和其他機關的職員培訓***
Article 130 **Training and exchange of staff** 1. The Commission may organise training activities for the staff of the competent authorities and, where appropriate, for staff of other authorities of the Member States involved in investigations of possible infringements of this Regulation and of the rules referred to in Article 1(2). The Commission shall organise those activities in cooperation with the Member States concerned. 2. The training activities referred to in paragraph 1 shall facilitate the development of a harmonised	*第 130 條* **職員培訓和交流** 1. 歐盟執委會可以為涉入調查可能違反本規章和第 1(2)條所提及之規範的會員國之權責機關之職員以及，適當時，其他機關的職員籌劃舉辦培訓活動。 歐盟執委會應與所涉會員國合作籌劃舉辦該等培訓活動。 2. 第 1 項所提及的培訓活動應著眼於促進會員國

approach to official controls and other official activities in Member States. They shall include, as appropriate, training on:	之調和的官方管制和其他官方活動之方法的開發。該等訓練應適當地包括關於下列內容：
(a) this Regulation and the rules referred to in Article 1(2);	(a)本規章及第 1(2)條所提及之規範；
(b) control methods and techniques relevant for the official controls and for the other official activities of the competent authorities;	(b)與權責機關的官方管制和其他官方活動有關的管制方法和技術；
(c) production, processing and marketing methods and techniques.	(c)生產、加工和行銷的方法和技術。
3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union.	3. 第 1 項所提及的培訓活動可對第三國之權責機關的職員開放，並可在歐盟之外籌劃舉辦。
4. Competent authorities shall ensure that the knowledge acquired through the training activities referred to in paragraph 1 of this Article is disseminated as necessary and appropriately used in the staff training activities referred to in Article 5(4). Training activities aimed at disseminating such knowledge shall be included in the training programmes referred to in Article 5(4).	4. 權責機關應確保透過本條第 1 項所提及的培訓活動所獲得的知識會在第 5(4)條所提及的職員培訓活動時加以如所需要之程度地傳播以及適當地使用。 旨在傳播此類知識的培訓活動應納入第 5(4)條所提及的培訓計畫中。
5. The Commission may organise, in cooperation with the Member States, programmes for the exchange of staff of the competent authorities performing official controls or other official activities between two or more Member States. Such exchange may take place through the temporary secondment of staff of the competent authorities from one Member State to the other or through the exchange of such staff between the relevant competent authorities.	5. 歐盟執委會可與會員國合作，籌劃舉辦兩個或兩個以上會員國之間於執行官方管制或其他官方活動的權責機關職員交流計畫。 此種交流可透過從一個會員國暫時調派權責機關的職員到另一個會員國，或是透過相關權責機關之間的此類職員的交換來進行。
6. The Commission may, by means of implementing acts, lay down rules on the organisation of the training activities referred to in paragraph 1, and of the programmes referred to in paragraph 5, of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	6. 歐盟執委會可，藉由施行細則，對第 1 項所提及的培訓活動的籌劃以及本條第 5 項所提及的(交流)計畫訂定規範。上開施行細則應按照第 145(2)條所提及的審查程序予以採用。
CHAPTER IV ***Information management system***	*第 IV 章* ***資訊管理系統***
Article 131 **Information management system for official controls (IMSOC)**	*第 131 條* **官方管制之資訊管理系統(IMSOC)**

1. The Commission shall, in collaboration with the Member States, set up and manage a computerised information management system for official controls (IMSOC) for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls and other official activities are managed, handled, and automatically exchanged. 2. The processing of personal data by the Member States and the Commission through the IMSOC and any one of its components shall only be carried out for the purpose of performing official controls and other official activities in accordance with this Regulation and with the rules referred to in Article 1(2).	1. 歐盟執委會應與會員國合作，建立和管理一個官方管制的電腦化資訊管理系統(IMSOC)，以利各種機制和工具之整體運作，透過該系統與官方管制和其他官方活動有關的數據資料、資訊和文件可受到管理、處理及自動交換。 2. 由會員國和歐盟執委會透過 IMSOC 及其任何一個組成部分所作的個人數據資料之處理，應只能係為按照本規章和第 1(2)條所提及之規範進行官方管制和其他官方活動之目的而加以執行(該類處理作業)。
Article 132 **General functionalities of the IMSOC** The IMSOC shall: (a) allow for the computerised handling and exchange of information, data and documents necessary for the performance of official controls, resulting from the performance of official controls or the recording of the performance or outcome of official controls in all cases where this Regulation, the rules referred to in Article 1(2) or the delegated and implementing acts provided for in Articles 16 to 27 provide for the exchange among competent authorities, between the competent authorities and the Commission, and where appropriate with other authorities and the operators, of such information, data and documents; (b) provide a mechanism for the exchange of data, information and documents in accordance with Articles 102 to 108; (c) provide a tool to collect and manage the reports on official controls provided by Member States to the Commission; (d) allow for the production, handling and transmission, including in electronic form, of the journey log referred to in Article 5(4) of Regulation (EC) No 1/2005, of the records obtained by the navigation system referred to in Article 6(9) of that Regulation, of official certificates and of the CHED referred to in Article 56 of this Regulation; and (e) integrate the existing computerised systems managed by the Commission and used for the rapid	*第 132 條* **IMSOC 的一般功能** IMSOC 應： (a)允許電腦化處理和交換該等執行官方管制所必需的資訊、數據和文件，而該等資訊、數據和文件是由官方管制之執行或對於所有情況下官方管制的執行或結果所產生。而該等情況係指本規章第 1(2)條所提及的規範或第 16 條至第 27 條所述的授權法規和施行細則中所規定於權責機關之間、權責機關與歐盟執委會之間，以及適當時，(權責機關) 與其他機關和營運者之此等資訊、數據資料和文件的交換; (b)根據第 102 至 108 條提供一個交換數據資料、資訊和文件的機制; (c)提供一個工具，以收集和管理會員國向歐盟執委會提供之關於官方管制的報告; (d)允許(EC)1/2005 號規章第 5(4)條所提及的(運送)旅途日誌、該規章第 6(9)條所提及由導航系統所獲得的紀錄、本規章第 56 條所提及的官方證書和 CHED(Common Health Entry Document)之產出、處理和傳輸，其中包括電子形式;以及 (e)整合歐盟執委會所管理及用於快速交換有關人類、動物健康和福利以及植物健康之風險而根據(EC)178/2002 規章第 50 條的規定，(EC)2016/429 號規章第 20 條和(EU)2016/2031 號規章第 103 條

exchange of data, information and documents in relation to risks to human, animal health and welfare, and plant health, as established by Article 50 of Regulation (EC) No 178/2002, Article 20 of Regulation (EU) 2016/429 and Article 103 of Regulation (EU) 2016/2031 and provide appropriate links between those systems and its other components.	所建立的數據資料、資訊和文件的現有電腦化系統，並提供該等系統與系統其他部分之間的適當聯繫。
Article 133 **Use of the IMSOC in the case of animals and goods subject to certain official controls** 1. In the case of animals or goods whose movements within the Union or placing on the market are subject to specific requirements or procedures established by the rules referred to in Article 1(2), the IMSOC shall enable the competent authorities at the place of dispatch and other competent authorities responsible for performing official controls on those animals or goods to exchange, in real time, data, information and documents concerning animals or goods being moved from one Member State to another and on official controls performed. The first subparagraph of this paragraph shall not apply to goods subject to the rules referred to in points (g) and (h) of Article 1(2). 2. In the case of exported animals and goods for which Union rules apply in relation to the issuance of the export certificate, the IMSOC shall enable the competent authorities of the place of dispatch and other competent authorities responsible for performing official controls to exchange, in real time, data, information and documents concerning such animals and goods and the outcome of controls performed on those animals and goods. 3. In the case of animals or goods subject to the official controls referred to in Articles 44 to 64, the IMSOC shall: (a) enable the competent authorities at the border control posts and other competent authorities responsible for performing official controls on those animals or goods to exchange, in real time, data, information and documents concerning those animals and goods and on controls performed on those animals or goods; (b) enable the competent authorities at the border control posts to share and exchange relevant data, information and documents with customs authorities and other authorities responsible for performing	*第 133 條* **在受到特定官方管制的動物和貨物的情況時之 IMSOC 的使用** 1. 如果是在歐盟內運送或上市行銷須接受由第 1(2)條所提及之規範所訂定的特定要求或程序的約束隻動物或貨物之情況時，IMSOC 應使在發運地之權責機關能夠和負責對該等動物或貨物執行官方管制之其他權責機關，即時交換有關從一個會員國轉運送到另一個會員國之動物或貨物的數據資料、資訊和文件，以及所執行的官方管制。 上述本項之第 1 款將不適用於受第 1(2)條第(g)和(h)點所提及之規範約束的貨物。 2. 如果是在歐盟規範所適用關於發給出口證書之出口動物和貨物的情況時，IMSOC 應使發運地之權責機關和負責執行官方管制的其他權責機關能夠即時進行交換關於該等動物和貨物之數據資料、資訊和文件以及對該等動物和貨物執行管制的結果。 3. 如果是在須受第 44 至 64 條所提及的官方管制之約束的動物或貨物的情況時，IMSOC 應： (a)使在邊境管制站的權責機關能夠和負責對該等動物或貨物執行官方管制的其他權責機關，即時交換有關該等動物和貨物的數據資料，資訊和文件以及對該等動物或貨物所執行之管制； (b)使在邊境管制站的權責機關能夠根據第 15(4)和 75(2)條所採用的規範及根據其他有關的歐盟規範與海關和負責對從第三國進入歐盟的動物或貨物執行管制的其他權責機關，以及與涉及入境程序的運營商分享和交換相關數據資料，資訊和文件；及

controls on animals or goods entering the Union from third countries, and with operators involved in entry procedures, in accordance with the rules adopted pursuant to Articles 15(4) and 75(2) and with other relevant Union rules; and (c) support and operate the procedures referred to in point (a) of Article 54(3) and in Article 65(6). 4. The IMSOC shall, for the purpose of this Article, integrate the existing Traces system.	(c)支持和運作第 54(3)條第(a)點和第 65(6)條所提及的程序。 4. 為了本條的目的，IMSOC 應整合現有的 Traces(TRAde control and Export System)系統。
Article 134 **The functioning of the IMSOC** The Commission shall adopt implementing acts for the functioning of the IMSOC which lay down: (a) the technical specifications of the IMSOC and its system components, including the electronic data exchange mechanism for exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures; (b) the specific rules for the functioning of the IMSOC and of its system components to ensure protection of personal data and security of exchange of information; (c) the specific rules for the functioning and use of the IMSOC and of its components, including the rules to update and create the necessary links between the systems referred to in point (e) of Article 132 and in Article 133(4); (d) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the IMSOC; (e) the cases where, and the conditions under which, the third countries and international organisations concerned may be granted partial access to the functionalities of the IMSOC and the practical arrangements of such access; (f) the cases where, and the conditions under which, the data, information and documents are to be transmitted using the IMSOC; (g) the rules concerning an electronic system under which electronic certificates issued by the competent authorities of third countries are to be accepted by the competent authorities; and (h) the cases where, and the conditions under which, exemptions from the use of the IMSOC can be granted to occasional users.	*第 134 條* **IMSOC 的運作** 歐盟執委會應採用有關 IMSOC 運作的施行細則，其訂定下列事宜： (a)IMSOC 及其系統組成部分的技術規範，其中包括用於與現有國家系統之交換、適用標準的確認、訊息結構的定義、數據資料字典，以及協議和程序的交換之電子數據資料交換機制; (b)IMSOC 及其系統組成部分的運作之具體規範，以確保個人數據資料的保護和資訊交換的安全性; (c)IMSOC 及其組成部分的運作和使用的具體規範，其中包括用以更新和建立第 132 條(e)項和第 133(4)條所提及系統間之必要聯繫的規範; (d)在 IMSOC 無法發揮任何功能的情況下所應用的應急安排; (e)所涉第三國和國際組織可被授與得以部分進入 IMSOC 功能的情況和條件，以及此種進入(該等功能)的實際安排; (f)可使用 IMSOC 傳輸數據資料，資訊和文件的情況和條件; (g)關於由第三國權責機關據以核發可被權責機關接受的電子證書之電子系統的規範;以及 (h)臨時使用者可被授予豁免使用 IMSOC 的情況和條件。

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	上開施行細則應按照第 145(2)條所提及的審查程序予以採用。
Article 135 **Data protection**	*第 135 條* **數據資料之保護**
▼C1 1. Directive 95/46/EC and Regulation (EC) No45/2001 of the European Parliament and of the Council[62] shall apply to the extent that the information processed through the IMSOC contains personal data as defined in point (a) of Article 2 of Directive 95/46/EC and in point (a) of Article 2 of Regulation (EC) No 45/2001. ◄C1 2. In relation to their responsibilities to transmit the relevant information to the IMSOC and the processing of any personal data that might result from that activity, the competent authorities of the Member States shall be regarded as controllers as defined in point (d) of Article 2 of Directive 95/46/EC. 3. In relation to its responsibility to manage the IMSOC and the processing of any personal data that might result from that activity, the Commission shall be regarded as controller as defined in point (d) of Article 2 of Regulation (EC) No 45/2001. 4. Member States may restrict the rights and obligations under Article 6(1), Article 10, Article 11(1) and Article 12 of Directive 95/46/EC as necessary to safeguard the interest referred to in points (d) and (f) of Article 13(1) of that Directive. 5. The Commission may restrict the rights and obligations under Article 4(1), Article 11, Article 12(1) and Articles 13 to 17 of Regulation (EC) No 45/2001 where such restriction constitutes a necessary measure to safeguard the interests referred to in points (a) and (e) of Article 20(1) of that Regulation during the period in which actions are being planned or performed to verify compliance with food or feed law or to ensure the enforcement of food or feed law in the specific case to which the information	1. 95/46/EC 指令及歐洲議會及歐盟理事會(EC)第 45/2001 號規章，其適用範圍應及於透過 IMSOC 所處理之包括如 95/46/EC 指令第 2 條第(a)點及 EC 第 45/2001 號規章第 2 條第(a)點所定義的個人資料的資訊。 2. 與會員國之權責機關他們將相關資訊發送給 IMSOC 及任何可能由該項活動的個人資料之處理的責任相關，會員國的權責機關應被視為如 95/46/EC 指令第 2 條第(d)點的規定所定義之管制者。 3. 與(歐盟執委會)其管理 IMSOC 及任何可能由該項活動所產生的個人資料之處理的責任相關，歐盟執委會應被視為如 EC 第 45/2001 號規章第 2 條第(d)點所定義之管制者。 4. 會員國得對架構於 95/46/EC 指令的第 6(1)條、第 10 條、第 11(1)條及第 12 條之下的權利及義務加以如所必須程度地限制，以保障規定在該指令第 13(1)條之第(d)及第(f)點所提及的利益。 5. 歐盟執委會得限制架構於 EC 第 45/2001 號規章第 4(1)條、第 11 條、第 12(1)條及第 13 至 17 條之下的權利及義務，該限制構成了一項必要的措施以在行動正被規劃或執行以查驗對食物及飼料法之福核性或確保食物及飼料法在與資訊相關的具體案件之執行的期間對該規章第 20(1)條第(a)點、第(e)點所提及的利益之保障。

