

**REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 28 January 2002 laying down the general principles and requirements of food law, establishing the
European Food Safety Authority and laying down procedures in matters of food safety** (OJ L31, 1.2.2002, p.1)
歐洲議會和理事會 2002 年 1 月 28 日第 178/2002 號規章關於制定食品法之通則及要求，建立歐洲食品安全局
和制定食品安全事務之程序

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原(修正)條文	中譯文(條款點次請參照原條文)
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	歐洲議會及歐盟理事會，
Having regard to the Treaty establishing the European Community, and in particular Article 37, 95, 133 and Article 152(4)(b) thereof,	鑒於建立歐洲歐盟的條約，特別是其中第37、95、133條和第152(4)(b)條，
Having regard to the proposal from the Commission ¹ ,	鑒於執委會的提案，
Having regard to the opinion of the Economic and Social Committee ² ,	鑒於經濟與社會委員會的意見，
Having regard to the opinion of the Committee of the Regions ³ ,	鑒於各區域委員會的意見，
Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁴ ,	依據條約第251條規定的程序制定，
Whereas:	茲以：
(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.	安全和合乎衛生的食品之自由流通是內部市場的一個要素，對公民健康和福祉以及其社經利益具顯著貢獻。
(2) A high level of protection of human life and health should be assured in the pursuit of Community policies.	在達成歐盟政策中，應確保對人類生命和健康的高度保護。
(3) The free movement of food and feed within the Community can be achieved only if food and feed safety requirements do not differ	只有在會員國之間的食物和飼料安全要求沒有顯著差別時，才能實現食物和飼料

¹ OJ C 96 E, 27.3.2001, p. 247.

² OJ C 155, 29.5.2001, p. 32.

³ Opinion delivered on 14 June 2001 (not yet published in the Official Journal).

⁴ Opinion of the European Parliament of 12 June 2001 (not yet published in the Official Journal), Council Common Position of 17 September 2001 (not yet published in the Official Journal) and Decision of the European Parliament of 11 December 2001 (not yet published in the Official Journal), Council Decision of 21 January 2002.

significantly from Member State to Member State.	料在歐盟境內的自由流通。
(4) There are important differences in relation to concepts, principles and procedures between the food laws of the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market.	會員國的食品法在觀念、原則和程序上存有重要差異。當會員國採行食品管制措施時，這些差異可能會阻礙食品的自由流通，致不平等競爭情形，進而直接影響內部市場秩序。
(5) Accordingly, it is necessary to approximate these concepts, principles and procedures so as to form a common basis for measures governing food and feed taken in the Member States and at Community level. It is however necessary to provide for sufficient time for the adaptation of any conflicting provisions in existing legislation, both at national and Community level, and to provide that, pending such adaptation, the relevant legislation be applied in the light of the principles set out in the present Regulation.	因此，有必要拉近這些觀念、原則和程序，以便在會員國間和歐盟層級採取的食品和飼料管制措施形成一個共同基礎。然而，在國家和歐盟層級，有必要提供足夠的時間對現有立法中的任何衝突條款進行調整，並在進行此類調整之前，依本規章制定原則提供相關立法之適用。
(6) Water is ingested directly or indirectly like other foods, thereby contributing to the overall exposure of a consumer to ingested substances, including chemical and microbiological contaminants. However, as the quality of water intended for human consumption is already controlled by Council Directives 80/778/EEC ⁵ and 98/83/EC ⁶ , it suffices to consider water after the point of compliance referred to in Article 6 of Directive 98/83/EC.	水像其他食物一樣被直接或間接攝入，因而對消費者攝入物質，包括化學和微生物污染物，總暴露量有所貢獻。然而，欲供人飲用的水之品質已受理事會指令80/778/EEC和98/83/EC的管控，因此在98/83/EC指令第6條提到的符合點之後考慮水就足夠了。
(7) Within the context of food law it is appropriate to include requirements for feed, including its production and use where that feed is intended for food-producing animals. This is without prejudice to the similar requirements which have been applied so far and which will be applied in the future in feed legislation applicable to all animals, including pets.	在食品法範圍內，涵括對飼料的要求是適當的，包括飼料生產和用於欲供食用動物的餵養。這不影響迄今已應用的類似要求，這些要求將在未來適用於所有動物，包括寵物的飼料法。
(8) The Community has chosen a high level of health protection as appropriate in the development of food law, which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally.	歐盟在發展食品法時，適當地選擇了高標準的健康保護，無論是在國內或國際市場上進行食品或飼料交易，皆以非歧視的方式應用之。
(9) It is necessary to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law, its scientific basis and the structures and independence of the institutions protecting health and other interests.	有必要確保消費者、其他利益關係者和貿易夥伴們，在支持食品法之決策過程、其科學基礎以及保護健康和其他利益的機構之結構和獨立性，充滿信心。
(10) Experience has shown that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not placed on the market and at ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health. Similar issues relating to feed safety should be addressed.	經驗顯示，有必要採行目的在於保證不安全食品不會投放市場和目的在於確保存在識別和對應到食品安全問題的系統之措施，以確保內部市場的正常秩序並保護人類健康。有關飼料安全的類似問題應得到解決。
(11) In order to take a sufficiently comprehensive and integrated approach to food safety, there should be a broad definition of food law covering a wide range of provisions with a direct or indirect effect on the safety of food and feed, including provisions on materials and articles in contact with food, animal feed and other agricultural inputs at the level of primary production.	為了對食品安全採取足夠全面和整合的方法，食品法應該有一個廣泛的定義以涵蓋對食品和飼料安全有直接或間接影響的廣泛規定，包括於初級生產階段對原料及與食品、動物飼料和其他農業投入品接觸物品之規定。
(12) In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety.	為確保食品安全，有必要將食品生產鏈的所有環節視為一個連續體，包括從初級生產和動物飼料生產，到向消費者銷售或供應食品，因為每個元素都可能對食品安全產生潛在影響。
(13) Experience has shown that for this reason it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals, including the production of animals which	經驗顯示，基於這個原因，有必要考慮供給食用動物的飼料之生產、製造、運輸和配銷，包括可能用作魚養殖場飼料

5 OJ L 229, 30.8.1980, p. 11. Directive repealed by Directive 98/83/EC.
6 OJ L 330, 5.12.1998, p. 32.

<p>may be used as feed on fish farms, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety.</p>	<p>的動物生產，因無意或故意污染飼料，和摻假或欺詐或其他不良的相關作業，都可能對食品安全產生直接或間接的影響。</p>
<p>(14)For the same reason, it is necessary to consider other practices and agricultural inputs at the level of primary production and their potential effect on the overall safety of food.</p>	<p>基於同樣原因，有必要在初級生產階段，考慮到其他作業和農業投入品以及它們對整體食品安全之潛在影響。</p>
<p>(15)Networking of laboratories of excellence, at regional and/or interregional level, with the aim of ensuring continuous monitoring of food safety, could play an important role in the prevention of potential health risks for citizens.</p>	<p>旨在確保持續監測食品安全之優良區域和/或跨區域實驗室網絡，可在預防公民潛在健康風險上擔任重要角色。</p>
<p>(16)Measures adopted by the Member States and the Community governing food and feed should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. Recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.</p>	<p>會員國和歐盟採取的管理食品和飼料之措施，通常應以風險分析為基礎，除非這不適合環境狀況或措施本質。在採取此類措施之前進行風險分析，應有利於避免對食品自由流通的不合理障礙。</p>
<p>(17)Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis - risk assessment, risk management, and risk communication - provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.</p>	<p>當食品法旨在減少、消除或避免健康風險時，風險分析的3個相互關聯組件 — 風險評估、風險管理和風險溝通 — 提供了系統性方法來確定有效、均衡和標的性的措施或其他保護健康的行動。</p>
<p>(18)In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.</p>	<p>為對食品法之科學基礎充滿信心，風險評估應在既有科學資訊和數據基礎上以獨立、客觀和透明的方式進行。</p>
<p>(19)It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.</p>	<p>一般認知在某些情況下，僅靠科學的風險評估無法提供建立風險管理決策應有的所有資訊，以及與所考慮事項相關的其他因素應被合理納入，包括社會、經濟、傳統、倫理和環境因素和管控的可行性。</p>
<p>(20)The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle.</p>	<p>援引預防原則來確保歐盟內的健康保護，對食品或飼料自由流通造成障礙。因此，有必要在整個歐盟對使用此原則採用一致性的基礎。</p>
<p>(21)In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community.</p>	<p>在生命或健康風險但科學不確定性持續存在的特定情況下，為確保選擇在歐盟內有高標準的健康保護，預防原則提供了確定風險管理措施或其他行動的機制。</p>
<p>(22)Food safety and the protection of consumer's interests is of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. It is necessary to ensure that consumer confidence and the confidence of trading partners is secured through the open and transparent development of food law and through public authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health.</p>	<p>食品安全和消費者利益保護是逐步受公眾、非政府組織、專業協會、國際貿易夥伴和貿易組織之關注。有必要透過食品法公開透明的發展和透過公共主管機關採取適當步驟通知公眾有合理的理由懷疑某食品可能存在健康風險，以確保消費者信心及貿易夥伴信心得到保障。</p>
<p>(23)The safety and confidence of consumers within the Community, and in third countries, are of paramount importance. The Community is a major global trader in food and feed and, in this context, it has entered into international trade agreements, it contributes to the development of international standards which underpin food law, and it supports the principles of free trade in safe feed and safe, wholesome food in a non-discriminatory manner, following fair and</p>	<p>歐盟境內和第三國消費者的安全和信心至關重要。歐盟是全球主要食品和飼料貿易夥伴，在此情況，加入國際貿易協定，為在食品法基礎下的國際標準發展做出貢獻，並在遵循公平和道德的貿易慣例下，支持以非歧視的方式提供安全飼料和安全衛生食品之自由貿易原則。</p>

<p>ethical trading practices.</p>	
<p>(24) It is necessary to ensure that food and feed exported or re-exported from the Community complies with Community law or the requirements set up by the importing country. In other circumstances, food and feed can only be exported or re-exported if the importing country has expressly agreed. However, it is necessary to ensure that even where there is agreement of the importing country, food injurious to health or unsafe feed is not exported or re-exported.</p>	<p>有必要確保從歐盟出口或再出口的食品和飼料符合歐盟法律或進口國要求。在其他情況下，只有在進口國明確同意下，食品和飼料才能出口或再出口。然而有必要確保即使在進口國同意的情況下，對健康有害食品或不安全飼料並不會出口或再出口。</p>
<p>(25) It is necessary to establish the general principles upon which food and feed may be traded and the objectives and principles for the contribution of the Community to developing international standards and trade agreements.</p>	<p>有必要對食品和飼料進行貿易，以及歐盟在發展國際標準和貿易協定作出貢獻的目標和原則，建立通則。</p>
<p>(26) Some Member States have adopted horizontal legislation on food safety imposing, in particular, a general obligation on economic operators to market only food that is safe. However, these Member States apply different basic criteria for establishing whether a food is safe. Given these different approaches, and in the absence of horizontal legislation in other Member States, barriers to trade in foods are liable to arise. Similarly such barriers may arise to trade in feed.</p>	<p>一些會員國通過了有關食品安全的橫向立法，特別是對經濟經營者規定了僅銷售安全食品的一般義務。然而，這些會員國應用不同的基本基準來確認食品是否安全。鑑於這些不同方法及在其他會員國缺乏橫向立法情況下，食品貿易壁壘很容易出現。同樣地此類壁壘也可能出現在飼料貿易上。</p>
<p>(27) It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the internal market in such products functions effectively.</p>	<p>因此有必要建立僅安全食品和飼料投放市場的一般要求，以確保此類產品的內部市場有效運作。</p>
<p>(28) Experience has shown that the functioning of the internal market in food or feed can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.</p>	<p>經驗顯示，當無法追溯食品和飼料時，食品或飼料內部市場運作會受到損害。因此，有必要在食品和飼料業內建立一個全面的可追溯性系統，以便可以採取針對性和準確的回收或提供消費者或管控官員資訊，從而避免在食品安全問題事件中造成更廣泛不必要的斷鏈。</p>
<p>(29) It is necessary to ensure that a food or feed business including an importer can identify at least the business from which the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.</p>	<p>有必要確保包括進口商在內的食物或飼料業者，能夠至少識別供應給他們的食品、飼料、動物或可能摻入食品或飼料中的物質之企業，以確保在所有階段的調查上，能確認可追溯性。<small>(譯註：意即業者對生產或進口產品，要能明確識別所有原物料的供應商。)</small></p>
<p>(30) A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety. Although this principle exists in some Member States and areas of food law, in other areas this is either not explicit or else responsibility is assumed by the competent authorities of the Member State through the control activities they carry out. Such disparities are liable to create barriers to trade and distort competition between food business operators in different Member States.</p>	<p>食品業者是最適合設計一個安全的食品供應系統並確保所供應的食品是安全的；因此，應承擔確保食品安全的首要法律責任。雖然此原則存在於一些會員國和食品法領域，但在其他領域，或不明確，或由會員國主管機關透過其開展的管控活動來承擔責任。此類差異可能產生貿易壁壘並扭曲為不同會員國食品業者間的競爭。</p>
<p>(31) Similar requirements should apply to feed and feed business operators.</p>	<p>類似要求應適用於飼料和飼料業者。</p>
<p>(32) The scientific and technical basis of Community legislation relating to the safety of food and feed should contribute to the achievement of a high level of health protection within the Community. The Community should have access to high-quality, independent and efficient scientific and technical support.</p>	<p>與食品和飼料安全相關的歐盟立法之科學和技術基礎，應有助於在歐盟境內達到高標準的健康保護。歐盟應獲得高品質、獨立和有效的科學和技術支持。</p>
<p>(33) The scientific and technical issues in relation to food and feed safety are becoming increasingly important and complex. The establishment of a European Food Safety Authority, hereinafter referred to as "the Authority", should reinforce the present system of</p>	<p>與食品和飼料安全相關的科學和技術議題變得越來越重要和複雜。成立歐洲食品安全局(EFSA)，以下簡稱「當局」，應強化現有的科學和技術支持體系，該</p>

<p>scientific and technical support which is no longer able to respond to increasing demands on it.</p>	<p>體系已無法回應日益增加的需求。(譯註：為方便閱讀，以下「當局」均以EFSA表示。)</p>
<p>(34) Pursuant to the general principles of food law, the Authority should take on the role of an independent scientific point of reference in risk assessment and in so doing should assist in ensuring the smooth functioning of the internal market. It may be called upon to give opinions on contentious scientific issues, thereby enabling the Community institutions and Member States to take informed risk management decisions necessary to ensure food and feed safety whilst helping avoid the fragmentation of the internal market through the adoption of unjustified or unnecessary obstacles to the free movement of food and feed.</p>	<p>根據食品法的通則，EFSA應在風險評估中擔任獨立科學參考點的角色，此將協助確保內部市場的順利運作。它可能被呼籲對有爭議的科學問題表示意見，從而使歐盟機構和會員國能夠做出必要的知情風險管理決策，以確保食品和飼料安全，同時透過對食品和飼料的自由流通設置不合理或不必要的障礙來幫助避免內部市場的分裂。</p>
<p>(35) The Authority should be an independent scientific source of advice, information and risk communication in order to improve consumer confidence; nevertheless, in order to promote coherence between the risk assessment, risk management and risk communication functions, the link between risk assessors and risk managers should be strengthened.</p>	<p>EFSA應成為提供建議、資訊和風險溝通的獨立科學來源，以提高消費者信心；然而，為了促進風險評估、風險管理和風險溝通功能間的連貫性，應強化風險評估者和風險管理者之間的聯繫。</p>
<p>(36) The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food and feed supply chains, which implies wide-ranging responsibilities for the Authority. These should include issues having a direct or indirect impact on the safety of the food and feed supply chains, animal health and welfare, and plant health. However, it is necessary to ensure that the Authority focuses on food safety, so its mission in relation to animal health, animal welfare and plant health issues that are not linked to the safety of the food supply chain should be limited to the provision of scientific opinions. The Authority's mission should also cover scientific advice and scientific and technical support on human nutrition in relation to Community legislation and assistance to the Commission at its request on communication linked to Community health programmes.</p>	<p>EFSA應就整個食品和飼料供應鏈的安全和其他面向提供周全獨立的科學觀點，此意指EFSA擔負廣泛的責任。這些應包括對食品和飼料供應鏈安全、動物健康福利和植物健康有直接或間接影響的議題。然而，有必要確保EFSA專注在食品安全，因此其在與食品供應鏈安全無關聯的動物健康、動物福利和植物健康議題上的使命應僅限於提供科學意見。EFSA的使命還應涵括與歐盟立法有關的人類營養之科學建議和科學及技術支持，以及對執委會要求與歐盟健康計畫溝通聯繫予以援助。</p>
<p>(37) Since some products authorised under food law such as pesticides or additives in animal feed may involve risks to the environment or to the safety of workers, some environmental and worker protection aspects should also be assessed by the Authority in accordance with the relevant legislation.</p>	<p>依食品法批准的某些產品，例如動物飼料中的殺蟲劑或添加劑，可能會對環境或勞工安全造成風險，因此EFSA還應依據相關法規評估某些環境和勞工保護面向。</p>
<p>(38) In order to avoid duplicated scientific assessments and related scientific opinions on genetically modified organisms (GMOs), the Authority should also provide scientific opinions on products other than food and feed relating to GMOs as defined by Directive 2001/18/EC⁷ and without prejudice to the procedures established therein.</p>	<p>為避免對基因改造生物(GMOs)的重複科學評估和相關科學意見，EFSA還應對於與2001/18/EC指令定義GMOs相關的食品和飼料以外之產品提供科學意見，且不損害其中已確立之程序。</p>
<p>(39) The Authority should contribute through the provision of support on scientific matters, to the Community's and Member States' role in the development and establishment of international food safety standards and trade agreements.</p>	<p>EFSA應透過在科學事務上提供支持，促進歐盟和會員國在制定和建立國際食品安全標準和貿易協定上之影響力。</p>
<p>(40) The confidence of the Community institutions, the general public and interested parties in the Authority is essential. For this reason, it is vital to ensure its independence, high scientific quality, transparency and efficiency. Cooperation with Member States is also indispensable.</p>	<p>歐盟機構、公眾和利害關係者對EFSA的信任是必要的。基此，確保其獨立性、高科學品質、透明度和效率至關重要。與會員國的合作也必不可少。</p>
<p>(41) To that effect the Management Board should be appointed in such a way as to secure the highest standard of competence, a broad range of relevant expertise, for instance in management and in public administration, and the broadest possible geographic distribution within the Union. This should be facilitated by a rotation of the</p>	<p>為此，管理委員會應以確保最高標的能力、廣泛的相關專業知識(例如在管理和公共行政方面)，和盡可能廣泛的地理分佈(會員國)之方式來任命。此應通過輪換管理委員會不同原籍國成員來促</p>

⁷ 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)/ 關於故意將 GMO 生物釋放至環境中及廢止理事會 90/220/EEC 指令

different countries of origin of the members of the Management Board without any post being reserved for nationals of any specific Member State.	進，而無需為任何特定會員國來保留任何職位。
(42)The Authority should have the means to perform all the tasks required to enable it to carry out its role.	EFSA應有能力完成使其能夠履行職責所需的所有任務。
(43)The Management Board should have the necessary powers to establish the budget, check its implementation, draw up internal rules, adopt financial regulations, appoint members of the Scientific Committee and Scientific Panels and appoint the Executive Director.	管理委員會應具有編列預算、檢核其執行成效、制定內部規定、通過財務規章、任命科學委員會和科學小組成員和任命執行長之必要權力。
(44)The Authority should cooperate closely with competent bodies in the Member States if it is to operate effectively. An Advisory Forum should be created in order to advise the Executive Director, to constitute a mechanism of exchange of information, and to ensure close cooperation in particular with regard to the networking system. Cooperation and appropriate exchange of information should also minimise the potential for diverging scientific opinions.	若要有效運作，EFSA應與會員國的主管機構密切合作。應成立一個諮詢論壇，以便向執行長提供建議，建立資訊交換機制，並特別在網絡系統方面確保密切合作。合作和適當的資訊交換也應盡量減少潛在的科學意見分歧。
(45)The Authority should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence. It is necessary to reorganise these Committees to ensure greater scientific consistency in relation to the food supply chain and to enable them to work more effectively. A Scientific Committee and Permanent Scientific Panels should therefore be set up within the Authority to provide these opinions.	EFSA應承擔附屬執委會的科學委員會之職責，在其主管領域發表科學意見。有必要再組織這些委員會，以確保在食品供應鏈方面具更好的科學一致性，並使他們能更有效地運作。因此在EFSA內應設立科學委員會和常設科學小組來提供這些意見。
(46)In order to guarantee independence, members of the Scientific Committee and Panels should be independent scientists recruited on the basis of an open application procedure.	為了保證獨立性，科學委員會和小組成員應是以公開申請程序基礎上招募的獨立科學家。
(47)The Authority's role as an independent scientific point of reference means that a scientific opinion may be requested not only by the Commission, but also by the European Parliament and the Member States. In order to ensure the manageability and consistency of the process of scientific advice, the Authority should be able to refuse or amend a request providing justification for this and on the basis of predetermined criteria. Steps should also be taken to help avoid diverging scientific opinions and, in the event of diverging scientific opinions between scientific bodies, procedures should be in place to resolve the divergence or provide the risk managers with a transparent basis of scientific information.	EFSA作為獨立科學參考點的角色意味著科學意見不僅可以由執委會提出，也可以由歐洲議會和會員國提出。為確保科學建議過程的可管理性和一致性，EFSA應能在預定基準基礎上拒絕或修正為此提供理由的請求。還應採取幫助避免科學意見分歧之步驟，以及在科學機構間發生科學意見分歧情形時，應有程序來解決分歧或為風險管理者提供透明的科學資訊基礎。
(48)The Authority should also be able to commission scientific studies necessary for the accomplishment of its duties, while ensuring that the links established by it with the Commission and the Member States prevent duplication of effort. It should be done in an open and transparent fashion and the Authority should take into account existing Community expertise and structures.	EFSA還應能委託完成其職責所必需的科學研究，同時確保其與執委會和會員國建立的聯繫可避免重複工作。EFSA應以公開和透明的方式進行，並且應考慮既有的歐盟專業知識和結構。
(49)The lack of an effective system of collection and analysis at Community level of data on the food supply chain is recognised as a major shortcoming. A system for the collection and analysis of relevant data in the fields covered by the Authority should therefore be set up, in the form of a network coordinated by the Authority. A review of Community data collection networks already existing in the fields covered by the Authority is called for.	歐盟層級缺乏有效的食品供應鏈數據收集和系統被認為是一個主要缺點。因此，應建立一個以EFSA協調的網絡形式來收集和系統。需要對EFSA涵括領域中已經存在的歐盟數據收集網絡進行審查。
(50)Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of the Member States and the Community in the exercise of its policies. It is therefore necessary to assign to the Authority an anticipatory task of collecting information and exercising vigilance and providing evaluation of and information on emerging risks with a view to their prevention.	長期來看，改善對新興風險的識別可能是會員國和歐盟在執行政策時可以使用的主要預防工具。因此，有必要為EFSA分配一項預期任務，即收集資訊並保持警惕，及以預防觀點來對新興風險提供評估和資訊。
(51)The establishment of the Authority should enable Member States to become more closely involved in scientific procedures. There should	EFSA的建立應使會員國能夠更密切地參與科學程序。因此，EFSA與會員國間應