62 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p.1)./ 歐洲議會及歐盟理事會 2000 年 12 月 18 日第 45/2001 號規章，關於在共同體機關與機構對於個人資料處理及其自由流通時之對個人的保護。

relates.	
Article 136 **Data security** Member States and the Commission shall ensure that the IMSOC complies with the rules on data security adopted by the Commission under Article 17 of Directive 95/46/EC and Article 22 of Regulation (EC) No 45/2001 respectively.	*第 136 條* **數據資料之安全** 會員國及歐盟執委會須確保 IMSOC 符合被歐盟執委會分別依 95/46/EC 指令第 17 條及 EC 第 45/2001 號規章第 22 條所採用之關於資料安全的規範。
TITLE VII **ENFORCEMENT ACTION** *CHAPTER I* ***Actions by the competent authorities and penalties***	第 VII 編 **執行之行動** *第 I 章* ***權責機關之行動及處罰***
Article 137 **General obligations of the competent authorities as regards enforcement action** 1. When acting in accordance with this Chapter, the competent authorities shall give priority to action to be taken to eliminate or contain risks to human, animal and plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment. 2. In case of suspicion of non-compliance, the competent authorities shall perform an investigation in order to confirm or to eliminate that suspicion. 3. Where necessary, actions taken in accordance with paragraph 2 shall include: (a) the performance of intensified official controls on animals, goods and operators for an appropriate period; (b)the official detention of animals and goods and of any unauthorised substances or products as appropriate.	*第 137 條* **關於權責機關於執行之行動的一般義務** 1. 當根據本章規定執行時，權責機關應給予所採取用以消除或遏止對人類、動物和植物健康、動物福祉或關於基因改造生物及植物保護產品，以及對環境的風險之行動給予優先權。 2. 在有不符合規定之懷疑的情況時，權責機關應執行調查以確認或消除該懷疑。 3. 在有必要時，(權責機關)依據第 2 項所採取的行動應包括： (a)在適當的其間中對動物、貨物及運營商之強化的官方管制的執行。 (b)適當地對動物與貨物及任何未經授權的物質或產品所執行的官方扣押。
Article 138 **Actions in the event of established non-compliance** 1. Where the non-compliance is established, the competent authorities shall take: (a) any action necessary to determine the origin and extent of the non-compliance and to establish the operator's responsibilities; and	*第 138 條* **在確定不符合的情況下所採取的行動** 1. 在不符合的情事已獲確定時，權責機關應採取以下措施： (a)任何必要的行動來確定不符合情事的起源及其程度並確立運營商的責任；及

(b) appropriate measures to ensure that the operator concerned remedies the non-compliance and prevents further occurrences of such non-compliance.

When deciding which measures to take, the competent authorities shall take account of the nature of that non-compliance and the operator's past record with regard to compliance.

2. When acting in accordance with paragraph 1 of this Article, competent authorities shall take any measure they deem appropriate to ensure compliance with the rules referred to in Article 1(2), including, but not limited, to the following:

(a) order or perform treatments on animals;

(b) order the unloading, transfer to another means of transport, holding and care of animals, quarantine periods, the postponement of the slaughter of animals, and, if necessary, order that veterinary assistance be sought;

(c) order treatments on goods, the alteration of labels or corrective information to be provided to consumers;

(d) restrict or prohibit the placing on the market, the movement, the entry into the Union or the export of animals and goods; and prohibit their return to the Member State of dispatch or order their return to the Member State of dispatch;

(e) order the operator to increase the frequency of own controls;

(f) order certain activities of the operator concerned to be subject to increased or systematic official controls;

(g) order the recall, withdrawal, removal and destruction of goods, authorising, where appropriate, the use of the goods for purposes other than those for which they were originally intended;

(h) order the isolation or closure, for an appropriate period of time, of all or part of the business of the operator concerned, or its establishments, holdings or other premises;

(i) order the cessation for an appropriate period of time of all or part of the activities of the operator concerned and, where relevant, of the internet sites it operates or employs;

(j) order the suspension or withdrawal of the registration or approval of the establishment, plant, holding or means of transport concerned, of the authorisation of a transporter or of the certificate of

(b)適當的措施以確保所涉運營商對於不符合情事的補救措施以及預防更多此類不符合情事發生。在決定要採取何種措施時，權責機關應將不符合情事的本質以及運營商以往關於符合規定的紀錄納入考量。

2. 當根據本條第 1 項而採取行動時，權責機關應採取任何他們認為妥適的措施來確保符合第 1(2)條所提及之規定，其中包括但不限於以下之措施：

(a)下令或是執行對動物的治療；

(b)下令卸貨、轉換成其他運送方式、對動物之保有和照顧、檢疫期、延後對動物的屠宰，以及，若有必要，得責令尋求獸醫的協助；

(c) 責令對貨物的處理、標籤的更換或提供改正的資訊給消費者；

(d)限制或禁止動物及貨物的上市、移運、進入歐盟或出口；以及禁止它們回到發運之會員國或責令它們回到發運之會員國；

(e)下令運營商提高自我管制的頻率；

(f)下令就所涉運營商的特定活動需接受增加的或系統性的官方管制；

(g)下令貨物的召回、回收下架及銷毀，適當時，核准該等貨物用於非其原定用途上；

(h)下令隔離或關閉所涉運營商之業務的全部或部分，或其廠場、持有物或其他房地財產一段妥適的期間；

(i)下令停止所涉運營商的全部或部分活動及，相關時，其操作或使用之網站一段妥適的期間；

(j)下令暫停或撤銷所涉廠場、工廠、持有物或運送方式之登記或許可，及運輸車的核准或駕駛的能力之證書；

(k) 下令對動物的屠宰或殺戮，若此方式為保障人類健康及動物健康和福祉的最妥適措施時。

competence of the driver; (k) order the slaughter or killing of animals provided that this is the most appropriate measure to safeguard human health as well as animal health and welfare. 3. The competent authorities shall provide the operator concerned, or its representative, with: (a) written notification of their decision concerning the action or measure to be taken in accordance with paragraphs 1 and 2, together with the reasons for that decision; and (b) information on any right of appeal against such decisions and on the applicable procedure and time limits with respect to such right of appeal. 4. All expenditure incurred under this Article shall be borne by the responsible operators. 5. The competent authorities, in the case of issuance of false or misleading official certificates or in the case of abuse of official certificates, shall take appropriate measures, including: (a) the temporary suspension of the certifying officer from its duties; (b) the withdrawal of the authorisation to sign official certificates; (c) any other measure to prevent a reoccurrence of the offences referred to in Article 89(2).	3. 權責機關應提供所涉運營商或其代表人下列事物： (a)一份關於他們依據第 1 項及第 2 項所採取的行動或措施的決定，及做出這個決定的理由之書面通知；以及 (b)關於對此項決定的上訴權，以及關於此上訴權的適用程序和時間限制的資訊。 4. 因本條衍生的所有支出須由負責的運營商承擔。 5. 在有不實的或誤導性的官方證書之核發的情況時或有官方證書的濫用情況時，權責機關應採取適當的措施，包括： (a)暫時的中止負責驗證的官員之職務； (b)撤銷簽發官方證書的權限； (c)其他任何防止第 89（2）條中所提及之犯行再發的措施。
Article 139 **Penalties** 1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by 14 December 2019, notify those provisions to the Commission and shall notify it without delay of any subsequent amendment affecting them. 2. Member States shall ensure that financial penalties for violations of this Regulation and of the rules referred to in Article 1(2), perpetrated through fraudulent or deceptive practices, reflect, in accordance with national law, at least either the economic advantage for the operator or, as appropriate, a percentage of the operator's turnover.	*第 139 條* **處罰** 1. 會員國應針對適用於違反本規章的處罰加以明定並採取一切必要措施以確保其執行。該等所規定的處罰內容應是效率的、有相稱性的以及具有勸誡效果的。所有會員國應在 2019 年 12 月 14 日前將該等規定通知歐盟執委會並應將任何影響該等規定的後續修正立即通知歐盟執委會。 2. 會員國應確保對透過詐欺及欺騙等手法所犯違反本規章以及第 1(2)條所提及的規範之情事的財務性處罰及在根據國家法律，至少反映了不是運營商的經濟利益就是在適當地反映了運營商營業額的一個比率。
Article 140 **Reporting of infringements**	*第 140 條* **違反(本規章)情形的報告**

1. Member States shall ensure that competent authorities have effective mechanisms to enable reporting of actual or potential infringements of this Regulation. 2. The mechanisms referred to in paragraph 1 shall include at least: (a) procedures for the receipt of reports of infringements and their follow-up; (b) appropriate protection for persons reporting an infringement against retaliation, discrimination or other types of unfair treatment; and (c) protection of personal data of the person reporting an infringement in accordance with Union and national law.	1. 會員國應確保權責機關具備有效率的機制以利能夠報告確實及潛在的違反本規章的情形。 2. 第 1 項所提及之機制至少應包括下列事宜： (a)收到違反(本規章)情況之報告以及其跟催處理的程序； (b)對於報告某違反(本規章)情事之人免於受到報復、歧視或其他類型的不公平對待的妥適的保護； (c)根據歐盟及國家對報告某違反(本規章)情事的人之個人的資料保護。
CHAPTER II ***Union enforcement measures***	*第 II 章* ***歐盟的執法措施***
Article 141 **Serious disruption in a Member State's control system** 1. Where the Commission has evidence of a serious disruption in a Member State's control system and such disruption may constitute a widespread risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, or result in a widespread infringement of the rules referred to in Article 1(2), it shall, by means of implementing acts, adopt one or more of the following measures, to be applied until such disruption is eliminated: (a) the prohibition to make available on the market or to transport, move or otherwise handle certain animals or goods concerned by the disruption in the control system; (b) special conditions for the activities, animals or goods referred to in point (a); (c) the suspension of the operation of official controls in border control posts or other control points concerned by the disruption in the official control system or the withdrawal of such border control posts or other control points; (d) other appropriate temporary measures necessary to contain that risk until the disruption in the control system is eliminated. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	*第 141 條* **某會員國管制系統的嚴重瓦解** 1. 當歐盟執委會已經得到某會員國管制系統之嚴重瓦解的證據，且此種瓦解可能構成對人類、動物或植物健康、動物福祉，或基因改造生物及植物保護性產品和對環境的廣泛的風險，或造成對第 1(2)條所提及之規範的廣泛違反時，歐盟執委會應藉由施行細則，採取一個或多個下列的措施，直到上述之瓦解的情況已經消除為止： (a)禁止在市面上販售或運送、移動與瓦解的情況有關聯的特定動物或貨物，否則的話，就必須在管制系統中加以處理； (b)在第(a)點中所提及的活動、動物或貨物的特殊條件； (c)中止官方管制系統中與上述瓦解有關聯的邊界管制站或其他管制點的官方管制之運作，或撤銷此等邊界管制站或其他管制點； (d)其他適當之暫時的必要措施以遏止該風險直到該管制系統中的瓦解已經消除。 上開施行細則應按照第 145(2)條所提及的審查程序予以採用。 2. 在第 1 項所提及之措施應只有在所涉的會員國

2. The measures referred to in paragraph 1 shall be adopted only where the Member State concerned has not corrected the situation upon request and within the appropriate time limit set by the Commission. 3. On duly justified imperative grounds of urgency relating to human and animal health or, as regards GMOs and plant protection products, also to the protection of the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 145(3).	未應(歐盟執委會)要求時即著手且在歐盟執委會所設定的適當期限內予以改正此一情形時始被採用。 3. 在有與人類及動物健康，或關於基因改造生物及植物保護產品，以及對環境保護的緊急情況之適切地確認的勢在必行的理由下，歐盟執委會應根據第 145(3)條所提及的程序立即採用適用的施行細則。
TITLE VIII **COMMON PROVISIONS** *CHAPTER I* ***Procedural provisions***	第 VIII 編 **共同條款** *第 I 章* ***程序性條文***
Article 142 **Amendment of Annexes and references to European standards** 1. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning amendments to Annexes II and III, in order to take into account changes to the rules referred to in Article 1(2), technical progress and scientific developments. 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the references to the European standards referred to in point (b)(iv) of Article 29, point (e) of Article 37(4) and point (a) of Article 93(3), in the event that CEN amends those standards.	*第 142 條* **附件及歐洲標準引用的修正** 1. 歐盟執委會被授權基於第 144 條之規定採用授權法規以修正本規章中關於附件 II 及附件 III 的修正，其目的在於將第 1(2)條所提及之規範的變化、技術的進步及科學的發展納入考量。 2. 歐盟執委會被授權基於第 144 條之規定採用授權法規以修正本規章中關於第 29 條第(b)(iv)點、第 37(4)條第(e)點及第 93(3)條第(a)點所提及之歐洲標準的引用，如果歐洲標準化委員會(CEN)修正該等標準的話。
Article 143 **Data protection** 1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation. 2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.	*第 143 條* **資料的保護** 1. 會員國應使用 95/46/EC 指令於會員國內，根據本規章所執行之個人資料的處理。 2. (EC)45/2001 號規章應適用於歐盟執委會根據本規章所執行之個人資料的處理。
Article 144	*第 144 條*

Exercise of the delegation	委託的行使
1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. 採用授權法規的權力係基於本條所提及之條件授予歐盟執委會。
2. The power to adopt delegated acts referred to in Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) shall be conferred on the Commission for a period of five years from 28 April 2017. The Commission shall draw up a report in respect of the delegation of power not later than nine months b efore the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.	2. 採取第 18(7)及 21(8)等條、第 41 條、第 45(4)及 47(3)等條、第 48 條、第 50(4)條、第 51 條，以及第 53(1)、62(3)、64(2)及(5)、77(1)及(2)、92(4)、99(2)、100(6)、101(2)、126(1)、142(1)及(2)、149(2)、150(3)、154(3)、155(3)及 165(3)等條所提及之授權法規的權力須自 2017 年 4 月 28 日授予歐盟執委會滿 5 年之期間。歐盟執委會應在不遲於 5 年期間結束之前 9 個月內就該項權利的委託完成 1 份報告。權力的委託應被默許地延展相同的期間(即 5 年為 1 期)，除非歐洲議會或歐盟理事會不遲於每段期間期滿之前 3 個月反對該項延展。
3. The delegation of power referred to in Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. 在第 18(7)及 21(8)等條、第 41 條、第 45(4)及 47(3)等條、第 48 條、第 50(4)條、第 51 條，以及第 53(1)、62(3)、64(2)和(5)、77(1)和(2)、92(4)、99(2)、100(6)、101(2)、126(1)、142(1)和(2)、149(2)、150(3)、154(3)、155(3)及 165(3)等條所提及之權力的委託，歐洲議會或歐盟理事會得在任何時間撤銷。該撤銷的決定須終止於該決定中所明示之權力的委託。該項撤銷應在該決定發布於《歐盟公報》之次日起或在公報指定更晚日期生效。該項撤銷不應影響已生效之任何授權法規的有效性。
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	4. 在採用授權法規之前，歐盟執委會應基於「2016 年 4 月 13 日關於更好的立法之機構間協議」當中所明訂的原則諮詢由各會員國所指定的專家之意見。
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. 在歐盟執委會採用授權法規時，其同時就必須通知歐洲議會及歐盟理事會。
6. A delegated act adopted pursuant to Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a	6. 只有在依第 18(7)及 21(8)等條、第 41 條、第 45(4)及 47(3)等條、第 48 條、第 50(4)條、第 51 條，以及第 53(1)、62(3)、64(2)和(5)、77(1)和(2)、92(4)、99(2)、100(6)、101(2)、126(1)、

period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	142(1)和(2)、149(2)、150(3)、154(3)、155(3)及165(3)等條規定所採用之授權法規，若歐洲議會或歐盟理事會並未在該法規送達歐洲議會或歐盟理事會後2個月內提出異議，或是在期間屆至之前，歐洲議會及歐盟理事會皆通知歐盟執委會將不會反對該法規時，則該授權法規應生效。惟在歐洲議會或歐盟理事會主動倡議的情況下，該期間應予延長2個月。
Article 145 **Committee procedure** 1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002, except in respect of Articles 25 and 26 of this Regulation for which the Commission shall be assisted respectively by the committees established pursuant to Regulation (EC) No 834/2007 and to Regulation (EU) No 1151/2012. Those committees shall be committees within the meaning of Regulation (EU) No 182/2011. 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply. 3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.	*第145條* **委員會程序** 1. 除了依本規章第25及26條規定，歐盟執委會應分別接受根據EC 834/2007號及1151/2012號規章所成立的委員會之協助外，歐盟執委會應接受基於EC 178/2002號規章第58(1)條所成立的植物、動物、食物及飼料常務委員會之協助。該等委員會應為(EU)第182/2011號規章中所謂的「委員會」。 2. 在提到本項時，(EU)182/2011號規章第5條應適用之。當委員會未表示意見時，歐盟執委會即應不得採用施行細則草案，此時須適用(EU)182/2011號規章第5(4)條的第3款。 3. 在提到本項時，(EU)182/2011號規章第8條，結合該規章第5條，均須適用。
CHAPTER II ***Transitional and final provisions***	*第II章* **過渡性及最後條文**
Article 146 **Repeals** 1. Regulations (EC) No 854/2004 and (EC) No 882/2004, Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Decision 92/438/EEC, are repealed with effect from 14 December 2019. 2. References to the repealed acts shall be construed as references to this Regulation and shall be read	*第146條* **廢止** 1. 第(EC)854/2004及882/2004號等規章、89/608/EEC、89/62/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC及97/78/EC等指令和92/438/EEC決定，自2019年12月14日起被廢止效力。

in accordance with the correlation tables in Annex V.	2. 對已廢止之法規的引用應解釋為對本規章的引用，並應根據附件 V 中的關聯性表格中加以讀取。
Article 147 **Relation with Regulation (EC) No 882/2004** The designation of each of the European Union reference laboratories referred to in Annex VII to Regulation (EC) No 882/2004 shall remain effective until a designation of a European Union reference laboratory in the same area takes place in accordance with Article 93 of this Regulation.	*第 147 條* **與(EC) 882/2004 號規章相關部分** 每個依(EC)882/2004 號規章附件 VII 所提及之歐盟參考實驗室的指定應繼續有效，直到有根據本規章第 93 條的規定在同一領域加以指定的歐盟參考實驗室為止。
Article 148 **Relation with Regulations (EC) No 852/2004 and (EC) No 853/2004 regarding approval of food business establishments** 1. Competent authorities shall establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with Regulations (EC) No 852/2004 and (EC) No 853/2004. 2. Upon receipt of an application for approval from a food business operator, the competent authority shall make an on-site visit. 3. The competent authority shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it complies with the relevant requirements of food law. 4. The competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new official control of the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not exceed a total of six months, except in the case of factory and freezer vessels flying the flag of Member States, for which such conditional approval shall not exceed a total of 12 months. 5. The competent authority shall keep the approval of establishments under review when carrying out official controls.	*第 148 條* **關於食品事業廠場的核准之(EC)852/2004 號與 853/2004 號規章的關係** 1. 當食品事業運營商根據(EC) 852/2004 號與 853/2004 號規章申請其廠場之許可時，權責機關應為該等運營商建立一套程序使之遵循。 2. 在收到食品事業運營商的許可申請後，權責機關應做一次現場的查訪。 3. 只有在食品事業運營商已經證明其符合食品法規的相關要求時，權責機關始可批准其廠場之活動。 4. 權責機關在廠場似符合所有基礎設施與設備的要求的情況下，得給予有條件的核准。只有在其於獲得有條件核准後三個月內於對其所執行之新的官方管制作業中顯示其亦符合食品法的其他相關要求時，才給予完全核准。如果廠場已經有了明確的進步，但其仍未能符合所有的相關要求時，權責機關得延長該有條件的核准。然而，，除掛有會員國的旗誌的工廠或冷凍船，其有條件的核准總共不得超過十二個月以外，該有條件的核准總共不得延長超過六個月。 5. 權責機關在執行官方管制時，應持續就廠場的核准進行審查。

Article 149 **Transitional measures related to the repeals of Directives 91/496/EEC and 97/78/EC** 1. ►M2The relevant provisions of Directives 91/496/EEC and 97/78/EC which govern matters referred to in point (b) of Article 47(2), Article 48, points (b), (c) and (d) of Article 51(1), point (a) of Article 53(1), Article 54(1) and (3), and point (a) of Article 58 of this Regulation shall apply instead of the corresponding provisions of this Regulation until 13 December 2019. The relevant provisions of Directive 97/78/EC which govern matters referred to in point (a) of Article 47(2) of this Regulation related to composite products shall continue to apply instead of that corresponding provision until 20 April 2021. ◄M2 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the date referred to in paragraph 1 of this Article. That date shall be the date of application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Article 47(2), Article 48, points (b), (c) and (d) of Article 51(1), point (a) of Article 53(1), Article 54(1) and (3), and point (a) of Article 58.	*第 149 條* **與 91/496/EEC 與 97/78/EC 指令之廢止有關的過渡性措施** 1. 91/496/EEC 與 97/78/EC 指令涉及本規章第 47(2)條之第(b)點、第 48 條、第 51(1)條之第(b)、(c)、(d)點、第 53(1)條第(a)點、第 54(1)和(3)條及第 58 條第(a)點所提及管理事宜之相關條文應適用到 2019 年 12 月 13 日。 97/78/EC 指令涉及本規章第 47(2)條第(a)點所提及管理複合性食品事宜之相關條文應繼續適用到 2021 年 4 月 20 日。 2. 歐盟執委會被授權根據第 144 條的規定採用授權法規，以修改本規章中關於本條第 1 項所提及之日期的部分。該日期應為根據第 47(2)條、第 48 條、第 51(1)條第(b)、(c)、(d)點、第 53(1)條第(a)點、第 54(1)和(3)條及第 58 條第(a)點所述的授權法規或施行細則所制定的相應規範之適用日期。
Article 150 **Transitional measures related to the repeal of Directive 96/23/EC** 1. Competent authorities shall continue to perform the official controls necessary to detect the presence of the substances and groups of residues listed in Annex I to Directive 96/23/EC, in accordance with Annexes II, III and IV to that Directive, instead of the corresponding provisions of this Regulation, until 14 December 2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 3 of this Article. 2. Article 29(1) and (2) of Directive 96/23/EC shall continue to apply instead of the corresponding provisions of this Regulation until 14 December 2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 3 of this Article. 3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the earlier date referred to in paragraphs 1 and 2 of this Article. That date shall be the date of application of the corresponding rules to be established pursuant to the delegated or	*第 150 條* **與 96/23/EC 指令廢止之相關的過渡性措施** 1. 權責機關應繼續依據 96/23/EC 指令的附件 II，III 和 IV 執行必要的官方管制以檢測該指令附件 I 中所列出的物質和殘留物群組的存在，直至 2022 年 12 月 14 日或根據本條第 3 項所採用的授權法規中所決定的更早之日期為止，在此期間將不適用本規章相對應之條文。 2. 第 96/23/EC 號指令的第 29(1)和(2)條應持續地適用，直到 2022 年 12 月 14 日或根據本條第 3 項所採用的授權法規中所決定的更早之日期為止，在此期間將不適用本規章相對應之條文。 3. 歐盟執委會被授權根據第 144 條的規定採用授權法規，以修改本規章中關於本條第 1 項及第 2 項所提及之更早日期的部分。該日期應為根據在第 19 及 112 條所述的授權法規或施行細則所制

implementing acts provided for in Articles 19 and 112.	定的相應規範之適用日期。
Article 151 **Amendments to Directive 98/58/EC** Directive 98/58/EC is amended as follows: (1) Article 2, point (3) is replaced by the following: '3. "competent authorities" means competent authorities as defined in Article 3(3) of Regulation (EU) 2017/625 of the European Parliament and of the Council(*). (*) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207, p.1).'; (2) Article 6 is amended as follows: (a) paragraph 1 is deleted; (b)paragraph 2 is replaced by the following: '2. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non–compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.'; (c) in paragraph 3, point (a) is deleted; (3) Article 7 is deleted.	*第 151 條* **對 98/58/EC 指令的修正** 第 98/58/EC 指令修正如下： (1) 第 2 條第(3)點由以下內容取代： 「3.『權責機關』是指歐洲議會及歐盟理事會(EU)2017/625 規章第 3(3)條所定義的權責機關(*). (*) (EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福祉、植物健康和植物保護產品規範的適用而執行的官方管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU) 2016/2031 規章、歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章)(OJ L 95,7.4.207, p.1).」； (2) 第 6 條修正如下： (a)刪除第 1 項； (b)第 2 項由以下內容取代： 「2. 會員國應在每年 8 月 31 日之前向歐盟執委會提交上一年度的年度報告，該報告係關於權責機關為查核是否符合本指令的要求所執行的檢查。該報告應附有一份對所發現之最嚴重的不符合規定之情事的分析，以及一份防止或減少其於未來年度再發生該等情事的國家行動計畫。歐盟執委會應向會員國該等這些報告的摘要。」； (c)在第 3 項中，刪除(a)點； (3) 刪除第 7 條。
Article 152	*第 152 條*

Amendments to Directive 1999/74/EC Directive 1999/74/EC is amended as follows: (1) Article 8 is amended as follows: (a) paragraph 1 is deleted; (b) paragraph 2 is replaced by the following: '2. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non–compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of these reports to the Member States.'; (c) in paragraph 3, point (a) is deleted; (2) Article 9 is deleted.	**對 1999/74/EC 指令的修正** 1999/74/EC 指令修改如下： (1) 第 8 條修訂如下： (a)刪除第 1 項; (b)第 2 項由以下內容取代： 「2. 會員國應在每年 8 月 31 日之前向歐盟執委會提交上一年度的年度報告，該報告係關於權責機關為查核是否符合本指令的要求所執行的檢查。該報告應附有一份對所發現之最嚴重的不符合規定之情事的分析，以及一份防止或減少其於未來年度再發生該等情事的國家行動計畫。歐盟執委會應向會員國該等這些報告的摘要。」; (c)在第 3 項中，刪除(a)點; (2) 刪除第 9 條。
Article 153 **Amendments to Regulation (EC) No 999/2001** Regulation (EC) No 999/2001 is amended as follows: (1) Articles 19 and 21 are deleted; (2) in Annex X, Chapters A and B are deleted.	*第 153 條* **對(EC) 999/2001 號規章的修正** (EC)999/2001 號規章修正如下： (1) 刪除第 19 條和第 21 條; (2) 在附件 X 中，刪除 A 章和 B 章。
Article 154 **Amendments to Regulation (EC) No 1/2005 and related transitional measures** 1. Regulation (EC) No 1/2005 is amended as follows: (1) Article 2 is amended as follows: (a) point (d) is replaced by the following: '(d) "border inspection post" means a border control post as defined in Article 3(38) of Regulation (EU) 2017/625 of the European Parliament and of the Council(*).; (*) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other	*第 154 條* **對(EC) 1/2005 號規章的修正和相關過渡措施** 1. (EC)第 1/2005 號規章修正如下： (1) 第 2 條修正如下： (a)第(d)點由以下內容取代： 「(d)『邊境檢查站』是指歐洲議會及歐盟理事會之規章(EU) 2017/625 規章第 3(38)條所定義的邊境管制站(*); (*) (EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福

official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207, p.1).';

社、植物健康和植物保護產品規範的適用而執行的官方管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU) 2016/2031 規章、歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章)(OJ L 95,7.4.207, p.1).」;

(b) point (f) is replaced the following:

'(f) "competent authority" means competent authorities as defined in Article 3(3) of Regulation (EU) 2017/625';

(b)將(f)點由以下內容取代：

「(f)『權責機關』意指(EU)2017/625 規章第 3(3)條所定義的權責機關」;

(c) point (i) is replaced by the following:

'(i) "exit point" means an exit point as defined in Article 3(39) of Regulation (EU) 2017/625';

(c)第(i)點由以下內容取代：

「(i)『出境點』指(EU)2017/625 規章第 3(39)條定義的出境點」;

(d) point (p) is replaced by the following:

'(p) "official veterinarian" means an official veterinarian as defined in Article 3(32) of Regulation (EU) 2017/625'.