<p>therefore be close cooperation between the Authority and the Member States for this purpose. In particular, the Authority should be able to assign certain tasks to organisations in the Member States.</p>	<p>為此目的密切合作。特別是，EFSA應能將某些任務分配給會員國的機關。</p>
<p>(52) It is necessary to ensure that a balance is struck between the need to use national organisations to carry out tasks for the Authority and the need to ensure for the purposes of overall consistency that such tasks are carried out in line with the criteria established for such tasks. Existing procedures for the allocation of scientific tasks to the Member States, in particular with regard to the evaluation of dossiers presented by industry for the authorisation of certain substances, products or procedures, should be re-examined within a year with the objective of taking into account the establishment of the Authority and the new facilities it offers, the evaluation procedures remaining at least as stringent as before.</p>	<p>有必要確保在使用國家機關為EFSA執行任務需要與確保按照既定基準執行此類任務需要之間取得平衡。對會員國分配科學任務的現有程序，特別是關於工業界為某些物質、產品或程序的批准而提交的評估檔案，應在1年內以考慮到成立EFSA及其提供的新設施之目的再次審查，評估程序至少與先前一樣嚴格。</p>
<p>(53) The Commission remains fully responsible for communicating risk management measures. The appropriate information should therefore be exchanged between the Authority and the Commission. Close cooperation between the Authority, the Commission and the Member States is also necessary to ensure the coherence of the global communication process.</p>	<p>執委會仍然完全對溝通風險管理措施負責。因此EFSA和執委會間應交換適當的資訊。亦有必要對於在EFSA、執委會和會員國之間的密切合作，以確保全球溝通過程的連貫性。</p>
<p>(54) The independence of the Authority and its role in informing the public mean that it should be able to communicate autonomously in the fields falling within its competence, its purpose being to provide objective, reliable and easily understandable information.</p>	<p>EFSA的獨立性及其在向公眾提供資訊的角色意味著它應能在其權限範圍內自主溝通，目的是在提供客觀、可靠和易理解的資訊。</p>
<p>(55) Appropriate cooperation with the Member States and other interested parties is necessary in the specific field of public information campaigns to take into account any regional parameters and any correlation with health policy.</p>	<p>考慮到任何區域參數和與任何衛生政策相關的特定領域之宣傳運動，必須與會員國和其他利害關係者進行適當合作。</p>
<p>(56) In addition to its operating principles based on independence and transparency, the Authority should be an organisation open to contacts with consumers and other interested groups.</p>	<p>除基於獨立性和透明性的運作原則外，EFSA應是一個可以開放與消費者和其他利害相關群體接觸的組織。</p>
<p>(57) The Authority should be financed by the general budget of the European Union. However, in the light of experience acquired, in particular with regard to the processing of authorisation dossiers presented by industry, the possibility of fees should be examined within three years following the entry into force of this Regulation. The Community budgetary procedure remains applicable as far as any subsidies chargeable to the general budget of the European Union are concerned. Moreover, the auditing of accounts should be undertaken by the Court of Auditors.</p>	<p>EFSA應得到歐盟一般預算的資助。然而，鑑於既有經驗，特別是關於處理工業界提交的批准評估檔案方面，應在本規章生效後3年內檢視收費的可能性。對應納入歐盟總預算的任何補貼而言，歐盟預算程序仍然適用。此外，賬目稽核應由審計院進行。</p>
<p>(58) It is necessary to allow for the participation of European countries which are not members of the European Union and which have concluded agreements obliging them to transpose and implement the body of Community law in the field covered by this Regulation.</p>	<p>有必要允許非歐盟會員國的歐洲國家參與，這些國家已締結協議，要求他們在本規章涵括範圍的歐盟法律主體進行轉換和實施。</p>
<p>(59) A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992 on general product safety⁸. The scope of the existing system includes food and industrial products but not feed. Recent food crises have demonstrated the need to set up an improved and broadened rapid alert system covering food and feed. This revised system should be managed by the Commission and include as members of the network the Member States, the Commission and the Authority. The system should not cover the Community arrangements for the early exchange of information in the event of a radiological emergency as defined in Council Decision 87/600/Euratom⁹.</p>	<p>1992年6月29日理事會92/59/EEC指令對一般產品安全的框架，已存在快速警示系統。現有系統的範圍包括食品和工業產品，但不包括飼料。最近的食物危機證實需要設立一個涵括食品和飼料之改良和擴大的快速警示系統。此改版的系統應由執委會管理，包括會員國、執委會和EFSA等網絡成員。該系統不應涵括在理事會第87/600/Euratom號決定中定義的放射緊急事件之早期資訊交換的歐盟安排。</p>
<p>(60) Recent food safety incidents have demonstrated the need to</p>	<p>最近的食物安全事件證實有必要在緊急</p>

8 OJ L 228, 11.8.1992, p.24.
9 OJ L 371, 30.12.1987, p.76.

<p>establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to common measures in the event of a serious risk to human health, animal health or the environment. Such a comprehensive approach to emergency food safety measures should allow effective action to be taken and avoid artificial disparities in the treatment of a serious risk in relation to food or feed.</p>	<p>情況下建立適當的措施，以確保所有食品(無論其類型和來源)和所有飼料，都應在對人類健康、動物健康或環境造成嚴重風險的情況下，採用共同措施。此緊急食品安全措施的綜合方法應允許採取有效行動，並避免在處理與食品或飼料有關的嚴重風險時人為的差異。</p>
<p>(61)Recent food crises have also shown the benefits to the Commission of having properly adapted, more rapid procedures for crisis management. These organisational procedures should make it possible to improve coordination of effort and to determine the most effective measures on the basis of the best scientific information. Therefore, revised procedures should take into account the Authority's responsibilities and should provide for its scientific and technical assistance in the form of advice in the event of a food crisis.</p>	<p>最近的食物危機也向執委會顯示了適當調整、更快速的危機管理程序之益處。這些機關程序應可改進工作的協調，並在最佳科學資訊的基礎上決定最有效的措施。因此，修訂程序應考慮到EFSA的責任，和應在發生食品危機事件時以建言形式提供科學和技術支援。</p>
<p>(62)In order to ensure a more effective, comprehensive approach to the food chain, a Committee on the Food Chain and Animal Health should be established to replace the Standing Veterinary Committee, the Standing Committee for Foodstuffs and the Standing Committee for Feedingstuffs. Accordingly, Council Decisions 68/361/EEC¹⁰, 69/414/EEC¹¹, and 70/372/EEC¹², should be repealed. For the same reason the Committee on the Food Chain and Animal Health should also replace the Standing Committee on Plant Health in relation to its competence (for Directives 76/895/EEC¹³, 86/362/EEC¹⁴, 86/363/EEC¹⁵, 90/642/EEC¹⁶ and 91/414/EEC¹⁷) on plant protection products and the setting of maximum residue levels.</p>	<p>為確保對食物鏈採取更有效、更周全的方法，應建立食物鏈和動物健康委員會，來取代獸醫常設委員會、食品常設委員會和飼料常設委員會。因此，應廢止理事會68/361/EEC、69/414/EEC和70/372/EEC等決定。基於相同原因，食物鏈和動物健康委員會亦應取代植物健康常設委員會關於在植物保護產品和最大殘留量設定之權限(對76/895/EEC、86/362/EEC、86/363/EEC、90/642/EEC和91/414/EEC等指令)。</p>
<p>(63)The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹⁸.</p>	<p>本規章之實施所必需的措施應依據1999年6月28日理事會1999/468/EC決定來採行，該決定規定了行使賦予執委會執行權力的程序。</p>
<p>(64)It is necessary that operators should have sufficient time to adapt to some of the requirements established by the present Regulation and that the European Food Safety Authority should commence its operations on 1 January 2002.</p>	<p>業者必須有充足的時間來適應目前規章設定的某些要求，並且EFSA應於2002年1月1日開始運作。</p>
<p>(65)It is important to avoid confusion between the missions of the Authority and the European Agency for the Evaluation of Medicinal Products (EMA) established by Council Regulation (EEC) No 2309/93¹⁹. Consequently, it is necessary to establish that this Regulation is without prejudice to the competence conferred on the EMA by Community legislation, including powers conferred by Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin²⁰.</p>	<p>對於EFSA和以理事會第(EEC)2309/93號規章設立的歐洲醫藥產品評估機構(EMA)之間的任務要避免混淆是重要的。因此，有必要確定本規章不影響歐盟立法賦予EMA的權限，包括被1990年6月2日理事會第(EEC)2377/90號規章賦予的權力，該規章規定了對建立動物源性食品中動物用藥品的最大殘留限量之歐盟程序。</p>
<p>(66)It is necessary and appropriate for the achievement of the basic objectives of this Regulation to provide for the approximation of the concepts, principles and procedures forming a common basis for food law in the Community and to establish a European Food Safety Authority. In accordance with the principle of proportionality as set out in Article 5 of the Treaty, this Regulation does not go beyond what is necessary in order to achieve the objectives pursued,</p>	<p>對達到本規章的基本目標，有必要和適當的提供形成歐盟食品法共同基礎的近似觀念、原則和程序，並設立EFSA。依據條約第5條規定的比例原則，本規章不超出為實現所追求目標所必要的範圍。</p>
<p>HAVE ADOPTED THIS REGULATION:</p>	<p>已通過本規章：</p>

10 OJ L 255, 18.10.1968, p.23.
11 OJ L 291, 19.11.1969, p. 9.
12 OJ L 170, 3.8.1970, p.1.
13 OJ L 340, 9.12.1976, p. 26. Directive as last amended by Commission Directive 2000/57/EC (OJ L 244, 29.9.2000, p.76).
14 OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2001/57/EC (OJ L 208, 1.8.2001, p.36).
15 OJ L 221, 7.8.1986, p. 43. Directive as last amended by Commission Directive 2001/57/EC.
16 OJ L 350, 14.12.1990, p. 71. Directive as last amended by Commission Directive 2001/57/EC.
17 OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2001/49/EC (OJ L 176, 29.6.2001, p.61).
18 OJ L 184, 17.7.1999, p.23.
19 OJ L 214, 24.8.1993, p. 1. Regulation amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p.7).
20 OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1553/2001 (OJ L 205, 31.7.2001, p.16).

<p style="text-align: center;">CHAPTER I SCOPE AND DEFINITIONS</p>	<p style="text-align: center;">第I章 範圍和定義</p>
<p style="text-align: center;"><i>Article 1</i> Aim and scope</p>	<p style="text-align: center;">第1條 目標和範圍</p>
<p>1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.</p>	<p>本規章為確保關於食品對高度保護人類健康和消費者利益提供了基礎，特別考慮到包括傳統產品的食品供應之多樣性，同時確保內部市場有效運作。它建立了共同原則和責任、提供強大科學基礎的方法、有效的組織安排和程序，以支持食品和飼料安全事務的決策。</p>
<p>2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.</p>	<p>就第1段而言，本規章規定了在歐盟和國家層級管理食品和飼料的通則，特別是食品和飼料安全。</p>
<p>It establishes the European Food Safety Authority.</p>	<p>它建立了歐洲食品安全局(EFSA)。</p>
<p>It lays down procedures for matters with a direct or indirect impact on food and feed safety.</p>	<p>它規定了對食品和飼料安全有直接或間接影響事務的程序。</p>
<p>3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.</p>	<p>本規章應適用於食品和飼料的生產、加工和運銷之所有階段。它不適用於私人家庭使用的初級生產或供家庭消費食品的家庭製備、處理或儲存。</p>
<p style="text-align: center;"><i>Article 2</i> Definition of 'food'</p>	<p style="text-align: center;">第2條 「食品」之定義</p>
<p>For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.</p>	<p>就本規章而言，「食品」(或「食物」)是指任何物質或產品，無論是經加工的、部分加工的或未加工的，欲供作或合理地預期會被人類攝入。</p>
<p>'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.</p>	<p>「食品」包括飲料、口香糖和任何物質，包括水，在食品製造、製備或處理過程中被有意地加入食品中。它包括在98/83/EC指令第6條定義的符合點之後的水，且不影响80/778/EEC和98/83/EC等指令的要求。</p>
<p>'Food' shall not include:</p>	<p>「食品」應不包括：</p>
<p>(a) feed;</p>	<p>飼料；</p>
<p>(b) live animals unless they are prepared for placing on the market for human consumption;</p>	<p>活動物，除非牠們預備上市供人食用；</p>
<p>(c) plants prior to harvesting;</p>	<p>在收穫前的植物；</p>
<p>(d) medicinal products within the meaning of Council Directives 65/65/EEC²¹ and 92/73/EEC²²;</p>	<p>理事會65/65/EEC和92/73/EEC等指令所指的醫藥產品；</p>
<p>(e) cosmetics within the meaning of Council Directive 76/768/EEC²³;</p>	<p>理事會76/768/EEC指令所指的化妝品；</p>
<p>(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC²⁴;</p>	<p>理事會89/622/EEC指令所指的煙草和煙草製品；</p>
<p>(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;</p>	<p>1961年聯合國麻醉藥品單一公約和1971年聯合國精神藥物公約所指的麻醉或精神用藥物；</p>
<p>(h) residues and contaminants;</p>	<p>殘留物和污染物；</p>
<p>▼ M7</p>	

21 OJ L 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p.22).

22 OJ L 297, 13.10.1992, p.8.

23 OJ L 262, 27.9.1976, p.169. Directive as last amended by Commission Directive 2000/41/EC (OJ L 145, 20.6.2000, p.25).

24 OJ L 359, 8.12.1989, p.1. Directive as last amended by Directive 92/41/EEC (OJ L 158, 11.6.1992, p.30).

(i) medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council ²⁵ . ◀M7	歐洲議會和理事會(EU)2017/745規章所指的醫療器械。
Article 3 Other definitions	第3條 其他定義
For the purposes of this Regulation:	為本規章目的：
1. 'food law' means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals;	「食品法」意指在歐盟或國家層級上管理一般食品，特別是食品安全的法律、規章和行政規定；它涵括食品生產、加工和配銷，以及為食用動物生產或餵給食用動物飼料的任何階段；
2. 'food business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;	「食品業」意指任何從事與食品生產、加工和配銷任何階段相關活動的企業，無論是否以營利為目的及公營或私營；
3. 'food business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;	「食品業者」意指負責確保在其管控食品經營範圍內符合食品法要求的自然人或法人；
4. 'feed' (or 'feedingstuff') means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;	「飼料」意指欲供作動物經口餵養的任何物質或產品，包括添加劑，無論經加工的、部分加工的或未加工的；
5. 'feed business' means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;	「飼料業」意指任何從事飼料生產、製造、加工、儲存、運輸或配銷作業的企業，無論是否以營利為目的及公營或私營，包括任何生產、加工或儲存飼料的持股生產者；
6. 'feed business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;	「飼料業者」意指負責確保在其管控的飼料經營範圍內符合食品法要求的自然人或法人；
7. 'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;	「零售」意指供給最終消費者之食品的處理和/或加工及其儲存，包括物流站、餐飲作業、工廠食堂、機構餐飲、餐館和其他類似的食品服務業務、商店、超市配銷中心和批發購物中心等銷售或運銷點；
8. 'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;	「投放市場/上市」意指為銷售目的而持有食品或飼料，包括提供銷售或任何其他形式的轉運，無論是否收費，及銷售、運銷和其他形式轉運等作業本身；
9. 'risk' means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;	「風險」意指對健康造成不利影響的機率和危害後果的影響嚴重程度的函數；
10. 'risk analysis' means a process consisting of three interconnected components: risk assessment, risk management and risk communication;	「風險分析」意指包含3個相互關聯要素組成的過程：風險評估、風險管理和風險溝通；
11. 'risk assessment' means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;	「風險評估」意指以科學為基礎的過程，包括4個步驟：危害辨識、危害特徵描述、暴露評估和風險特徵描述；
12. 'risk management' means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;	「風險管理」意指有別於風險評估的過程，在考慮風險評估和其他合法因素，並在需要時選擇適當預防和管控方案，與利害關係者協商以權衡政策選擇；
13. 'risk communication' means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food	「風險溝通」意指風險評估者、風險管理者、消費者、飼料和食品業、學術界和其他利害方在整個風險分析過程中就危害和風險、風險相關因素和風險認知

²⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p.1)/ 在醫療器械上，修正及廢止若干指令及規章

businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;	進行資訊和意見的互動交流，包括對風險評估發現結果的解釋和風險管理決策的依據基礎；
14. 'hazard' means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;	「危害」意指可能在食品或飼料中存有對健康造成不利影響之生物、化學或物理因素，或環境條件；
15. 'traceability' means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;	「可追溯性」意指在生產、加工和運銷所有階段，對食品、飼料、供食用動物或欲供作或預期加入食品或飼料中物質之可追溯和追蹤能力；
16. 'stages of production, processing and distribution' means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;	「生產、加工和運銷階段」意指任何階段，包括食品進口、從(和包括)初級生產，直至(並包括)其儲存、運輸、銷售或供應給最終消費者，及相關之飼料進口、生產、製造、儲存、運輸、運銷、銷售和供應；
17. 'primary production' means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;	「初級生產」意指初級產品的生產、飼養或種植，包括採收、擠乳和畜養動物屠宰前的生產。亦包括狩獵和捕魚以及野生產品的收穫；
18. 'final consumer' means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.	「最終消費者」意指食物的最終消費者，不會再將之用於任何營業或活動。
CHAPTER II GENERAL FOOD LAW	第二章 通用食品法
<i>Article 4</i> Scope	<i>第4條</i> 範圍
1. This Chapter relates to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.	本章涉及食品生產、加工和配銷的所有階段，也涉及為食用動物生產的或飼餵的飼料。
2. The principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature to be followed when measures are taken.	第5條至第10條規定的原則，應構成採取措施時，橫向性質所遵循之總框架。
3. Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10.	現行食品法原則和程序，應盡快並最遲在2007年1月1日之前調整，以符合第5條至第10條規定。
4. Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 5 to 10.	在此之前，作為第2段規定的例外，現行立法應根據第5條至第10條規定的原則施行。
SECTION 1 GENERAL PRINCIPLES OF FOOD LAW	第 1 節 食品法之通則
<i>Article 5</i> General objectives	<i>第5條</i> 總體目標
1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.	食品法應追求對人類生命和健康以及消費者利益高標準保護的一個或多個總體目標，包括食品貿易中的公平實踐，酌情考量動物健康和福利、植物健康和環境之保護。
2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.	食品法應以實現按照本章通則和一般要求來生產或銷售之食品和飼料能在歐盟境內自由流通為目的。
3. Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate	如果國際標準已存在或即將完成，則在制定或修正食品法時應納入考慮，除非此類標準或相關規定對於實現食品法的合法目標或有科學依據而言，是無效或

objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community.	不適當的方式，或它們會導致與歐盟內部的酌情確定的保護程度有不同的情況。
Article 6 Risk analysis	第6條 風險分析
1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.	為了實現對人類健康和生命高標準保護的總體目標，食品法應以風險分析為基礎，除非這對具體情況或措施本質是不適切的。
2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.	風險評估應以現有科學證據為基礎，並以獨立、客觀和透明的方式進行。
3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.	風險管理應考慮風險評估的結果，特別是第22條所述的EFSA意見，及與第7(1)條規定的條件相關的考慮事項和預防原則等其他合法因素，以實現第5條確立的食品法總體目標。
▼ M9	
4. Risk communication shall fulfil the objectives and respect the general principles set out in Articles 8a and 8b. ◀ M9	風險溝通應履行第8a條規定的目標並尊重第8b條規定的一般原則。
Article 7 Precautionary principle	第7條 預防原則
1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.	在特定情況下對現有資訊進行評估後，辨識了但存有科學不確定性的對健康有害影響之可能性，有必要的採取臨時性風險管理措施，以確保在歐盟境內採行高標準的健康保護選項，等待進一步的科學資訊以進行更周全的風險評估。
2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.	以第1段為基礎採取的措施，應是相稱的，並且不得超過為實現歐盟高標準健康保護選項所要求的貿易限制，同時考慮到技術和經濟可行性和被認為在該問題上合法的其他因素。應根據已識別對生命或健康風險本質和澄清科學不確定性所需的科學資訊類型並導入更周全的風險評估，在合理的時間內對這些措施進行審查。
Article 8 Protection of consumers' interests	第8條 消費者利益之保護
1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:	食品法應以保護消費者利益為目標，並為消費者就其所消費的食品做出知情選擇提供依據。它應標的於預防：
(a) fraudulent or deceptive practices;	欺詐或欺騙行為；
(b) the adulteration of food; and	食品摻假；和
(c) any other practices which may mislead the consumer.	任何其他可能誤導消費者的做法。
▼ M9	
SECTION 1A RISK COMMUNICATION	第 1A 節 風險溝通
Article 8a Objectives of risk communication	第8a條 風險溝通之目標
Taking into account the respective roles of risk assessors and risk managers, risk communication shall pursue the following objectives:	考慮到風險評估者和風險管理者各自的角色，風險溝通應追求以下目標：