(d)第(p)點由以下內容取代：

「(p)『官方獸醫』指(EU) 2017/625 規章第 3(32)條所定義的官方獸醫」。

(2) Articles 14, 15, 16 and 21, Article 22(2), and Articles 23, 24 and 26 are deleted.

(2) 刪除第 14、15、16 和 21 條、第 22(2)條和第 23、24 和 26 條。

(3) Article 27 is amended as follows:

(3) 第 27 條修正如下：

(a) paragraph 1 is deleted;

(a)刪除第 1 項;

(b) paragraph 2 is replaced by the following:

(b)第 2 項由以下內容取代：

'2. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried by the competent authority to verify compliance with the requirements of this Regulation. The report shall be accompanied by an analysis of the major deficiencies detected and an action plan to address them.';

「2. 會員國應在每年 8 月 31 日之前向歐盟執委會提交上一年度的年度報告，該報告係關於權責機關為查核是否符合本指令的要求所執行的檢查。該報告應附有一份對所發現主要缺失的分析，以及一份解決這些缺失的行動計畫。」

(4) Article 28 is deleted.

(4) 刪除第 28 條。

2. Articles 14, 15, 16 and 21, Article 22(2), and Articles 23, 24 and 26 of Regulation (EC) No 1/2005 shall continue to apply, instead of the corresponding provisions of this Regulation, until 14 December

2. (EC)1/2005 號規章第 14、15、16 和 21 條、第 22(2)條和第 23、24 和 26 條應繼續適用，直至 2022 年 12 月 14 日或在根據本條第 3 項所採用

2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 3 of this Article. 3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the date referred to in paragraph 2 of this Article. That date shall be the date of application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Article 21.	的授權法規中所決定的更早日期為止，在此期間將不適用本規章相對應之條文。 3. 歐盟執委會有權根據第 144 條採用授權法規以修訂本規章中關於本條第 2 項所提及之日期。該日期應為根據在第 21 條所述的授權法規或施行細則所制定的相應規範之適用日期。
Article 155 **Amendments to Regulation (EC) No 396/2005 and related transitional measures** 1. Articles 26 and 27, Article 28(1) and (2) and Article 30 of Regulation (EC) No 396/2005 are deleted. 2. Article 26, Article 27(1) and Article 30 of Regulation (EC) No 396/2005 shall continue to apply instead of the corresponding provisions of this Regulation until 14 December 2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 3 of this Article. 3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the date referred to in paragraph 2 of this Article. That date shall be the date of application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Article 19.	*第 155 條* **對(EC)396/2005 號規章的修正和相關過渡措施** 1. 刪除(EC)396/2005 號規章第 26 和 27 條、第 28(1)和(2)條以及第 30 條。 2. (EC)396/2005 號規章第 26 條、第 27(1)條和第 30 條應繼續適用，直至 2022 年 12 月 14 日或根據本條第 3 項所採用的授權法規中所決定的更早日期為止，在此前間將不適用本規章之相對應的條文。 3. 歐盟執委會有權根據第 144 條採用授權法規以修訂本規章中關於本條第 2 項所提及之日期。該日期應為根據在第 19 條所述的授權法規或施行細則所制定的相應規範之適用日期。
Article 156 **Amendments to Directive 2007/43/EC** Directive 2007/43/EC is amended as follows: (1) In Article 2(1), points (c) and (d) are replaced by the following: '(c) "competent authorities" means competent authorities as defined in Article 3(3) of Regulation (EU) 2017/625 of the European Parliament and of the Council(*); (d) "officia veterinarian" means an official veterinarian as defined in Article 3(32) of Regulation (EU) 2017/625;	*第 156 條* **對 2007/43/EC 指令的修正** 指令 2007/43/EC 修正如下： (1) 在第 2(1) 條中，(c)和(d)點由以下內容取代： 「(c)『權責機關』指歐洲議會及歐盟理事會(EU) 2017/625 規章第 3(3)條定義的權責機關(*)； (d)『官方獸醫』指歐洲議會及歐盟理事會(EU) 2017/625 規章第 3(32)條定義的官方獸醫；
(*) 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	(*) (EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福祉、植物健康和植物保護產品規範的適用而執行的官方

and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207, p.1).';

(2) Article 7 is amended as follows:

(a) paragraph 1 is deleted;

(b) paragraph 2 is replaced by the following:

'2. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non–compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.'.

管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU) 2016/2031 規章、歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章)(OJ L 95,7.4.207, p.1).」；

(2) 第 7 條修正如下：

(a)刪除第 1 項;

(b)第 2 項由以下內容取代：

「2. 會員國應在每年 8 月 31 日之前向歐盟執委會提交上一年度的年度報告，該報告係關於權責機關為查核是否符合本指令的要求所執行的檢查。該報告應附有一份對所發現之最嚴重的不符合規定之情事的分析，以及一份防止或減少其於未來年度再發生該等情事的國家行動計畫。歐盟執委會應向會員國該等這些報告的摘要。」。

Article 157

Amendments to Directive 2008/119/EC

Directive 2008/119/EC is amended as follows:

(1) In Article 2, point (2) is replaced by the following:

'2. "competent authorities" means competent authorities as defined in Article 3(3) of Regulation (EU) 2017/625 of the European Parliament and of the Council(*).

第 157 條

對指令 2008/119/EC 的修正

指令 2008/119/EC 修訂如下：

(1) 在第 2 條中，第(2)點由以下內容取代：

「2.『權責機關』是指歐洲議會及歐盟理事會(EU) 2017/625 規章第 3(3)條定義的權責機關(*)。

(*) 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,

(*) (EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福祉、植物健康和植物保護產品規範的適用而執行的官方管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU) 2016/2031 規章、

2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207, p.1).';	歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章)(OJ L 95,7.4.207, p.1).」；
(2) Article 7 is amended as follows: (a) paragraphs 1 and 2 are deleted; (b) paragraph 3 is replaced by the following: '3. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non–compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.'; (3) Article 9 is deleted.	(2) 第 7 條修正如下： (a)刪除第 1 和第 2 項； (b)第 3 項由以下內容取代： 「3. 會員國應在每年 8 月 31 日之前向歐盟執委會提交上一年度的年度報告，該報告係關於權責機關為查核是否符合本指令的要求所執行的檢查。該報告應附有一份對所發現之最嚴重的不符合規定之情事的分析，以及一份防止或減少其於未來年度再發生該等情事的國家行動計畫。歐盟執委會應向會員國該等這些報告的摘要。」； (3) 刪除第 9 條。
Article 158 **Amendments to Directive 2008/120/EC** Directive 2008/120/EC is amended as follows: (1) In Article 2, point (10) is replaced by the following: '10. "competent authorities" means competent authorities as defined in Article 3(3) of Regulation (EU) 2017/625 of the European Parliament and of the Council(*). (*) 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	*第 158 條* **對指令 2008/120/EC 的修正** 指令 2008/120/EC 修改如下： (1) 在第 2 條中，第(10)點由以下內容取代： 「10.『權責機關』是指歐洲議會及歐盟理事會(EU) 2017/625 規章第 3(3)條所定義的權責機關(*)。 (*) (EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福祉、植物健康和植物保護產品規範的適用而執行的官方管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU) 2016/2031 規章、歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、

European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207, p.1).'; (2) Article 8 is amended as follows: (a) paragraphs 1 and 2 are deleted; (b) paragraph 3 is replaced by the following: '3. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non–compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.'; (3) Article 10 is deleted.	2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章)(OJ L 95,7.4.207, p.1).」； (2) 第 8 條修正如下： (a)刪除第 1 和第 2 項； (b)第 3 項由以下內容取代： 「3. 會員國應在每年 8 月 31 日之前向歐盟執委會提交上一年度的年度報告，該報告係關於權責機關為查核是否符合本指令的要求所執行的檢查。該報告應附有一份對所發現之最嚴重的不符合規定之情事的分析，以及一份防止或減少其於未來年度再發生該等情事的國家行動計畫。歐盟執委會應向會員國該等這些報告的摘要。」； (3) 刪除第 10 條。
Article 159 **Amendments to Regulation (EC) No 1099/2009** Regulation (EC) No 1099/2009 is amended as follows: (1) In Article 2, point (q) is replaced by the following: '(q) "competent authorities" means competent authorities as defined in point (3) of Article 3 of Regulation (EU) 2017/625 of the European Parliament and of the Council(*). (*) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207,	*第 159 條* **對(EC)1099/2009 號規章的修正** (EC)1099/2009 號規章修正如下： (1) 在第 2 條中，(q)點由以下內容取代： 「(q)『權責機關』是指歐洲議會及歐盟理事會(EU) 2017/625 規章*第 3(3)條所定義的權責機關(*)。 (*) (EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福祉、植物健康和植物保護產品規範的適用而執行的官方管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU) 2016/2031 規章、歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、

p.1).'; (2) Article 22 is deleted.	91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章)(OJ L 95,7.4.207, p.1).」; (2) 刪除第 22 條。
Article 160 **Amendments to Regulation (EC) No 1069/2009** Regulation (EC) No 1069/2009 is amended as follows: (1) Article 3 is amended as follows: (a) point (10) is replaced by the following: '10. "competent authority" means competent authorities as defined in point (3) of Article 3 of Regulation (EU) 2017/625 of the European Parliament and of the Council(*). (*) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207, p.1).'; (b) point (15) is replaced by the following: '15. "transit" means transit as defined in Article 3(44) of Regulation (EU) 2017/625.'; (2) Articles 45, 49 and 50 are deleted.	*第 160 條* **對(EC)1069/2009 號規章修正** (EC)1069/2009 號規章修正如下： (1) 第 3 條修正如下： (a)第(10)點由以下內容取代： 「10.『權責機關』是指歐洲議會及歐盟理事會(EU) 2017/625 規章第 3(3)條定義的權責機關(*)。 (*)(EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福祉、植物健康和植物保護產品規範的適用而執行的官方管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU) 2016/2031 規章、歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章)(OJ L 95,7.4.207, p.1).」; (b)第(15)點由以下內容取代： 「15.『過境』指(EU) 2017/625 規章第 3(44)條中所定義的過境。」 (2) 刪除第 45、49 和 50 條。
Article 161 **Amendments to Regulation (EC) No 1107/2009** Regulation (EC) No 1107/2009 is amended as follows: (1) Article 68 is amended as follows: (a) the first paragraph is replaced by the following:	*第 161 條* **對(EC) 1107/2009 號規章的修正案** (EC) 1107/2009 號規章修正如下： (1) 第 68 條修正如下： (a)第 1 項由以下內容取代： 「會員國應在每年 8 月 31 日之前向歐盟執

'Member States shall submit to the Commission by 31 August each year a report, for the previous year, on the scope and the outcome of the official controls performed in order to verify compliance with this Regulation'; (b) the second and third paragraphs are deleted. (2) point (n) of Article 78(1) is deleted.	委會提交上一年度關於用以查驗是否符合本規章官方管制的範圍和結果的報告」； (b) 刪除第 2 和第 3 項。 (2) 刪除第 78(1)條的第(n)點。
Article 162 **Amendments to Regulation (EU) No 1151/2012** Regulation (EU) No 1151/2012 is amended as follows: (1) Article 36 is amended as follows: (a) the heading is replaced by the following: 'Content of official controls'; (b) paragraphs 1 and 2 are deleted; (c) in paragraph 3, the introductory phrase is replaced by the following: '3. Official controls performed in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council(*) shall cover: (*) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207, p.1).'; (2) Article 37 is amended as follows: (a) in paragraph 1, the first subparagraph is replaced by the following: '1. In respect of protected designations of origin, protected geographical indications and traditional specialities guaranteed that designate products originating within the Union, verification of compliance with the product specification, before placing the product on the market, shall be	*第 162 條* **對(EU) 1151/2012 號規章修正** (EU) 1151/2012 號規章修訂如下： (1) 第 36 條修正如下： (a)標題由以下內容取代：「官方管制的內容」； (b)刪除第 1 和第 2 項； (c)在第 3 項中，引言由以下內容取代： 「3. 根據歐洲議會及歐盟理事會(EU) 2017/625 規章所執行的官方管制*應包括： (*) (EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福祉、植物健康和植物保護產品規範的適用而執行的官方管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU) 2016/2031 規章、歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章)(OJ L 95, 7.4.207, p.1).」； (2) 第 37 條修正如下： (a) 在第 1 項中，第 1 款由下列內容取代： 「1. 對於源自歐盟境內之受保護的原產地名稱、受保護的地理標示和受保護的傳統特產，在將產品投放於市面銷售之前對產品規格的符合性之查驗，應

carried out by: (a) the competent authorities designated in accordance with Article 4 of Regulation (EU) 2017/625; or (b) delegated bodies as defined in Article 3(5) of Regulation (EU) 2017/625.'; (b) in paragraph 3, the first subparagraph is deleted; (c) in paragraph 4, the words 'paragraphs 1 and 2' are replaced by the words: 'paragraph 2'; (3) Article 38 is deleted; (4) Article 39 is replaced by the following: 'Article 39 **Delegated bodies performing controls in third countries** The delegated bodies performing controls in the third countries referred to in paragraph 2(b) of Article 37 shall be accredited to the relevant harmonised standard for "Conformity assessment-Requirements for bodies certifying products, processes and services". These delegated bodies may be accredited either by a national accreditation body outside the Union, in accordance with Regulation (EC) No 765/2008, or by an accreditation body outside the Union that is a signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum.'.	由以下單位執行： (a)根據(EU) 2017/625 規章第 4 條所指定的權責機關;或是 (b) (EU) 2017/625 規章第 3(5)條所定義的受託機構。 (b) 在第 3 項中刪除第 1 款; (c) (c)在第 4 項中，「第 1 及 2 節」一詞改為「第 2 項」; (3) 刪除第 38 條; (4) 第 39 條由以下內容取代： 「第 39 條 **第三國執行管制之受託機構** 執行在第 37 條第 2(b)節所提及的第三國之管制的受託機構應取得依「符合性評鑑 – 對驗證產品、流程和服務之機構的要求」的相關調和標準所作的認證資格。該等受託機構可以由歐盟以外的國家認證機構根據(EC)765/2008 號規章進行認證;也可以由歐盟以外之在國際認證論壇主持下的多邊相互承認協議之簽約國的認證機構加以認證。」。
Article 163 **Amendments to Regulation (EU) No 652/2014** Regulation (EU) No 652/2014 is amended as follows: (1) Article 30(1) is replaced by the following: '1. To cover the costs they incur to implement the work programmes approved by the Commission, grants may be awarded to: (a) the European Union reference laboratories referred to in Article 93 of Regulation (EU) 2017/625 of the European Parliament and of the Council(*) and to the European Union reference centres referred to in Article 29 of Regulation (EU) 2016/1012 of the European Parliament and of the Council(**); (b) the European Union reference centres for animal welfare referred to in Article 95 of Regulation	*第 163 條* **對(EU) 652/2014 號規章的修正** (EU) 652/2014 號規章修訂如下： (1) 第 30(1)條由以下內容取代： 「1. 為支付以下對象他們為執行歐盟執委會核准的工作計劃而產生的費用，可以給予下列對象補助： (a) 歐洲議會及歐盟理事會(EU) 2017/625 規章第 93 條中所提及之歐盟參考實驗室(*)以及歐洲議會及歐盟理事會(EU) 2016/1012 規章(**)第 29 條中所提及之歐盟參考中心； (b) (EU) 2017/625 規章第 95 條所提及之歐盟