(a) raise awareness and understanding of the specific issues under consideration, including in cases of divergences in scientific assessment, during the entire risk analysis process;	在完整的風險分析過程中，包括在科學評估分歧的情況下，提高對正在考慮的具體議題的覺知和理解；
(b) ensure consistency, transparency and clarity in formulating risk management recommendations and decisions;	確保制定風險管理建議和決策的一致性、透明度和清晰度；
(c) provide a sound basis, including, where appropriate, a scientific basis, for understanding risk management decisions;	為理解風險管理決策提供合理的基礎，包括適當的科學基礎；
(d) improve the overall effectiveness and efficiency of the risk analysis;	提高風險分析的整體有效性和效率；
(e) foster public understanding of the risk analysis, including of the respective tasks and responsibilities of risk assessors and risk managers to enhance confidence in its outcome;	促進公眾對風險分析的理解，包括風險評估者和風險管理者各自的任務和責任，以增進對其成果的信心；
(f) ensure appropriate involvement of consumers, feed and food businesses, the academic community and all other interested parties;	確保消費者、飼料和食品業、學術界和所有其他利害方的適當參與；
(g) ensure appropriate and transparent exchange of information with interested parties in relation to risks associated with the food chain;	確保與相關利害方就與食物鏈相關風險進行適當和透明的資訊交換；
(h) ensure the provision of information to consumers about risk prevention strategies; and	確保對消費者有關風險預防策略的資訊提供；和
(i) contribute to the fight against the dissemination of false information and the sources thereof.	有助於打擊虛假資訊及其來源的傳播。
Article 8b	第8b條
General principles of risk communication	風險溝通之通則
Taking into account the respective roles of risk assessors and risk managers, risk communication shall:	考慮到風險評估者和風險管理者各自的角色，風險溝通應：
(a) ensure that accurate and all appropriate information is exchanged in an interactive and timely manner with all interested parties, based on the principles of transparency, openness, and responsiveness;	基於透明性、公開性和反應性原則，確保與所有利害方以互動和及時的方式交換準確和適當的所有資訊；
(b) provide transparent information at each stage of the risk analysis process from the framing of requests for scientific advice to the provision of risk assessment and the adoption of risk management decisions, including information on how risk management decisions were reached and which factors were considered;	在風險分析過程的每個階段提供透明的資訊，從提出科學建議請求之框架到提供風險評估和通過風險管理決策，包括如何達成風險管理決策以及考慮了哪些因素的資訊；
(c) take into account risk perceptions of all interested parties;	考慮所有利害方的風險認知；
(d) facilitate understanding and dialogue amongst all interested parties; and	促進所有利害方之間的理解和對話；和
(e) be clear and accessible, including to those not directly involved in the process or not having a scientific background, while duly respecting the applicable legal provisions on confidentiality and protection of personal data.	清晰及易懂，包括那些不直接參與過程或沒有科學背景的人，同時妥適尊重對個人數據保密和保護的適用法律規定。
Article 8c	第8c條
General plan for risk communication	對風險溝通之總體計畫
1. The Commission shall adopt, by means of implementing acts, a general plan for risk communication in order to achieve the objectives set out in Article 8a, in accordance with the general principles set out in Article 8b. The Commission shall keep that general plan updated, taking into account technical and scientific progress and experience gained. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2). When preparing those implementing acts, the Commission shall consult the Authority.	執委會應依據第8b條規定的通則，通過施行法案所制定的風險溝通總體計畫，以實現第8a條設定的目標。執委會應在考慮技術和科學進程和相關經驗值來持續更新該總體計畫。這些施行法案應按照第58(2)條規定的程序採行。在準備這些施行法案時，執委會應諮詢EFSA。
2. The general plan for risk communication shall promote an integrated risk communication framework to be followed both by the risk assessors and the risk managers in a coherent and systematic manner both at Union and national level. It shall:	風險溝通的總體計畫應促進風險評估者和風險管理者雙方，以連貫和系統性方式在歐盟和國家層級均遵循完整的風險溝通框架。它應：
(a) identify the key factors that need to be taken into account when considering the type and level of risk communication activities	當考慮所需風險溝通活動的類型和層級時，辨識所需考慮的關鍵因素；

needed;	
(b) identify the different types and levels of risk communication activities, and the appropriate main tools and channels to be used for risk communication purposes, taking into account the needs of relevant target audience groups;	考慮到相關目標受眾團體的需求，辨識風險溝通活動的不同類型和層級，和用於風險溝通目的的適當主要工具和管道；
(c) establish appropriate mechanisms of coordination and cooperation in order to strengthen coherence of risk communication amongst risk assessors and risk managers; and	建立適當的協調與合作機制，以強化風險評估者和風險管理者之間風險溝通的一致性；和
(d) establish appropriate mechanisms to ensure an open dialogue amongst consumers, food and feed businesses, the academic community and all other interested parties, and their appropriate involvement. ◀M9	建立適當的機制，以確保消費者、食品和飼料業、學術界和其他所有利害方間的公開對話以及他們的適當參與。
SECTION 2 PRINCIPLES OF TRANSPARENCY	
<i>Article 9</i> Public consultation	
There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.	第 2 節 透明原則 第 9 條 公眾諮詢 在食品法的制定、評估和修訂過程中，除非因事情的緊迫性外，應直接或通過代表機構進行公開和透明的公眾諮詢。
<i>Article 10</i> Public information	
Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.	第 10 條 公開資訊 在不影響關於獲取文件的歐盟和國家法律之適用規定下，如有合理理由懷疑食品或飼料可能存有對人類或動物健康風險時，則視該風險性質、嚴重性和程度，主管機關應採取適當步驟向公眾通報影響健康之風險性質，盡最大可能辨識風險可能存在的食品或飼料，或食品或飼料的類型，及為防止、減少或消除該風險而採取或即將採取的措施。
SECTION 3 GENERAL OBLIGATIONS OF FOOD TRADE	
<i>Article 11</i> Food and feed imported into the Community	
Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.	第 3 節 食品貿易之一般義務 第 11 條 進口到歐盟的食品和飼料 進口到歐盟並在歐盟境內上市的食品和飼料應符合食品法相關要求或歐盟認可至少相等效的條件，或在歐盟與出口國之間存有相關要求含在內的特定協議。
<i>Article 12</i> Food and feed exported from the Community	
1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.	第 12 條 從歐盟出口的食品和飼料 自歐盟出口或再出口供第三國上市的食品和飼料，應符合食品法相關要求，除非進口國主管機關另有要求或進口國規定的法律、規章、標準、規範及可能生效的其他法律和行政程序。
In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for	在其他情況下，除非是食品有害於健康或飼料不安全的例子，食品和飼料只有在目的地國主管機關明確表達同意，並在充分知悉食品或飼料無法在歐盟上市

which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.	的原因和狀況後，才能出口或再出口。
2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.	在適用歐盟或其一個會員國與第三國間締結的雙邊協定規定下，歐盟或該會員國向該第三國出口的食品和飼料應符合所締結的規定。
Article 13 International standards	第13條 國際標準
Without prejudice to their rights and obligations, the Community and the Member States shall:	在不損害權利和義務下，歐盟和會員國應：
(a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;	為制定食品和飼料國際技術標準及衛生和植物檢疫標準做出貢獻；
(b) promote the coordination of work on food and feed standards undertaken by international governmental and non-governmental organisations;	促進國際上政府和非政府組織開展食品和飼料標準工作的協調；
(c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures;	在相關和適當情況下，為制定對認可特定食品和飼料相關措施等效性的協議做出貢獻；
(d) give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries;	特別關注開發中國家的具體發展、金融和貿易需求，以確保國際標準不會對開發中國家的出口造成不必要的障礙；
(e) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced.	促進國際技術標準和食品法之間的一致性，同時確保歐盟採取的高標準保護不會降低。
SECTION 4 GENERAL REQUIREMENTS OF FOOD LAW	第 4 節 食品法之一般要求
Article 14 Food safety requirements	第14條 食品安全要求
1. Food shall not be placed on the market if it is unsafe.	不安全食品不應進入市場。
2. Food shall be deemed to be unsafe if it is considered to be:	下列情形被認為食品是不安全的：
(a) injurious to health;	對健康有害；
(b) unfit for human consumption.	不適合人類食用。
3. In determining whether any food is unsafe, regard shall be had:	在決定任何食品是否不安全時，應考慮到：
(a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and	在正常條件下的消費者食品消費和在生產、加工和配銷的每個階段，以及
(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.	提供給消費者的資訊，包括標籤資訊，或消費者通常可取得關於避免特定食品或食品類別對健康具特定不利影響的其他資訊。
4. In determining whether any food is injurious to health, regard shall be had:	在決定任何食品是否對健康有害時，應考慮到：
(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;	不只對可能食用該食物的人產生立即和/或短期和/或長期的健康影響，還可能對後代產生影響；
(b) to the probable cumulative toxic effects;	可能累積的毒性影響；
(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.	具特殊健康敏感性的特定消費者族群，欲對該類消費者所提供的食品。
5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination,	在決定任何食品是否不適合人類食用時，應考慮到該食品是否因污染(無論是外來物質或其他原因)，或由於腐

whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.	敗、變質或腐爛等原因，而不能按其預期用途供人食用。
6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.	如果任何不安全的食品是屬於同級或同類食品批次或託運貨物的部分，則應假定該批次或託運貨物的所有食品也是不安全的，除非經過詳細評估，沒有證據證明所餘批次或託運貨物是不安全。
7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.	就涉及所涵括的具體歐盟規定而言，符合關於食品安全的特定歐盟規定的食品，應被認為是安全的。
8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.	符合適用於該食品具體規定的食品，儘管有這種符合性，如果有理由懷疑食物是不安全的，不應阻止主管機關採取適當措施對其上市施加限制或要求從市場下架。
9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.	如果沒有具體的歐盟規定，當食品符合在會員國領土上銷售食品的國家食品法具體規定時，該食品應被視為是安全的，這些規定的制定和適用性，不影響條約，特別是其中的第28條和第30條。
Article 15 Feed safety requirements	第15條 飼料安全要求
1. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.	不安全的飼料不得上市或餵食任何食用動物。
2. Feed shall be deemed to be unsafe for its intended use if it is considered to:	下列情形被認為飼料用於預期用途是不安全的：
— have an adverse effect on human or animal health;	對人類或動物健康有不利影響；
— make the food derived from food-producing animals unsafe for human consumption.	會造成源自食用動物之供人食用的食品不安全。
3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.	若被辨識為不符合飼料安全要求的飼料是屬於同級或同類飼料批次或託運貨物的部分，則應假定該批次或託運貨物中所有飼料受影響，除非經過詳細評估，沒有證據證明所餘批次或託運貨物是不符合飼料安全要求。
4. Feed that complies with specific Community provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.	就涉及所涵括的具體歐盟規定而言，符合關於飼料安全的特定歐盟規定的飼料，應被認為是安全的。
5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.	符合適用於該飼料具體規定的飼料，儘管有這種符合性，如果有理由懷疑飼料是不安全的，不應阻止主管機關採取適當措施對其上市施加限制或要求從市場下架。
6. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.	如果沒有具體的歐盟規定，當飼料符合在會員國領土上銷售飼料的國家飼料法具體規定時，該飼料應被視為是安全的，這些規定的制定和適用性，不影響條約，特別是其中的第28條和第30條。
Article 16 Presentation	第16條 呈現
Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and	在不影響食品法更具體規定的情況下，食品或飼料的標籤、廣告和展示，包括產品形狀、外觀或包裝、所使用的包材、排列方式和展示設置，及透過任何