(EU) 2017/625;

(c) the European Union reference centres for the authenticity and integrity of the agri-food chain referred to in Article 97 of Regulation (EU) 2017/625.

(*) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207, p.1).;

(**) Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding ("Animal Breeding Regulation") (OJ L 171, 29.6.2016, p.66).';

(2) the following Article is inserted:

'Article 30a

Accreditation of national reference laboratories for plant health

1. Grants may be awarded to the national reference laboratories referred to in Article 100 of Regulation (EU) 2017/625 for costs incurred for obtaining accreditation according to the standard EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories" for the use of methods of laboratory analysis, test and diagnosis to verify compliance with the rules on protective measures against pests of plants.

2. Grants may be awarded to a single national reference laboratory in each Member State for each

動物福祉參考中心；

(c) (EU) 2017/625 規章第 97 條所提及之以調查農業食品供應鏈的真實性和完整性為任務的歐盟參考中心。

(*) (EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福祉、植物健康和植物保護產品規範的適用而執行的官方管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU) 2016/2031 規章、歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章) (OJ L 95, 7.4.207, p.1).」；

(**) 歐洲議會及歐盟理事會於 2016 年 6 月 8 日制定(EU)2016/1012 號規章係關於純種繁殖動物、雜交育種豬和因此而來的胚種產品之育種、貿易和進入歐盟的畜牧學和家系條件，(EU)652/2014 號規章、歐盟理事會第 89/608/EEC 和 90/425/EEC 號指令，並廢止動物育種領域的特定法規(『動物育種規章』) (OJ L 171, 29.6.2016, p.66)。」；

(2) 加入以下條文：

「第 30a 條

植物健康之國家參考實驗室的認證

1. ，可授予(EU)2017/625 規章第 100 條所提及的國家參考實驗室根據 EN ISO/IEC 17025『測試和校驗實驗室能力的一般要求』就為查驗是否符合關於植物害蟲防護措施的規範之實驗室分析、測試和診斷方法的使用所獲得之認證其衍生的費用之補助。

2. 在每個受指定為歐盟植物健康參考實驗之指定日期後的三年內，可對每個會員國內(為該歐盟參考實驗室服務)之單一國家參

European Union reference laboratory for plant health, up to three years after the designation of that European Union reference laboratory.'.	考實驗室授予補助。」。
Article 164 **Amendments to Regulation (EU) 2016/429 and related transitional provisions** 1. Regulation (EU) 2016/429 is amended as follows: (1) Article 4 is amended as follows: (a) point (33) is replaced by the following: '(33) "official control" means any form of control performed in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council(*); (*) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207, p.1).'; (b) point (51) is replaced by the following: '(51) "Traces" means a system component integrated into the IMSOC as referred to in Articles 131 to 136 of Regulation (EU) 2017/625;'; (c) point (53) is replaced by the following: '(53) "official veterinarian" means an official veterinarian as defined in Article 3(32) of Regulation (EU) 2017/625;'; (d) point (55) is replaced by the following: '(55) "competent authority" means the central veterinary authority of a Member State responsible for the organisation of official controls and any other official activities in accordance with this Regulation and Regulation (EU) 2017/625, or any other authority to which that responsibility	*第 164 條* **對(EU)2016/429 規章的修正和相關過渡條文** 1. (EC)2016/429 號規章修正如下： (1) 第 4 條修正如下： (a)第(33)點由以下內容取代： 「(33)『官方管制』是指根據歐洲議會及歐盟理事會(EU)2017/625 規章所執行的任何形式的管制(*)； (*) (EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福祉、植物健康和植物保護產品規範的適用而執行的官方管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU) 2016/2031 規章、歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章)(OJ L 95, 7.4.207, p.1).」； (b)第(51)點由以下內容取代： 「(51)『Traces』是指(EU)2017/625 規章第 131 至 136 條所提及的整合到 IMSOC 系統中的組成部分；」； (c)第(53)點由以下內容取代： 「(53)『官方獸醫』是指(EU)2017/625 規章第 3 條第(32)點所定義的官方獸醫；」； (d)第(55)點由以下內容取代： 「(55)『權責機關』是指根據本規章及(EU)2017/625 規章負責籌劃官方管制及任何其他官方活動的某會員國之中

has been delegated;';

(2) in Article 229, paragraph (2) is replaced by the following:

'2. The operators responsible for the consignment in question shall present consignments of animals, germinal products and products of animal origin from third countries or territories for the purposes of official control as provided for in Article 47 of Regulation (EU) 2017/625.';

(3) Article 281 is deleted.

2. The following provisions shall continue to apply in relation to the matters governed by Regulation (EU) 2016/429, until the date of application of that Regulation:

(a) Article 9 of Directive 89/662/EEC;

(b) Article 10 of Directive 90/425/EEC;

(c) Article 18(1), (3), (4), (5), (6), (7) and (8) of Directive 91/496/EEC;

(d) Article 22(1), (3), (4), (5), (6) and (7) of Directive 97/78/EC.

3. Having regard to Article 14 of Regulation (EU) 2016/429 and notwithstanding the date of application provided for in that Regulation, for the purpose of Article 31(2) of this Regulation, the condition for its application shall be considered to be fulfilled already from 14 December 2019.

央獸醫機關，或任何已被委派該責任的機關;」;

(2) 在第 229 條中，第(2)節由以下內容取代：

「2. 負責所涉貨物的運營商應規章第 47 條所述之官方管制的目的提交來自第三國或區域的動物、生物製品和動物源產品。」;

(3) 刪除第 281 條。

2. 以下規定應繼續適用於有關(EU)2016/429 規章所管理的事項，直至該規章所規定的適用日期為止：

(a)89/662/EEC 指令第 9 條;

(b)90/425/EEC 指令第 10 條;

(c)91/496/EEC 指令第 18(1)、(3)、(4)、(5)、(6)、(7)和(8)條;

(d)97/78/EC 指令第 22(1)、(3)、(4)、(5)、(6)和(7)條。

3. 考慮到 (EU)第 2016/429 號規章第 14 條，儘管該規則已明定了適用日期，但為了本規章第 31(2)條所提及之目的，其適用條件應視為將於 2019 年 12 月 14 日完成。

Article 165

Amendments to Regulation (EU) 2016/2031 and related transitional provisions

1. Regulation (EU) 2016/2031 is amended as follows:

(1) Article 2, point (6) is replaced by the following:

'(6) "competent authority" means competent authorities as defined in Article 3(3) of Regulation (EU) 2017/625 of the European Parliament and of the Council(*);

第 165 條

對(EU)2016/2031 號規章的修正和相關的過渡條文

1. (EU)2016/2031 號規章修正如下：

(1) 第 2 條第(6)點由以下內容取代：

「(6)『權責機關』是指歐洲議會及歐盟理事會(EU)2017/625 規章第 3(3)條所定義的權責機關(*);

(*) 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

(*) (EU) 2017/625 規章係 2017 年 3 月 15 日歐洲議會及歐盟理事會關於為確保落實食品和飼料法及動物健康和福祉、植物健康和植物保護產品規範的適用而執行的官方管制和其他官方活動，故修訂歐洲議會和歐盟理事會(EC) 999/2001 號、(EC) 396/2005 號、(EC) 1069/2009 號、(EC) 1107/2009 號、(EU) 1151/2012 號、(EU) 652/2014 號、(EU) 2016/429 及(EU)

98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95,7.4.207, p.1).';

2016/2031 規章、歐盟理事會(EC) 1/2005 號及(EC) 1099/2009 號規章以及歐盟理事會 98/58/EC、1999/74/EC、2007/43/EC、2008/119/EC 和 2008/120/EC 指令，並廢止歐洲議會和歐盟理事會(EC) 854/2004 號及(EC) 882/2004 號規章、歐盟理事會 89/608/EEC、89/662/EEC、90/425/EEC、91/496/EEC、96/23/EC、96/93/EC 及 97/78/EC 指令，以及歐盟理事會 92/438/EEC 決議(官方管制規章)(OJ L 95,7.4.207, p.1).」；

(2) Article 10 is replaced by the following:

(2) 第 10 條由以下內容取代：

'Article 10

「第 10 條

Official confirmation by the competent authorities of the presence of a Union quarantine pest

權責機關對歐盟的檢疫性害蟲之存在性的官方確認

Where a competent authority suspects, or has received evidence concerning, the presence of a Union quarantine pest, or a pest subject to measures adopted pursuant to Article 30(1), in a part of the territory of the respective Member State where that pest was previously not known to be present, or in a consignment of plants, plant products or other objects introduced into, intended to be introduced into, or moved within the Union territory, it shall immediately take any measures necessary to confirm on the basis of a diagnosis of an official laboratory as referred to in Article 37 of Regulation (EU) 2017/625 ("to officially confirm"), whether that pest is present or not.

如果權責機關懷疑，或已收到關於有某一檢疫性害蟲或某一受到依第 30(1)條所採取措施管制的害蟲，存在於以前不知道存在該害蟲的個別會員國境內的一部分，或在某一引進、擬引進或於歐盟境內遺韻之植物、植物產品或其他物品的託運物中之證據時，該權責機關應立即採取任何必要措施以便在(EU)2017/625 規章第 37 條所提及之官方實驗室(『正式確認』)診斷的基礎上確認是否存在該害蟲。

Pending the official confirmation of the presence of that pest, the Member States concerned shall, where applicable, take phytosanitary measures to eliminate the risk of spread of that pest.

在正式確認有該害蟲存在之前，所涉會員國應適當地採取植物檢疫措施，以消除該害蟲傳播的風險。

The suspicion or evidence referred to in the first paragraph of this Article may be based on any information received pursuant to Articles 14 and 15, or from any other source.';

本條第 1 項中所提及之懷疑或證據，可以基於根據第 14 條和第 15 條或從任何其他來源所收到的任何資訊而為之。」；

(3) in Article 11, the second paragraph is replaced by the following:

(3) 第 11 條中第 2 項由以下內容取代：

'Notifications under the first paragraph shall be made by the single authority, as referred to in Article 4(2) of Regulation (EU) 2017/625, of the Member State concerned and through the electronic notification system referred to in Article 103.';

「基於第 1 項所為的通知應由所涉會員國於(EU)2017/625 規章第 4(2)條所提及之單一機構透過第 103 條所提及的電子通知系統進行。」；

(4) in Article 25(2), point (a) is replaced by the following:

(4) 第 25(2)條(a)點由以下內容取代：

'(a) the roles and responsibilities of the bodies involved in the execution of the plan, in case of a

「(a)參與計畫之執行的機構在確認或懷疑所涉之須優先處理的害蟲存在的情況下的角色

confirmed or suspected presence of the priority pest concerned, as well as the chain of command and procedures for the co-ordination of actions to be taken by competent authorities, other public authorities, as referred to in Article 4(2) of Regulation (EU) 2017/625, delegated bodies or natural persons involved, as referred to in Article 28(1) of that Regulation, laboratories and professional operators, including the co-ordination with neighbouring Member States and neighbouring third countries, where appropriate;

(5) in Article 41, paragraph 4 is replaced by the following:

'4. In the event that plants, plant products or other objects have been introduced into, or moved within, the Union territory in violation of paragraph 1 of this Article, Member States shall adopt the necessary measures, as referred to in Article 66(3) of Regulation (EU) 2017/625, and shall notify the Commission and other Member States through the electronic notification system referred to in Article 103.