<p>the information which is made available about them through whatever medium, shall not mislead consumers.</p>	<p>媒體提供的產品資訊，不得誤導消費者</p>
<p>Article 17 Responsibilities</p>	<p>第17條 責任</p>
<p>1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.</p>	<p>食品和飼料業者在其所控制企業內的生產、加工和流通的所有階段，應當確保食品或飼料符合與其營運活動相關的食品法要求，並應驗證是否符合要求。</p>
<p>2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.</p>	<p>會員國應執行食品法，並監測和驗證食品及飼料業者在生產、加工和配銷的所有階段均滿足食品法的相關要求。</p>
<p>For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.</p>	<p>為此目的，他們應視情況維持官方管控和其他活動之系統，包括關於食品和飼料安全和風險的公眾溝通、食品和飼料安全監督和其他涵括生產、加工和配銷所有階段的監測活動。</p>
<p>Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.</p>	<p>會員國還應制定適用於違反食品及飼料法的措施和處罰規定。措施和處罰規定應是有效的、相稱的和具勸阻性的。</p>
<p>Article 18 Traceability</p>	<p>第18條 可追溯性</p>
<p>1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.</p>	<p>在生產、加工和配銷的所有階段應建立食品、飼料、食用動物和其他任何意欲或預期摻入食品或飼料的物質的可追溯性。</p>
<p>2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.</p>	<p>食品和飼料業者應能辨識任何向其提供食品、飼料、食用動物或任何意欲或預期摻入食品或飼料中物質的人。(可追溯性)</p>
<p>To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.</p>	<p>為此，此類業者應有相應的系統和程序，以允許一經要求即能提供此資訊給主管機關。</p>
<p>3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.</p>	<p>食品和飼料業者應有相應的系統和程序來辨識其產品所供應的其他企業。該資訊應一經要求即能提供給主管機關。(可追蹤性)</p>
<p>4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.</p>	<p>要上市或可能進入歐盟市場的食品或飼料，應按照更具體規定的相關要求，透過相關文件或資訊來進行充分標示或識別，以有助於其可追溯性。</p>
<p>5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).</p>	<p>可以依第58(2)條規定的程序，來通過在特定部門適用本條要求的規定。</p>
<p>Article 19 Responsibilities for food: food business operators</p>	<p>第19條 食品責任：食品業者</p>
<p>1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its</p>	<p>若食品業者認為或有理由相信其進口、生產、加工、製造或者銷售的食品不符合食品安全要求，應立即啟動從市場回收該食品的程序，其中對已脫離該初始食品業者直接控制的食物，要通知主管機關。產品可能已達消費者端，業者應有效並準確地通知消費者其回收原因，必要時，在其他措施不足以實現高標準</p>

<p>withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.</p>	<p>健康保護時，自消費者端召回已供應給他們的產品。</p>
<p>2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.</p>	<p>對不會影響食品包裝、標示、安全或完整性之負責零售或配銷活動的食品業者，應在各自活動範圍內，啟動將不符合食品安全要求的產品自市場回收的程序，並應與生產者、加工者、製造商和/或主管機關採取行動進行合作，藉由參與傳遞追蹤食品必要相關資訊，來為食品安全做出貢獻。</p>
<p>3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.</p>	<p>食品業者認為或有理由相信其上市食品可能危害人體健康，應立即通知主管機關。業者為防止對最終消費者的風險所採取的行動，應通知主管機關，並應不妨礙或阻止任何人按照國家法律和法律慣例與主管機關合作，以防止、減少或消除由食物產生的風險。</p>
<p>4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.</p>	<p>食品業者應與主管機關合作，採取措施來避免或降低其供應或已供應的食品所帶來的風險。</p>
<p><i>Article 20</i> Responsibilities for feed: feed business operators</p>	<p><i>第20條</i> 飼料責任：飼料業者</p>
<p>1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.</p>	<p>若飼料業者認為或有理由相信其進口、生產、加工、製造或者銷售的飼料不符合飼料安全要求，應立即啟動從市場回收該該飼料的程序，並通知主管機關。在這些情況下，或在第15(3)條的情況下，對不符合飼料安全要求的同批次或託運貨物應予銷毀，除非主管機關另有採認。業者應有效並準確地通知飼料用戶其回收原因，必要時，在其他措施不足以實現高標準健康保護時，自用戶端召回已供應的產品。</p>
<p>2. A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.</p>	<p>對不影響飼料包裝、標示、安全或完整性之負責零售或配銷活動的飼料業者，應在各自活動範圍內，啟動將不符合飼料安全要求的產品自市場回收的程序，並應與生產者、加工者、製造商和/或主管機關採取行動進行合作，並應藉由參與傳遞追蹤飼料必要相關資訊，來為食品安全做出貢獻。</p>
<p>3. A feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.</p>	<p>飼料業者認為或有理由相信其上市飼料可能不符合飼料安全要求，應立即通知主管機關。為防止使用該飼料引起的風險所採取的行動，應通知主管機關，並應不得妨礙或阻止任何人按照國家法律和法律慣例與主管機關合作，以防止、減少或消除由飼料產生的風險。</p>
<p>4. Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied.</p>	<p>飼料業者應與主管機關合作，採取措施來避免其供應或已供應的飼料所帶來的風險。</p>
<p><i>Article 21</i></p>	<p><i>第21條</i></p>

Liability	職責
The provisions of this Chapter shall be without prejudice to Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products ²⁶ .	本章規定應不影響1985年7月25日理事會85/374/EEC指令，對於會員國有關瑕疵產品責任之法律、法規和行政規定的相近似規定。
<p style="text-align: center;">CHAPTER III EUROPEAN FOOD SAFETY AUTHORITY</p>	<p style="text-align: center;">第三章 歐洲食品安全局(EFSA)</p>
<p style="text-align: center;">SECTION 1 MISSION AND TASKS</p>	<p style="text-align: center;">第 1 節 使命和任務</p>
<p style="text-align: center;"><i>Article 22</i> Mission of the Authority</p>	<p style="text-align: center;"><i>第22條</i> EFSA的使命</p>
1. A European Food Safety Authority, hereinafter referred to as the 'Authority', is hereby established.	特此成立歐洲食品安全局，以下簡稱「當局」。(譯註：為利閱讀，the Authority均以EFSA表示)
2. The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks.	(略，EFSA應對歐盟在食品和飼料安全領域有直接或間接影響之立法和政策提供科學建議和科學及技術支持，並應提供獨立資訊並進行風險溝通。)
3. The Authority shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market.	(略，EFSA應對人類生命和健康高標準保護、動物健康福利、植物健康和環境作出貢獻，並考慮到內部市場運作機制。)
4. The Authority shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.	(略，EFSA應蒐集和分析數據，以便對對食品和飼料安全有直接或間接影響的風險進行特徵描述和監測。)
5. The mission of the Authority shall also include the provision of:	(略，EFSA的使命)
(a) scientific advice and scientific and technical support on human nutrition in relation to Community legislation and, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme;	(略，與歐盟立法有關的人類營養科學建議和科學技術支持，並應執委會要求，支持關於營養議題之交流。)
(b) scientific opinions on other matters relating to animal health and welfare and plant health;	(略，提供與動物健康福利和植物健康相關的科學意見)
(c) scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC and without prejudice to the procedures established therein.	(略，提供2001/18/EC指令定義GMO食品和飼料以外產品的科學意見)
6. The Authority shall provide scientific opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission.	(略，EFSA應提供作為起草和通過歐盟措施科學依據之科學意見。)
7. The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.	(略，EFSA執行任務應具獨立性、意見和資訊具科學和技術品質、程序和作業方式具透明度等。)
▼ M9	
It shall act in close cooperation with the competent bodies in the Member States that carry out similar tasks to those of the Authority and, where appropriate, with the relevant Union agencies. ◀ M9	(略，應和執行與EFSA類似任務的會員國主管機構及相關歐盟機構密切合作)
8. The Authority, Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.	(略，EFSA、執委會和會員國應在風險評估、風險管理和風險溝通之間合作以達有效的連貫性。)
9. The Member States shall cooperate with the Authority to ensure the accomplishment of its mission.	(略，會員國應與EFSA合作以確保達成使命。)

26 OJ L 210, 7.8.1985, p. 29. Directive as last amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20).

Article 23 Tasks of the Authority	第23條 EFSA之任務
The tasks of the Authority shall be the following:	(略，EFSA的任務)
(a) to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission;	(略，在與歐盟立法及其使命任何問題相關的所有情況下，向歐盟機構和會員國提供最佳科學意見)
(b) to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission;	(略，促進和協調一致的風險評估方法)
(c) to provide scientific and technical support to the Commission in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions;	(略，提供執委會科學和技術支持，並應要求在解釋和考慮風險評估意見時，提供科學和技術支持)
(d) to commission scientific studies necessary for the accomplishment of its mission;	(略，委託完成必要的科學研究)
(e) to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission;	(略，搜尋、收集、彙整、分析和歸納科學和技術數據)
(f) to undertake action to identify and characterise emerging risks, in the fields within its mission;	(略，採取行動以識別和描述新興風險)
(g) to establish a system of networks of organisations operating in the fields within its mission and be responsible for their operation;	(略，建立組織網絡運作系統並對其運作負責)
(h) to provide scientific and technical assistance, when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed;	(略，應執委會要求，在執委會實施食品和飼料安全危機管理程序中提供科學和技術支援)
(i) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Community, applicant countries, international organisations and third countries, in the fields within its mission;	(略，在執委會要求時提供科學和技術支援，以改善歐盟、申請國、國際組織和第三國間的合作)
(j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;	(略，確保公眾和利害關係者獲得快速、可靠、客觀和可理解的資訊)
(k) to express independently its own conclusions and orientations on matters within its mission;	(略，在任務範圍相關事務上，能獨立表達自身的結論和方向)
(l) to undertake any other task assigned to it by the Commission within its mission.	(略，承擔執委會賦予的其他任何任務)
SECTION 2 ORGANISATION	第 2 節 組織
Article 24 Bodies of the Authority	第24條 EFSA機構
The Authority shall comprise:	EFSA應由下列組成：
(a) a Management Board;	1個管理委員會；
(b) an Executive Director and his staff;	1位執行長及其職員；
(c) an Advisory Forum;	1個諮詢論壇；
(d) a Scientific Committee and Scientific Panels.	1個科學委員會和科學小組。
Article 25 Management Board	第 25 條 管理委員會
▼ M9	
1. Each Member State shall nominate a member and an alternate member as its representatives to the Management Board. The members and alternate members thus nominated shall be appointed by the Council and have the right to vote.	每個會員國應提名1位委員和1位候補委員為其管理委員會代表。受提名的委員和候補委員由理事會任命，並具表決投票權。
1a. In addition to members and alternate members referred to in paragraph 1, the Management Board shall include:	除第1段提及的委員和候補委員外，管理委員會應包括：
(a) two members and two alternate members appointed by the	由執委會任命具投票權的2名委員和2名

Commission as its representatives, with the right to vote;	候補委員；
(b) two members appointed by the European Parliament, with the right to vote;	由歐洲議會任命具投票權的2名委員；
(c) four members and four alternate members with the right to vote as representatives of civil society and food chain interests, namely one member and one alternate member from consumer organisations, one member and one alternate member from environmental non-governmental organisations, one member and one alternate member from farmers organisations, and one member and one alternate member from industry organisations.	作為公民社會和食物鏈利害關係者代表具投票權的4名委員和4名候補委員，分別來自消費者組織、環境非政府組織、農民組織和產業組織各1名委員和1名候補委員。
The members and alternate members referred to in point (c) of the first subparagraph shall be appointed by the Council in consultation with the European Parliament on the basis of a list which shall be drawn up by the Commission and sent to the Council. The list shall include more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament by the Council, together with the relevant background documents. As quickly as possible and at the latest within three months of the receipt of that list, the European Parliament may submit its views for consideration to the Council which shall then appoint those members.	第1小段(c)點中提及的委員和候補委員應由理事會在按執委會擬定並送交理事會的名單，在經與歐洲議會磋商後任命。名單應多於要填補的職位。執委會擬定名單應連同相關背景文件由理事會提交歐洲議會。盡快並最遲在收到名單後3個月內，歐洲議會可將意見提交理事會審議，然後由理事會任命那些委員。
1b. The members and the alternate members of the Management Board shall be nominated and appointed on the basis of their relevant experience and expertise in the field of food chain law and policy, including risk assessment, whilst ensuring that there is relevant expertise in the fields of managerial, administrative, financial and legal matters within the Management Board.	管理委員會委員和候補委員應根據其在食品鏈法律和政策領域的相關經驗和專業知識，包括風險評估，進行提名和任命，同時確保在管理委員會內的相關管理、行政、財務和法律事務等領域具有相關專業。
2. The term of office of members and alternate members shall be four years and may be renewed. However, the term of office of the members and alternate members referred to in point (c) of the first subparagraph of paragraph 1a may be renewed only once. ◀M9	委員和候補委員任期4年並可連任。但第1a段第1小段(c)點所述的委員和候補委員只能連任1次。
3. The Management Board shall adopt the Authority's internal rules on the basis of a proposal by the Executive Director. These rules shall be made public.	管理委員會應依執行長的提議通過EFSA內部規定。這些規定應予公開。
4. The Management Board shall elect one of its members as its Chair for a two-year period, which shall be renewable.	管理委員會應選舉1名委員擔任主席，任期2年並可連任。
5. The Management Board shall adopt its rules of procedure.	管理委員會應通過其議事規則。
▼ M9	
Unless otherwise provided, the Management Board shall act by a majority of its members. Alternate members shall represent the members in their absence and vote on their behalf. ◀M9	除非另有規定，管理委員會應以多數決運作。候補委員應在委員缺席時代表委員行使投票權。
6. The Management Board shall meet at the invitation of the Chair or at the request of at least a third of its members.	管理委員會應在主席邀請或至少1/3委員要求下召開會議。
7. The Management Board shall ensure that the Authority carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation.	管理委員會應確保EFSA在本規章規定條件下履行其使命並完成賦予任務。
8. Before 31 January each year, the Management Board shall adopt the Authority's programme of work for the coming year. It shall also adopt a revisable multi-annual programme. The Management Board shall ensure that these programmes are consistent with the Community's legislative and policy priorities in the area of food safety.	每年1月31日前，管理委員會應通過EFSA次年度的工作計畫。它還應採用可修訂的多年度計畫。管理委員會應確保這些計畫符合歐盟在食品安全領域的立法和政策重點。
Before 30 March each year, the Management Board shall adopt the general report on the Authority's activities for the previous year.	每年3月30日前，管理委員會應採納EFSA前一年度活動的綜合報告。
▼ M1	
9. The financial rules applicable to the Authority shall be adopted by the Management Board after the Commission has been consulted. They may not depart from Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies	適用於EFSA的財務規則應在與執委會磋商後由管理委員會通過。他們可以在不背離2002年11月19日執委會規章(EC, Euratom) No 2343/2002 關於適用歐盟

referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities ²⁷ unless such departure is specifically required for the Authority's operation and the Commission has given its prior consent. ◀M1	總預算的理事會規章(EC, Euratom) No 1605/2002第185條中所述的機構財務規章框架，除非此等偏離是EFSA運作特別需要的，並且執委會已事先同意。
10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat. The Management Board shall invite the Chair of the Scientific Committee to attend its meetings without voting rights.	執行長應參加管理委員會會議，但無表決權，並應告知秘書處。管理委員會應邀請科學委員會主席出席會議，但無表決權。
Article 26 Executive Director	第26條 執行長
1. The Executive Director shall be appointed by the Management Board, on the basis of a list of candidates proposed by the Commission after an open competition, following publication in the <i>Official Journal of the European Communities</i> and elsewhere of a call for expressions of interest, for a period of five years which shall be renewable. Before appointment the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and answer questions put by members of this institution. The Executive Director may be removed from office by a majority of the Management Board.	執行長應以執委會在公開徵選後所提名的候選人名單為基礎，由管理委員會任命，並公布在歐盟官方公報和其他公開徵集意向書上，任期5年並得連任。管理委員會在任命前，應無延誤的邀請提名候選人在歐洲議會上發表聲明並回答該機構成員提出的問題。執行長可由管理委員會多數決予以免職。
2. The Executive Director shall be the legal representative of the Authority and shall be responsible for:	執行長應是EFSA的法定代表人，並應負責：
(a) the day-to-day administration of the Authority;	EFSA的日常行政管理；
(b) drawing up a proposal for the Authority's work programmes in consultation with the Commission;	與執委會諮商擬定EFSA工作計畫的提案；
(c) implementing the work programmes and the decisions adopted by the Management Board;	施行管理委員會通過的工作計畫和決定；
(d) ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee and the Scientific Panels;	確保對科學委員會和科學小組提供適當的科學、技術和行政支持；
(e) ensuring that the Authority carries out its tasks in accordance with the requirements of its users, in particular with regard to the adequacy of the services provided and the time taken;	確保EFSA按照其用戶的要求執行其任務，特別是在關於所提供服務和所用時間的充分性；
▼ M1	
(f) the preparation of the Authority's draft statement of estimates of revenue and expenditure, and the execution of its budget; ◀M1	編列EFSA收支概算表草案，並執行預算；
(g) all staff matters;	所有員工事務；
(h) developing and maintaining contact with the European Parliament, and for ensuring a regular dialogue with its relevant committees.	發展和保持與歐洲議會的聯繫，並確保與相關委員會進行定期對話。
▼ M1	
3. Each year, the Executive Director shall submit to the Management Board for approval:	執行長應每年提交下列資料給管理委員會批准：
(a) a draft general report covering all the activities of the Authority in the previous year;	涵括EFSA前年度所有活動的綜合報告草案；
(b) draft programmes of work.	工作計畫草案。
The Executive Director shall, following adoption by the Management Board, forward the programmes of work to the European Parliament, the Council, the Commission and the Member States, and shall have them published.	執行長應在管理委員會通過後隨即將工作計畫遞交至歐洲議會、理事會、執委會和會員國，並應予以公布。
The Executive Director shall, following adoption by the Management Board and by 15 June, forward the Authority's general report to the European Parliament, the Council, the Commission, the Court of	執行長應於管理委員會通過後，在6月15日前遞交EFSA綜合性報告至歐洲議會、理事會、執委會、審計院、歐洲經

27 OJ L 357, 31.12.2002, p. 72; corrigendum in OJ L 2, 7.1.2003, p.39.

<p>Auditors, the European Economic and Social Committee and the Committee of the Regions, and shall have it published.</p>	<p>濟和社會委員會和地區委員會，並應予以公布。</p>
<p>The Executive Director shall forward annually to the budgetary authority all information relevant to the outcome of the evaluation procedures.</p>	<p>執行長應每年向預算主管機關提交與評估程序結果相關的所有資訊。</p>
<p>◀M1</p>	
<p>Article 27 Advisory Forum</p>	<p>第27條 諮詢論壇</p>
<p>1. The Advisory Forum shall be composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority, on the basis of one representative designated by each Member State. Representatives may be replaced by alternates, appointed at the same time.</p>	<p>諮詢論壇應由會員國主管機構的代表組成，他們承擔與EFSA類似的任務，每個會員國指定1名代表。代表可由同時任命的候補者代替。</p>
<p>2. Members of the Advisory Forum may not be members of the Management Board.</p>	<p>諮詢論壇的成員可以不是管理委員會的委員。</p>
<p>3. The Advisory Forum shall advise the Executive Director in the performance of his duties under this Regulation, in particular in drawing up a proposal for the Authority's work programme. The Executive Director may also ask the Advisory Forum for advice on the prioritisation of requests for scientific opinions.</p>	<p>諮詢論壇應就執行長依本規章履行職責情況下，特別是在起草EFSA工作計畫提案時提供建言。執行長還可就科學意見請求的優先順序向諮詢論壇徵求意見。</p>
<p>4. The Advisory Forum shall constitute a mechanism for an exchange of information on potential risks and the pooling of knowledge. It shall ensure close cooperation between the Authority and the competent bodies in the Member States in particular on the following items:</p>	<p>諮詢論壇應就潛在風險和知識匯集之資訊交換上構成一個機制。它應確保在EFSA和會員國主管機構間的密切合作，特別是在下列項目：</p>
<p>(a) avoidance of duplication of the Authority's scientific studies with Member States, in accordance with Article 32;</p>	<p>依據第32條，避免EFSA與會員國的科學研究重複；</p>
<p>(b) in those circumstances identified in Article 30(4), where the Authority and a national body are obliged to cooperate;</p>	<p>在第30(4)條確定的情況下，EFSA和國家機構有義務進行合作；</p>
<p>(c) in the promoting of the European networking of organisations operating within the fields of the Authority's mission, in accordance with Article 36(1);</p>	<p>依據第36(1)條，促進在EFSA任務領域內運作組織的歐洲網絡；</p>
<p>(d) where the Authority or a Member State identifies an emerging risk.</p>	<p>EFSA或會員國發現新興風險時。</p>
<p>5. The Advisory Forum shall be chaired by the Executive Director. It shall meet regularly at the invitation of the Chair or at the request of at least a third of its members, and not less than four times per year. Its operational procedures shall be specified in the Authority's internal rules and shall be made public.</p>	<p>諮詢論壇應由執行長主持。應在主席邀請或至少1/3成員要求下定期召開會議，每年不少於4次。其操作程序應訂於EFSA內部規則並公開。</p>
<p>6. The Authority shall provide the technical and logistic support necessary for the Advisory Forum and provide the Secretariat for its meetings.</p>	<p>EFSA應為諮詢論壇提供必要的技術和後勤支持，並將辦理會議通知秘書處。</p>
<p>7. Representatives of the Commission's departments may participate in the work of the Advisory Forum. The Executive Director may invite representatives of the European Parliament and from other relevant bodies to take part.</p>	<p>執委會各部門代表可以參加諮詢論壇的工作。執行長可邀請歐洲議會和其他相關機構代表參加。</p>
<p>Where the Advisory Forum discusses the matters referred to in Article 22(5)(b), representatives from competent bodies in the Member States which undertake tasks similar to those referred to in Article 22(5)(b) may participate in the work of the Advisory Forum, on the basis of one representative designated by each Member State.</p>	<p>當諮詢論壇討論第22(5)(b)條所述的事項時，承擔與第22(5)(b)條所述類似任務的會員國主管機構，可以由每個會員國指定1名代表參加諮詢論壇。</p>
<p>Article 28 Scientific Committee and Scientific Panels</p>	<p>第28條 科學委員會和科學小組</p>
<p>1. The Scientific Committee and permanent Scientific Panels shall be responsible for providing the scientific opinions of the Authority, each within their own spheres of competence, and shall have the possibility, where necessary, of organising public hearings.</p>	<p>科學委員會和常設科學小組應負責在各自的職權範圍內，提供EFSA科學意見，並應有可能在必要時辦辦公聽會。</p>