Where applicable, that notification shall also be made to the third country from which the plants, plant products or other objects were introduced into the Union territory.';

(6) in Article 44, paragraph 2 is replaced by the following:

'2.Where appropriate, the Commission shall carry out investigations in the third country concerned and in accordance with Article 120 of Regulation (EU) 2017/625, to verify whether the conditions referred to in points (a) and (b) of the first subparagraph of paragraph 1 of this Article are fulfilled.';

(7) in Article 49(6), the third subparagraph is replaced by the following:

'MemberStates shall notify, through the electronic notification system referred to in Article 103 of this Regulation, the Commission and the other Member States of any case where the introduction of a plant, plant product or other object into the Union territory was refused, or its movement within the Union territory prohibited, because the Member State concerned considered that the prohibition referred to in point (c) of the second subparagraph of paragraph 2 of this Article was violated. Where applicable, that notification shall include the measures taken by that Member State on the plants, plant products or other objects concerned pursuant to Article 66(3) of Regulation (EU) 2017/625.';

(8) in Article 76, paragraphs 4 and 5 are replaced by the following:

和責任，以及由(EU)2017/625 規章第 4(2)條所提及之權責機關、其他公家機關，與該規章第 28(1)條所提及之受委託機構或自然人，以及實驗室和專業運營商所採取的行動之協調，其中，在適當時，包括與鄰近會員國和鄰近第三國的協調之指揮和程序鏈;」；

(5) 在第 41 條中，第 4 項由以下內容取代：

「4. 如果植物、植物產品或其他物體被引入或於歐盟境內移運而違反本條第 1 項的規定時，則會員國應採取(EU)2017/625 規章第 66(3)條所提及之必要措施。並應透過第 103 條所提及的電子通知系統通知歐盟執委會和其他會員國。

在適用時，亦應通知上述被引入歐盟境內的植物，植物產品或其他物體之來源地的第三國。」

(6) 在第 44 條中，第 2 項由以下內容取代：

「2. 在適當時，歐盟執委會應根據(EU)2017/625 規章第 120 條在所涉第三國執行調查，以查驗本條第 1 項第 1 款之(a)和(b)點中所提及之條件。是否已經被滿足。」;

(7) 在第 49(6)條中，第 3 項由以下內容取代：

「會員國應透過本規章第 103 條所提及的電子通知系統，向歐盟執委會和其他會員國通報任何植物、植物產品或其他物體被拒絕引入歐盟，或由於所涉會員國認為違反了本條第 2 項第 2 款第(c)點所提及的禁令，因此禁止其在歐盟境內的移運之情事。在可行時，該通知應包括該會員國根據(EU)2017/625 規章第 66(3)條對植物、植物產品或其他有關物體所採取的措施。」

(8) 第 76 條第 4 和第 5 項由以下內容取代：

‘4. In the case of a third country which is not a contracting party to the IPPC, the competent authority shall only accept the phytosanitary certificates issued by the authorities which are competent in accordance with the national rules of that third country and notified to the Commission.

The Commission shall inform the Member States and the operators, through the electronic notification system referred to in Article 103, in accordance with point (a) of Article 132 of Regulation (EU) 2017/625, of the notifications received.

The Commission is empowered to adopt delegated acts, in accordance with Article 105, to supplement this Regulation concerning the conditions for acceptance referred to in the first subparagraph of this paragraph, to ensure the reliability of those certificates.

5. Electronic phytosanitary certificates shall only be accepted when provided through, or in electronic exchange with, the IMSOC referred to in Article 131(1) of Regulation (EU) 2017/625.’;

「4. 如果第三國不是國際植物保護公約(International Plant Protection Convention, IPPC)的締約國，權責機關應只接受由該第三國按該國法規定有主管權限並被通知到歐盟執委會的機關所頒發的植物檢疫證書。

歐盟執委會應將所收到的通知，按照(EU)2017/625 規章第 132 條第(a)點的規定，透過第 103 條所提及之電子通知系統通知各會員國和運營商。

歐盟執委會有權根據第 105 條採用授權法規，以補充本規章關於本項第 1 款所提及的接受之條件，以確保該等證書的可靠性。

5. 電子植物檢疫證書只應在透過(EU)2017/625 規章第 131(1)條提及的官方管制之資訊管理系統(IMSOC)提供以該系統作或電子交換的方式才能被接受。」

(9) in Article 77(1), the first subparagraph is replaced by the following:

‘1.Where a phytosanitary certificate has been issued in accordance with Article 71(1), (2) and (3), and the competent authority concerned concludes that the conditions referred to in Article 76 are not fulfilled, it shall invalidate that phytosanitary certificate and ensure that it does not accompany any longer those plants, plant products or other objects concerned. In that case, and in respect of the plants, plant products or other objects concerned, the competent authority shall take one of the measures set out in Article 66(3) of Regulation (EU) 2017/625.’;

(9) 在第 77(1)條中，第 1 款由以下內容取代：

「1. 如果根據第 71(1)、(2)和(3)條頒發了植物檢疫證書後，然而所涉權責機關認為第 76 條所提及之條件未得到滿足時，則該權責機關應使該植物檢疫證書無效並確保它不再附隨於該等所涉的植物、植物產品或其他物體。在該種情況下，且有關於所涉的植物、植物產品或其他物體時，權責機關應採取(EU)2017/625 規章第 66(3)條所訂的措施之一。」；

(10) in Article 91(1), the second subparagraph is replaced by the following:

‘Authorised operators implementing an approved pest risk management plan may be subject to inspections with a reduced frequency, as referred to in point (b) of Article 22(3) of Regulation (EU) 2017/625.’;

(10) 在第 91(1)條中，第 2 款由以下內容取代：

「執行已核准的害蟲風險管理計畫的被授權運營商可能需要接受如(EU)2017/625 規章第 22(3)條中的(b)點所提及的降低頻率的檢查。」；

(11) in Article 94(1), the first subparagraph is replaced by the following:

‘1. By way of derogation from Article 87 of this Regulation, where a plant, plant product or other object, introduced into the Union territory from a third country which, for movement within the

(11) 在第 94(1)條中，第 1 款由以下內容取代：

「1. 作為本規章第 87 條的例外情形，當從第三國引入歐盟境內並欲在歐盟境內移運的植物、植物產品或其他物體，需要有依據本

Union territory, requires a plant passport pursuant to Article 79(1) and 80(1) of this Regulation, the passport shall be issued if the checks under Article 49(1) of Regulation (EU) 2017/625. concerning its introduction have been completed satisfactorily and have led to the conclusion that the plant, plant product or other object concerned fulfils the substantive requirements for issuance of a plant passport in accordance with to Article 85 of this Regulation and, where appropriate, Article 86 of this Regulation.’;	規章第 79(1)條和第 80(1)條所要求的植物護照時，若根據(EU)2017/625 規章第 49(1)條關於其引入所執行的檢查後，已經令人滿意地完成並且得出該所涉植物、植物產品或其他物體符合依據本規章第 85 條之核發植物護照的實質性要求，並且適當時，符合本規章第 86 條的規定之結論時，則該護照應予核發。」；
(12) in Article 100, paragraph 5 is replaced by the following:	(12) 第 100 條第 5 項由以下內容取代：
‘5. Electronic phytosanitary certificates for export shall be provided through, or in electronic exchange with, the IMSOC.’;	「5. 為出口之用的電子植物檢疫證書應透過 IMSOC 系統提供或以該系統作電子交換的方式為之。」；
(13) in Article 101, paragraph 6 is replaced by the following:	(13) 在第 101 條中，第 6 項由以下內容取代：
‘6. Electronic phytosanitary certificates for re-export shall be provided through, or in electronic exchange with, the IMSOC.’;	「6. 再輸出之情形的電子植物檢疫證書應透過 IMSOC 系統提供或以該系統作電子交換的方式為之。」；
(14) in Article 102, paragraph 4 is replaced by the following:	(14) 第 102 條第 4 項由以下內容取代：
‘4. The pre-export certificate shall accompany the plants, plant products and other objects concerned during their movement within the Union territory, unless the information contained in it is exchanged between the Member States concerned through, or in electronic exchange with, the IMSOC.’;	「4. 當所涉的植物、植物產品和其他物體，在歐盟境內移運之期間內，其出口前證書應予隨附之，除非其中所含資訊已透過 IMSOC 系統與所涉會員國之間進行交換，或以該系統作電子交換的方式為之。」；
(15) Article 103 is replaced by the following:	(15) 第 103 條由以下內容取代：
‘Article 103 **Establishment of electronic notification system** The Commission shall establish an electronic system for the submission of notifications by the Member States. That system shall be connected to, and compatible with, the IMSOC.’;	「第 103 條 **電子通知系統之建立** 歐盟執委會應建立一個由會員國提交通知之用的電子系統。 該系統應與 IMSOC 系統連接並與之相容。」；
(16) in Article 109, paragraph 1 is replaced by the following:	(16) 在第 109 條中，第 1 項由以下內容取代：
‘Directive 2000/29/EC is repealed, without prejudice to Article 165(2), (3) and (4) of Regulation (EU) 2017/625.’.	「指令 2000/29/EC 被廢止，但不影響(EU)2017/625 規章第 165(2)、(3)和(4)條。」。
2. ►**M2** In relation to matters governed by Directive 2000/29/EC, Article 47(2), Article 48, points (b), (c)	2. 本規章第 47(2)條、第 48 條、第 51(1)條第(b)、

and (d) of Article 51(1), and point (a) of Article 58 of this Regulation shall apply from 15 December 2019 instead of the relevant provisions of that Directive, which shall cease to be applicable as of the same date. The relevant provisions of Directive 2000/29/EC shall continue to apply in relation to the matters governed by points (a) of Article 53(1) of this Regulation instead of that latter provision until 13 December 2020. The relevant provisions of Directive 2000/29/EC shall continue to apply in relation to the matters governed by Article 54(1) and (3) of this Regulation instead of these latter provisions until 13 December 2022. ◄M2 3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the date referred to in paragraph 2 of this Article. 4. Without prejudice to paragraphs 2 and 3 of this Article and the date of application provided for in Article 167(1), the Commission shall adopt the delegated acts referred to in points (a) and (e) of Article 53(1), as regards goods referred to in point (c) of Article 47(1), at the latest 12 months before their date of application.	(c)和(d)點，以及第 58 條第(a)點管理事項應自 2019 年 12 月 15 日起適用並取代於 2000/29/EC 指令中涉及之相關條文且自同日停止適用。 2000/29/EC 指令涉及本規章第 53(1)條第(a)點管理事項應繼續適用直至 2020 年 12 月 13 日才被本規章取代。 2000/29/EC 指令涉及本規章第 54(1)及(3)條管理事項應繼續適用直至 2022 年 12 月 13 日才被本規章取代。 3. 歐盟執委會有權根據第 144 條採用授權法規以修訂本規章關於本條第 2 項所提及之日期。 4. 在不影響本條第 2 和第 3 項以及第 167(1)條所述的適用日期的情況下，歐盟執委會應至遲於其適用日期前的 12 個月，就第 47(1)條第(c)點所提及之貨物採用第 53(1)條第(a)和(e)點所提及之授權法規。
Article 166 **Transitional measures for the adoption of delegated and implementing acts** Without prejudice to the dates of application referred to in Article 167 and transitional provisions provided for in this Chapter, the Commission is empowered to adopt delegated and implementing acts provided for in this Regulation as from 28 April 2017. Such acts shall apply from the date of application in accordance with Article 167, without prejudice to any transitional rules provided for in this Chapter.	*第 166 條* **採用授權法規和施行細則的過渡措施** 在不影響第 167 條所提及適用日期和本章所述的過渡性條文的情況下，歐盟執委會有權自 2017 年 4 月 28 日起採用本規章所述的授權法規與施行細則。上開授權法規與施行細則自根據第 167 條所提及適用之日起施行，但不影響本章所述的任何過渡性規範。
Article 167 **Entry into force and application** 1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. Unless otherwise provided for in paragraphs 2 to 4, it shall apply from 14 December 2019. 2. In the area governed by the rules referred to in point (g) of Article 1(2), Article 34(1), (2) and (3), point	*第 167 條* **生效和施行** 1. 本規章應於其在歐盟官方公報上公佈後的第二十天生效。 除非第 2 至 4 節另有規定，否則應自 2019 年 12 月 14 日起施行。 2. 在第 1(2)條第(g)點、第 34(1)、(2)和(3)條、

(e) of Article 37(4) and Article 37(5) shall apply from 29 April 2022. 3. Articles 92 to 101 of this Regulation shall apply from 29 April 2018, instead of Articles 32 and 33 of Regulation (EC) No 882/2004, which is repealed by this Regulation. 4. Article 163 shall apply from 28 April 2017.	第 37(4)條第(e)點和第 37(5)條所提及之規範所規理的領域內，自 2022 年 4 月 29 日起施行。 3. 本規章第 92 至 101 條自 2018 年 4 月 29 日起施行，已取代本規章所廢止的(EC)882/2004 號規章第 32 和 33 條。 4. 第 163 條自 2017 年 4 月 28 日起施行。
This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Strasbourg, 15 March 2017. *For the Council* *The President* I. BORG *For the European Parliament* *The President* A. TAJANI	本規章應全部具有約束力，並直接適用於所有會員國。 2017 年 3 月 15 日於史特拉斯堡。 *致歐盟理事會* *主席* I. BORG *致歐洲議會* *主席* A. TAJANI

ANNEX I **TERRITORIES REFERRED TO IN POINT 40 OF ARTICLE 3, EXCEPT FOR THE APPLICATION OF POINT (G) OF ARTICLE 1(2)**	*附件 I* **第 3 條第 40 點所提及之領土，但為適用第 1(2)條(G)點者除外**
1. The territory of the Kingdom of Belgium	1. 比利時王國的領土
2. The territory of the Republic of Bulgaria	2. 保加利亞共和國的領土
3. The territory of the Czech Republic	3. 捷克共和國的領土
4. The territory of the Kingdom of Denmark with the exception of the Faroe Islands and Greenland	4. 丹麥王國的領土，但法羅群島和格陵蘭島除外
5. The territory of the Federal Republic of Germany	5. 德意志聯邦共和國的領土
6. The territory of the Republic of Estonia	6. 愛沙尼亞共和國的領土
7. The territory of Ireland	7. 愛爾蘭領土
8. The territory of the Hellenic Republic	8. 希臘共和國的領土
9. The territory of the Kingdom of Spain with the exception of Ceuta and Melilla	9. 西班牙王國的領土，但休達和梅利利亞除外
10. The territory of the French Republic	10. 法蘭西共和國的領土
11. The territory of the Republic of Croatia	11. 克羅地亞共和國領土
12. The territory of the Italian Republic	12. 意大利共和國的領土
13. The territory of the Republic of Cyprus	13. 塞浦路斯共和國領土 14. 拉脫維亞共和國領土 15. 立陶宛共和國領土 16. 盧森堡大公國的領土 17. 匈牙利領土 18. 馬耳他共和國的領土

14. The territory of the Republic of Latvia 15. The territory of the Republic of Lithuania 16. The territory of the Grand Duchy of Luxembourg 17. The territory of Hungary 18. The territory of the Republic of Malta 19. The territory of the Kingdom of the Netherlands in Europe 20. The territory of the Republic of Austria 21. The territory of the Republic of Poland 22. The territory of the Portuguese Republic 23. The territory of Romania 24. The territory of the Republic of Slovenia 25. The territory of the Slovak Republic 26. The territory of the Republic of Finland 27. The territory of the Kingdom of Sweden 28. The territory of the United Kingdom of Great Britain and Northern Ireland	19. 荷蘭王國在歐洲的領土 20. 奧地利共和國的領土 21. 波蘭共和國領土 22. 葡萄牙共和國的領土 23. 羅馬尼亞領土 24. 斯洛文尼亞共和國領土 25. 斯洛伐克共和國的領土 26. 芬蘭共和國的領土 27. 瑞典王國的領土 28. 大不列顛及北愛爾蘭聯合王國的領土
ANNEX II **TRAINING OF STAFF OF THE COMPETENT AUTHORITIES**	*附件 II* **對權責機關職員的培訓**
CHAPTER I ***Subject matter for the training of staff performing official controls and other official activities***	*第 I 章* ***執行官方管制和其他官方活動的職員的培訓事項***
1. Different control methods and techniques, such as inspection, verification, screening, targeted screening, sampling, and laboratory analysis, testing and diagnosis 2. Control procedures 3. The rules referred to in Article 1(2) 4. Assessment of non-compliance with the rules referred to in Article 1(2) 5. The hazards in the production, processing and distribution of animals and goods 6. The different stages of production, processing and distribution, and the possible risks to human health, and where appropriate to the health of animals and plants, to the welfare of animals, to the	1. 不同的管制方法和技術，如檢查、查驗、篩選、有針對性的篩選、取樣，及實驗室分析、測試和診斷 2. 管制程序 3. 第 1(2)條所提及之規範 4. 對不符合第 1(2)條所提及之規範的情況之評鑑 5. 動物和貨物的生產、加工和分銷中的危害 6. 生產、加工和分銷的不同階段，及可能對人類健康造成的風險，以及適當時，對動植物健康、動物福祉和環境的風險

environment 7. The evaluation of the application of HACCP procedures and of good agricultural practices 8. Management systems such as quality assurance programmes that the operators manage and their assessment in so far as these are relevant for the requirements set out in the rules referred to in Article 1(2) 9. Official certification systems 10. Contingency arrangements for emergencies, including communication between Member States and the Commission 11. Legal proceedings and implications of official controls 12. Examination of written, documentary material and other records, including those related to inter-laboratory comparative testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with the rules referred to in Article 1(2); this may include financial and commercial aspects 13. Control procedures and requirements for entry into the Union of animals and goods arriving from third countries 14. Any other area necessary to ensure that official controls are performed in accordance with this Regulation	7. 危害分析重要管制點系統（HACCP）程序之應用和良好農業作為的評估 8. 管理系統，例如運營商管理的品質保證計畫及其於與第 1(2)條所提及之規範的要求相關之範圍內之評鑑 9. 官方驗證系統 10. 緊急情況的應急安排，其中包括會員國與歐盟執委會之間的溝通 11. 官方管制的法律行動和可能的影響 12. 書面的文件的材料和其他記錄的審查，其中包括與可能和評估對第 1(2)條所提及之規範的符合性有關之實驗室間比較測試、認證和風險評估有關者，此種審查可能包括財務和商業方面 13. 來自第三國的動物和貨物之進入歐盟的管制程序和要求 14. 確保按照本規章執行官方管制所需的任何其他領域
CHAPTER II ***Subject areas for control procedures***	*第 II 章* ***管制程序的主題領域***
1. The organisation of the competent authorities and the relationship between central competent authorities and authorities to which they have conferred tasks to perform official controls or other official activities 2. The relationship between competent authorities and delegated bodies or natural persons to which they have delegated tasks related to official controls or other official activities 3. A statement on the objectives to be achieved 4. Tasks, responsibilities and duties of staff 5. Sampling procedures, control methods and techniques, including laboratory analysis, testing and	1. 權責機關的組織，以及中央權責機關與其授權執行官方管制或其他官方活動之任務的機關間的關係 2. 權責機關與其委託和官方管制或其他官方活動有關任務的受委託機構或自然人之間的關係 3. 關於要達成的目標之聲明 4. 職員的任務、責任和義務 5. 抽樣程序、管制方法和技術，其中包括實驗室分析、測試和診斷，該等結果之解釋和後續的決定

diagnosis, interpretation of results and consequent decisions 6. Screening and targeted screening programmes 7. Mutual assistance in the event that official controls require more than one Member State to take action 8. Action to be taken following official controls 9. Cooperation with other services and departments that may have relevant responsibilities or with operators 10. Verification of the appropriateness of methods of sampling and of laboratory analysis, testing and diagnosis 11. Any other activity or information required for the effective functioning of the official controls	6. 篩選和有針對性的篩選計畫 7. 如官方管制需要一個以上的會員國採取行動時的互助 8. 在官方管制之後採取的行動 9. 與可能負有相關責任的其他服務和部門或與運營商之合作 10. 取樣方法和實驗室分析、測試和診斷方法的適當性之查驗 11. 為官方管制措施有效運作所需的任何其他活動或資訊
ANNEX III ***CHARACTERISATION OF METHODS OF ANALYSIS***	*附件 III* ***分析方法的特性描述***
1. Methods of analysis and measurement results should be characterised by the following criteria: (a) accuracy (trueness and precision), (b) applicability (matrix and concentration range), (c) limit of detection, (d) limit of quantification, (e) precision, (f) repeatability, (g) reproducibility, (h) recovery, (i) selectivity, (j) sensitivity, (k) linearity, (l) measurement uncertainty, (m) other criteria that may be selected as required. 2. The precision values referred to in point 1(e) shall either be obtained from a collaborative trial which	1. 分析方法和測量結果應按以下標準作特性描述： (a) 準確度（真實性和精密性）， (b) 應用性（基質和濃度範圍）， (c) 偵測極限， (d) 量化極限， (e) 精確度， (f) 重複性， (g) 再現性， (h) 回收率， (i) 選擇性， (j) 敏感度， (k) 線性， (l) 量測不確定度 (m) 可根據需要選擇的其他標準。 2. 第 1(e) 點中提到的精確度值應不是從根據國際公認的協作試驗協議（例如 ISO 5725「測量方法和結果的準確度（真實性和精密性）」）所執行的協作試驗中獲得，就是從在分析方法的性能標準已建立時，基於標準符合性測試的結果所獲得。重複性和再現性值應以國際公認的形式表

has been conducted in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725 'Accuracy (trueness and precision) of measurement methods and results') or, where performance criteria for analytical methods have been established, be based on criteria compliance tests. The repeatability and reproducibility values shall be expressed in an internationally recognised form (e.g. the 95 % confidence intervals as defined by ISO 5725 'Accuracy (trueness and precision) of measurement methods and results'). The results from the collaborative trial shall be published or freely available.	示（例如前述 ISO 5725 所定義的 95%信賴區間）。協作試驗的結果應公佈或免費提供。
3. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.	3. 統一適用於各類商品的分析方法應優先於僅適用於個別商品的方法。
4. In situations where methods of analysis can only be validated within a single laboratory, those methods should be validated in accordance with internationally accepted scientific protocols or guidelines or, where performance criteria for analytical methods have been established, be based on criteria compliance tests.	4. 在分析方法只能在單一實驗室內進行確效的情況時，該等方法應根據國際間所接受的科學協議或指南進行確效，或者，在分析方法的性能標準已建立的情況時，則應基於該等標準之符合性試驗進行確效。
5. Methods of analysis adopted under this Regulation should be edited in the standard layout for methods of analysis recommended by the ISO.	5. 於本規章所採用的分析方法應以 ISO 所推薦的分析方法的標準格式進行編輯。
ANNEX IV *CHAPTER I* ***Fees or charges for the official controls on consignments of animals and goods entering the Union***	*附件 IV* *第 I 章* ***進入歐盟的動物和貨物的託運物之官方管制的規費***
I. CONSIGNMENTS OF LIVE ANIMALS	I. 活體動物的託運物
(a) Bovine animals, equidae, pigs, sheep, goats, poultry, rabbits and small game birds or ground game, wild boar and wild ruminants: — EUR 55 per consignment, up to 6 tonnes, and — EUR 9 per tonne, over 6 and up to 46 tonnes, or — EUR 420 per consignment, over 46 tonnes.	(a)牛科動物、馬科動物、豬隻、綿羊、山羊、家禽、兔子和小型野鳥或陸地獵物、野豬和野生反芻動物： — 6 噸以下，每批託運物 55 歐元，以及 — 超過 6 噸至 46 噸以下，每噸 9 歐元，或 — 超過 46 噸，每批託運物 420 歐元。
(b) Animals of other species: — EUR 55 per consignment, up to 46 tonnes, or — EUR 420 per consignment, over 46 tonnes.	(b)其他物種的動物： — 46 噸以下，每批託運物 55 歐元，或 — 超過 46 噸，每批託運物 420 歐元。

II. CONSIGNMENTS OF MEAT

— EUR 55 per consignment, up to 6 tonnes, and

— EUR 9 per tonne, over 6 and up to 46 tonnes, or

— EUR 420 per consignment, over 46 tonnes.

III. CONSIGNMENTS OF FISHERY PRODUCTS

(a) Fishery products not in bulk:

(i) EUR 55 per consignment, up to 6 tonnes, and

(ii) EUR 9 per tonne, over 6 and up to 46 tonnes, or

(iii) EUR 420 per consignment, over 46 tonnes.

(b) Fishery products, transported as break bulk shipment:

(i) EUR 600 per vessel, with a cargo of fishery products up to 500 tonnes,

(ii) EUR 1 200 per vessel, with a cargo of fishery products over 500 and up to 1 000 tonnes,

(iii) EUR 2 400 per vessel, with a cargo of fishery products over 1 000 and up to 2 000 tonnes,

(iv) EUR 3 600 per vessel, with a cargo of fishery products of more than 2 000 tonnes.

IV. CONSIGNMENTS OF MEAT PRODUCTS, POULTRY MEAT, WILD GAME MEAT, RABBIT MEAT OR FARMED GAME MEAT

(a) EUR 55 per consignment, up to 6 tonnes, and

(b) EUR 9 per tonne, over 6 and up to 46 tonnes, or

(c) EUR 420 per consignment, over 46 tonnes.

V. CONSIGNMENTS OF OTHER PRODUCTS OF ANIMAL ORIGIN DIFFERENT FROM MEAT PRODUCTS FOR HUMAN CONSUMPTION

(a) Other products of animal origin for human consumption not in bulk;

(i) EUR 55 per consignment, up to 6 tonnes, and

(ii) EUR 9 per tonne, over 6 and up to 46 tonnes, or

II. 肉類託運物

— 46 噸以下，每批推運物 55 歐元，以及

— 超過 6 噸至 46 噸以下，每噸 9 歐元，或

— 超過 46 噸，每批託運物 420 歐元。

III. 漁產品託運物

(a)非大體積之漁業產品：

(i) 每批託運物 55 歐元，6 噸以下，以及

(ii) 超過 6 噸至 46 噸以下，每噸 9 歐元，或

(iii)超過 46 噸，每批託運物 420 歐元。

(b)散裝運輸之漁產品：

(i) 載運 500 噸以下的漁產品貨物之船隻，每艘船 600 歐元，

(ii) 載運超過 500 噸至 1,000 噸以下的漁產品貨物之船隻，每艘船 1,200 歐元，

(iii)載運超過 1,000 噸至 2,000 噸以下的漁類產品貨物之船隻，每艘船 2,400 歐元，

(iv) 載運超過 2,000 噸的漁類產品貨物之船隻，每艘船 3,600 歐元。

IV. 肉類產品、家禽肉、野生動物肉、兔子肉或圈養的野禽肉類之託運物

(a)6 噸以下，每批託運物 55 歐元，以及

(b)超過 6 噸至 46 噸以下，每噸 9 歐元，或

(c)超過 46 噸，每批託運物 420 歐元。

V. 與人類消費之肉製品不同的其他動物源產品之託運物

(a)非散裝之供人類消費之其他動物源產品；

(i) 6 噸以下，每批託運物 55 歐元，以及

(ii) 超過 6 噸至 46 噸以下，每噸 9 歐元，或

(iii) EUR 420 per consignment, over 46 tonnes.

(b) Other products of animal origin for human consumption transported as break bulk shipment:

(i) EUR 600 per vessel, with a cargo of products up to 500 tonnes,

(ii) EUR 1 200 per vessel, with a cargo of products over 500 and up to 1 000 tonnes,

(iii) EUR 2 400 per vessel, with a cargo of products over 1 000 and up to 2 000 tonnes,

(iv) EUR 3 600 per vessel, with a cargo products of more than 2 000 tonnes.

VI. CONSIGNMENTS OF ANIMAL BY-PRODUCTS AND FEED OF ANIMAL ORIGIN

(a) Consignment of animal by-product and feed of animal origin transported not in bulk:

(i) EUR 55 per consignment, up to 6 tonnes, and

(ii) EUR 9 per tonne, over 6 and up to 46 tonnes, or

(iii) EUR 420 per consignment, over 46 tonnes.

(b) Animal by-products and feed of animal origin, transported as break bulk shipment:

(i) EUR 600 per vessel, with a cargo of products up to 500 tonnes,

(ii) EUR 1 200 per vessel, with a cargo of products over 500 and up to 1 000 tonnes,

(iii) EUR 2 400 per vessel, with a cargo of products over 1 000 and up to 2 000 tonnes,

(iv) EUR 3 600 per vessel, with a cargo products of more than 2 000 tonnes.

VII. CONSIGNMENTS OF ANIMALS AND GOODS FROM THIRD COUNTRIES TRANSITING OR TRANSHIPPED

EUR 30 for consignment increased by EUR 20 per quarter of an hour for every member of staff involved in the controls.

VIII. CONSIGNMENTS OF PLANTS, PLANT PRODUCTS AND OTHER PRODUCTS, OBJECTS AND MATERIALS CAPABLE OF HARBOURING OR SPREADING PESTS OF PLANTS

(iii)超過 46 噸，每批託運物 420 歐元，

(b)其他供人類消費之動物源產品作為散裝貨物運輸者：

(i) 載運 500 噸以下產品貨物之船隻，每船 600 歐元，

(ii) 載運超過 500 噸至 1,000 噸以下產品貨物之船隻，每船 1,200 歐元，

(iii)載運超過 1,000 噸至 2,000 噸以下產品貨物之船隻，每船 2,400 歐元，

(iv) 載運超過 2,000 噸產品貨物之船隻，每船 3,600 歐元。

VI. 動物副產品和動物源飼料之託運物

(a)非散裝之動物副產品和動物源飼料之託運物：

(i) 6 噸以下，每批託運物 55 歐元，以及

(ii) 超過 6 噸至 46 噸以下，每噸 9 歐元，或

(iii)超過 46 噸，每批託運物 420 歐元。

(b)散裝運輸之動物副產品和動物源飼料：

(i) 載運 500 噸以下產品貨物之船隻，每船 600 歐元，

(ii) 載運超過 500 噸至 1,000 噸產品貨物之船隻，每船 1,200 歐元，

(iii)載運超過 1,000 噸至 2,000 噸產品貨物之船隻，每船 2,400 歐元，

(iv) 載運超過 2,000 噸產品貨物之船隻，每船 3,600 歐元。

VII. 來自過境或被轉運第三國的動物和貨物託運物

30 歐元託運物費用以及對於參與管制的每位職員以每 15 分鐘增加 20 歐元計。

VIII. 能夠攜帶或散播植物害蟲的植物、植物產品及其他產品、物品和材料的托運物

(a) For documentary checks: EUR 7 per consignment.

(b) For identity checks:

(i) EUR 7 per consignment up to a size of a truck load, a railway wagon load or the load of a container of comparable size,

(ii) EUR 14 per consignment bigger than the above size.

(c) For plant health checks, in accordance with the following specifications:

(i) cuttings, seedlings (except forestry reproductive material), young plants of strawberries or of vegetables:

— EUR 17,5 per consignment up to 10 000 in number,

— EUR 0,70 per consignment for each additional 1 000 units,

— EUR 140 per consignment maximum fee,

(ii) shrubs, trees (other than cut Christmas trees), other woody nursery plants including forest reproductive material (other than seed):

— EUR 17,5 per consignment up to 10 000 in number,

— EUR 0,44 per consignment for each additional 1000 units,

— EUR 140 per consignment maximum fee,

(iii) bulbs, corms, rhizomes, tubers, intended for planting (other than tubers of potatoes):

— EUR 17,5 per consignment up to 200 kg of weight,

— EUR 0,16 per consignment for each additional 10 kg,

— EUR 140 per consignment maximum fee,

(iv) seeds, tissue cultures:

— EUR 7,5 per consignment up to 100 kg of weight,

— EUR 0,175 per consignment for each additional 10 kg,

— EUR 140 per consignment maximum fee,

(a)文件檢查：每批託運物 7 歐元。

(b)識別檢查：

（i） 一卡車載貨量、一火車廂載貨量或相當大小的貨櫃載貨量以下者，每批託運物 7 歐元，

（ii）超過上述容積，每批託運物 14 歐元。

(c)對於植物健康檢查，按照下列規範：

（i） 插條、幼苗(林業繁殖材料除外)、草莓或蔬菜的幼苗：

— 10,000 株以下，每批託運物 17.5 歐元，

— 每增加 1,000 株，每批託運物增加 0.7 歐元，

— 每批託運物最高費用 140 歐元，

（ii）灌木、樹木(切割聖誕樹除外)、其他木本苗圃植物，其中包括森林繁殖材料(種子除外)：

— 10,000 株以下，每批託運物 17.5 歐元，

— 每增加 1,000 株，每批託運物增加 0.44 歐元，

— 每批託運物最高費用 140 歐元，

（iii)鱗莖、球莖、根莖、塊莖(馬鈴薯塊莖除外)：

— 200 公斤以下，每批託運物 17.5 歐元，

— 每增加 10 公斤，每批託運物增加 0.16 歐元，

— 每批託運物最高費用 140 歐元，

（iv）種子、組織培養：

— 100 公斤以下，每批託運物 7.5 歐元，

— 每增加 10 公斤，每批託運物增加 0.175 歐元，

— 每批託運物最高費用 140 歐元，

(v) other plants intended for planting, not specified elsewhere in this point: — EUR 17,5 per consignment up to 5 000 in number, — EUR 0,18 per consignment for each additional 100 units, — EUR 140 per consignment maximum fee,	(v) 其他用於種植之植物，在上述之本點內容中未提及者： — 5,000 株以下，每批託運物 17.5 歐元， — 每增加 100 株，每批託運物增加 0.18 歐元， — 每批託運物最高 140 歐元，
(vi) cut flowers: — EUR 17,5 per consignment up to 20 000 in number, — EUR 0,14 per consignment for each additional 1 000 units, — EUR 140 per consignment maximum fee,	(vi) 切花： — 每批託運物 17.5 歐元，最多 20,000 株， — 每增加 1,000 株，每批託運物 0.14 歐元， — 每批託運物最高費用 140 歐元，
(vii) branches with foliage, parts of conifers (other than cut Christmas trees): — EUR 17,5 per consignment up to 100 kg of weight, — EUR 1,75 per consignment for each additional 100 kg, — EUR 140 per consignment maximum fee,	(vii)帶葉的樹枝、針葉樹的一部分(切割聖誕樹除外)： — 100 公斤以下，每批託運物 17.5 歐元， — 每增加 100 公斤，每批託運物增加 1.75 歐元， — 每批託運物最高費用 140 歐元，
(viii) cut Christmas trees: — EUR 17,5 per consignment up to 1 000 in number, — EUR 1,75 per consignment for each additional 100 units, — EUR 140 per consignment maximum fee,	(viii)切割之聖誕樹： — 1,000 棵以下，每批託運物 17.5 歐元， — 每增加 100 棵，每批託運物增加 1.75 歐元， — 每批託運物最高費用 140 歐元，
(ix) leaves of plants, such as herbs, spices and leafy vegetables: — EUR 17,5 per consignment up to 100 kg of weight, — EUR 1,75 per consignment for each additional 10 kg, — EUR 140 per consignment maximum fee,	(ix) 水果、蔬菜(葉類蔬菜除外)： — 25,000 公斤以下，每批託運物 17.5 歐元， — 每增加 1,000 公斤，每批託運物增加 0.7 歐元，
(x) fruits, vegetables (other than leafy vegetables): — EUR 17,5 per consignment up to 25 000 kg of weight, — EUR 0,7 per consignment for each additional 1 000 kg,	(x) 馬鈴薯塊莖： — 25,000 公斤以下，每批 52.5 歐元， — 每增加 25,000 公斤，每批增加 52.5 歐元，
(xi) tubers of potatoes:	(xi) 木頭(樹皮除外)：

— EUR 52,5 per lot up to 25 000 kg of weight, — EUR 52,5 per lot for each additional 25 000 kg, (xii) wood (other than bark): — EUR 17,5 per consignment up to 1 000 m^3 of volume, — EUR 0,175 per consignment for each additional 10 m^3, (xiii) soil and growing medium, bark: — EUR 17,5 per consignment up to 25 000 kg of weight, — EUR 0,7 per consignment for each additional 1 000 kg, — EUR 140 per consignment maximum fee, (xiv) grain: — EUR 17,5 per consignment up to 25 000 kg of weight, — EUR 0,7 per consignment for each additional 1 000 kg, — EUR 700 per consignment maximum fee, (xv) other plants or plant products not specified elsewhere in this point: — EUR 17,5 per consignment. Where a consignment does not consist exclusively of products coming under the description of the relevant indent, those parts thereof consisting of products coming under the description of the relevant indent (lot or lots) shall be treated as a separate consignment.	— 體積 1,000 立方公尺以下，每批託運物 17.5 歐元， — 每增加 10 立方公尺，每批託運物增加 0.175 歐元， (xii)土壤和生長媒介、樹皮： — 重量 25,000 公斤以下，每批託運物 17.5 歐元， — 每增加 1,000 公斤，每批託運物增加 0.7 歐元， — 每批託運物最高費用 140 歐元， (xiii) 穀物： — 重量 25,000 公斤以下，每批託運物 17.5 歐元， — 每增加 1,000 公斤，每批託運物增加 0.7 歐元， — 每批託運物最高費用 700 歐元， (xiv)其他植物或植物產品，在上述之本點內容未提及者： — 每批託運物 17.5 歐元。 若託運物不僅只包含由相關訂貨契約所描述的產品內容所組成，則其中包含由相關訂貨契約(批或批次)所描述的產品所組成的那些部分應視為另外分開處理的託運物。
CHAPTER II ***Fees or charges for the official controls in slaughterhouses, cutting plants, game-processing plants, milk production and producing and placing on the market fishery products and aquaculture products***	*第 II 章* ***屠宰場、分切廠、獵物加工廠、牛奶產製廠以及漁產品和水產養殖產品的生產及上市銷售之官方管制的規費***
I. FEES OR CHARGES FOR THE OFFICIAL CONTROLS IN SLAUGHTERHOUSES (a) Beef meat: (i) adult bovine animals: 5 EUR/animal, (ii) young bovine animals: 2 EUR/animal, (b) solipeds/equidae meat: 3 EUR/animal, (c) pigmeat: animals of a carcass weight:	I. 屠宰場之官方管制規費 (a)牛肉： (i) 成年牛：5 歐元/頭， (ii) 小牛：2 歐元/頭， (b)單蹄/馬科動物肉：3 歐元/頭， (c)豬肉：每頭重量： (i) 少於 25 公斤：0.5 歐元/頭， (ii) 等於或大於 25 公斤：1 歐元/頭，

(i) of less than 25 kg: 0,5 EUR/animal,	
(ii) equal to or greater than 25 kg: 1 EUR/animal,	
(d) sheepmeat and goatmeat: animals of a carcass weight:	(d)綿羊肉和山羊肉：每頭重量：
(i) of less than 12 kg: 0,15 EUR/animal,	（i） 少於 12 公斤：0.15 歐元/頭，
(ii) equal to or greater than 12 kg: 0,25 EUR/animal,	（ii） 等於或大於 12 公斤：0.25 歐元/頭
(e) poultry meat:	(e)禽肉：
(i) poultry of genus Gallus and guinea fowl: 0,005 EUR/animal,	（i） 原雞和珍珠雞之禽類:0.005 歐元/隻，
(ii) ducks and geese: 0,01 EUR/animal,	（ii） 鴨子和鵝：0.01 歐元/隻，
(iii) turkeys: 0,025 EUR/animal,	（iii）火雞：0.025 歐元/隻，
(iv) farmed rabbit meat: 0,005 EUR/animal,	（iv） 圈養兔子肉：0.005 歐元/隻
(v) quails and partridges: 0,002 EUR/animal.	（v） 鵪鶉和鷓鴣：0.002 歐元/隻
II. FEES OR CHARGES FOR THE OFFICIAL CONTROLS IN CUTTING PLANTS	II. 分切廠的官方管制規費
Per tonne of meat:	每噸肉：
(a) beef, veal, pig, solipeds/equidae, sheep and goat meat: 2 EUR,	(a)牛、小牛、豬、單蹄/馬科動物、綿羊和山羊肉：2 歐元，
(b) poultry and farmed rabbit meat: 1,5 EUR,	(b)禽和圈養兔肉：1,5 歐元，
(c) farmed and wild game meat:	(c)圈養和野生狩獵肉：
— small game birds and ground game: 1,5 EUR,	— 小型獵鳥和陸地獵物(如野兔)：1,5 歐元，
— ratites (ostrich, emu, nandou): 3 EUR,	— 走禽類（鴕鳥、食火雞、美洲鴕鳥）：3 歐元，
— boar and ruminants: 2 EUR.	— 野豬和反芻動物：2 歐元。
III. FEES OR CHARGES FOR THE OFFICIAL CONTROLS IN GAME-PROCESSING PLANTS	III. 獵物加工廠的官方管制規費
(a) small game birds: 0,005 EUR/animal,	（a）小型獵鳥：0,005 歐元/隻，
(b) small ground game: 0,01 EUR/animal,	（b）小型陸地獵物：0,01 歐元/隻，
(c) ratites: 0,5 EUR/animal,	（c）走禽類：0,5 歐元/動物，
(d) land mammals:	（d）陸地哺乳類：
(i) boar: 1,5 EUR/animal,	（i） 野豬：1,5 歐元/隻，
(ii) ruminants: 0,5 EUR/animal.	（ii）反芻動物：0.5 歐元/隻。
IV. FEES OR CHARGES FOR THE OFFICIAL CONTROLS ON MILK PRODUCTION	IV. 牛奶產製廠的官方管制規費
	（a）每 30 噸 1 歐元及
	（b）之後，每噸 0.5 歐元。
	V. 對漁產品和水產養殖產品的生產和上市之官方管制的規費

(a) 1 EUR per 30 tonnes and

(b) 0,5 EUR/tonne thereafter.

V. FEES OR CHARGES FOR THE OFFICIAL CONTROLS ON PRODUCING AND PLACING ON THE MARKET FISHERY PRODUCTS AND AQUACULTURE PRODUCTS

(a) First placing on the market of fishery and aquaculture products:

(i) 1 EUR/tonne for the first 50 tonnes in the month;

(ii) 0,5 EUR/tonne thereafter.

(b) First sale in fish market

(i) 0,5 EUR/tonne for the first 50 tonnes in the month;

(ii) 0,25 EUR/tonne thereafter;

(c) First sale in case of lack of or insufficient gradation for freshness and/or size:

(i) 1 EUR/tonne for the first 50 tonnes in the month;

(ii) 0,5 EUR/tonne thereafter.t.

（a）漁產品及水產養殖產品之首次上市：

（i） 當月最初 50 噸，每噸 1 歐元；

（ii）之後，每噸 0.5 歐元。

（b）在魚市場的首次銷售

（i） 當月最初 50 噸，每噸 0,5 歐元；

（ii）之後，每噸 0.25 歐元；

（c）在沒有新鮮度及/或大小之變化的情況下之首次銷售：

（i） 本月最初 50 噸，每噸 1 歐元；

（ii）之後，每噸 0,5 歐元。

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