<p>2. The Scientific Committee shall be responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonisation of working methods. It shall provide opinions on multisectoral issues falling within the competence of more than one Scientific Panel, and on issues which do not fall within the competence of any of the Scientific Panels.</p>	<p>科學委員會應負責為確保科學意見程序的一致性，進行所必需的總體協調，特別是關於工作程序的採行和工作方法的協調。它應就屬於多個科學小組職權範圍內的跨部門問題以及不屬於任何一個科學小組職權範圍的問題提供意見。</p>
<p>Where necessary, and particularly in the case of subjects which do not fall within the competence of any of the Scientific Panels, the Scientific Committee shall set up working groups. In such cases, it shall draw on the expertise of those working groups when establishing scientific opinions.</p>	<p>必要時，特別是在不屬於任何科學小組權限範圍內的主題情況，科學委員會應成立工作小組。在此類情況下，它應在建立科學意見時，應用那些工作小組的專業。</p>
<p>3. The Scientific Committee shall be composed of the Chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the Scientific Panels.</p>	<p>科學委員會由科學小組主席和6名不隸屬任何科學小組的獨立科學專家組成。</p>
<p>4. The Scientific Panels shall be composed of independent scientific experts. When the Authority is established, the following Scientific Panels shall be set up:</p>	<p>科學小組應由獨立科學專家組成。當EFSA成立時，應設立下列科學小組：</p>
<p>▼ M6</p>	
<p>(a) the Panel on food additives and flavourings; ◀ M6</p>	<p>食品添加劑和調味劑小組；</p>
<p>(b) the Panel on additives and products or substances used in animal feed;</p>	<p>使用於動物飼料之添加劑和產品或物質小組；</p>
<p>▼ M2</p>	
<p>(c) the Panel on plant protection products and their residues; ◀ M2</p>	<p>植物保護產品及其殘留物小組；</p>
<p>(d) the Panel on genetically modified organisms;</p>	<p>GMO小組；</p>
<p>▼ M6</p>	
<p>(e) the Panel on nutrition, novel foods and food allergens; ◀ M6</p>	<p>營養、新興食品 and 食品過敏原小組；</p>
<p>(f) the Panel on biological hazards;</p>	<p>生物危害小組；</p>
<p>(g) the Panel on contaminants in the food chain;</p>	<p>食物鏈污染物小組；</p>
<p>(h) the Panel on animal health and welfare;</p>	<p>動物健康和福利小組；</p>
<p>▼ M2</p>	
<p>(i) the Panel on plant health; ◀ M2</p>	<p>植物健康小組；</p>
<p>▼ M6</p>	
<p>(j) the Panel on food contact materials and enzymes and processing aids. ◀ M6</p>	<p>食品接觸材料和酵素和加工助劑小組。</p>
<p>▼ M8</p>	
<p>The Commission is empowered to adopt delegated acts in accordance with Article 57a amending the first subparagraph as regards the number and names of the Scientific Panels, in the light of technical and scientific development, at the Authority's request. ◀ M8</p>	<p>鑑於技術和科學發展，執委會有權應EFSA要求，依據第57a條通過授權法案，對第1小段的科學小組人數和名稱進行修正。</p>
<p>▼ M9</p>	
<p>5. The members of the Scientific Committee who are not members of the Scientific Panels and the members of the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a five-year term of office, which may be renewed, following publication of a call for expression of interest in the <i>Official Journal of the European Union</i>, in relevant leading scientific publications and on the Authority's website. The Authority shall publish such a call for expression of interest after having informed the Member States about the necessary criteria and fields of expertise.</p>	<p>非科學小組成員的科學委員會成員和科學小組成員，應由管理委員會依執行長提案進行任命，任期5年可連任，隨後在歐盟官方公報、相關領先科學出版物和在EFSA網站上發布意向書。EFSA應在向會員國通報必要的標準和專業領域後發布此類意向書。</p>
<p>The Member States shall:</p>	<p>會員國應：</p>
<p>(a) publish the call for expression of interest on the websites of their competent authorities and of their competent bodies which undertake tasks similar to those of the Authority;</p>	<p>在其主管機關及承擔與EFSA類似任務機構的網站上公開徵集意向書；</p>
<p>(b) inform relevant scientific organisations located on their territory;</p>	<p>通知領土內相關科學組織；</p>

(c) encourage potential candidates to apply; and	鼓勵潛在候選人提出申請；和
(d) take any other appropriate measures to support the call for expression of interest.	採取任何其他適當措施來支持意向書。
5a. The members of the Scientific Committee who are not members of Scientific Panels and the members of the Scientific Panels shall be selected and appointed in accordance with the following procedure:	非科學小組成員的科學委員會成員和科學小組成員應依下列程序選擇及任命：
(a) on the basis of the applications received to a call for expression of interest, the Executive Director shall draw up a draft list of suitable candidates including at least twice the number of candidates necessary to fill the posts in the Scientific Committee and the Scientific Panels and send the draft list to the Management Board, indicating the specific multidisciplinary expertise needed in each Scientific Panel;	執行長應根據收到的意向書申請，起草一份適合的候選人名單稿，包括至少兩倍的所需填補科學委員會和科學小組職位候選人人數，並送交至管理委員會，說明每一個科學小組需要的特定多學科專業；
(b) on the basis of that draft list, the Management Board shall appoint the members of the Scientific Committee who are not members of the Scientific Panels and the members of the Scientific Panels and draw up the reserve list of candidates for the scientific Committee and the Scientific Panels;	管理委員會應根據該名單稿，任命非科學小組成員的科學委員會委員和科學小組成員，並擬定科學委員會和科學小組的候選人保留名單；
(c) the selection procedure and the appointments of the members of the Scientific Committee who are not members of the Scientific Panels and the members of the Scientific Panels shall be made on the basis of the following criteria:	非科學小組成員的科學委員會委員和科學小組成員的遴選程序和任命應根據以下標準辦理：
(i) a high level of scientific expertise;	高水準的科學專業；
(ii) independence and absence of conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementation of that policy in respect of the members of the Scientific Panels;	根據第37(2)條和EFSA獨立政策及該政策對科學小組成員的執行情況的獨立性和不存在利益衝突；
(iii) meeting the needs for the specific multi-disciplinary expertise of the Scientific Panel to which they will be appointed and the applicable language regime;	符合他們將被任命的科學小組特定多學科專業和適用語言體系之需求；
(d) where candidates have equivalent scientific expertise, the Management Board shall ensure that the broadest possible geographical distribution is achieved in the appointments.	候選人具有等同科學專長時，管理委員會應確保在任用時盡量達到廣泛的地域分佈。
5b. When the Authority identifies that specific expertise is missing in one or several Scientific Panels, the Executive Director shall propose to the Management Board, in accordance with the procedure laid down in paragraphs 5 and 5a, the appointment of additional members of the relevant Scientific Panels.	當EFSA發現一個或多個科學小組缺少特定專業時，執行長應根據第5和第5a段規定程序，向管理委員會提議任命相關科學小組的其他成員。
5c. The Management Board shall adopt, on the basis of a proposal of the Executive Director, rules on the detailed organisation and timing of the procedures set up in paragraphs 5a and 5b.	管理委員會應根據執行長的提議，通過第5a和第5b段對於詳細組織和時間安排程序之規定。
5d. Member States and employers of the members of the Scientific Committee and of the Scientific Panels shall refrain from giving those members, or the external experts participating in the working groups of the Scientific Committee or the Scientific Panels, any instruction which is incompatible with the individual tasks of those members and experts, or with the tasks, responsibilities and independence of the Authority.	科學委員會和科學小組成員所屬會員國和雇主，應避免對這些成員或參加科學委員會或科學小組工作組的外部專家，提供與個別任務或與EFSA任務、責任和獨立性不相符的任何指示。
5e. The Authority shall support the tasks of the Scientific Committee and Scientific Panels by organising their work, in particular the preparatory work to be undertaken by the Authority's staff or by designated national scientific organisations referred to in Article 36, including by organising the possibility for preparing scientific opinions to be peer-reviewed by the Scientific Panels before they adopt them.	EFSA應通過組織其工作來支持科學委員會和科學小組的任務，特別是由EFSA職員或由第36條所述的指定國家科學組織進行的準備工作，包括藉由組織準備可能供在科學小組採納意見之前進行同行評審。
5f. Each Scientific Panel shall include a maximum of 21 members.	每個科學小組應至多為21名成員。
5g. Members of Scientific Panels shall have access to comprehensive training on the risk assessment. ◀M9	科學小組成員應獲得關於風險評估的全面性培訓。
6. The Scientific Committee and the Scientific Panels shall each choose	科學委員會和科學小組應各自從成員中

a Chair and two Vice-Chairs from among their members.	選出1位主席和2位副主席。
7. The Scientific Committee and the Scientific Panels shall act by a majority of their members. Minority opinions shall be recorded.	科學委員會和科學小組應行多數決。少數意見應被記錄在案。
8. The representatives of the Commission's departments shall be entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.	執委會各部門代表應有權出席科學委員會、科學小組及其工作組的會議。若被邀請出席，他們可以協助澄清或提供資訊，但不得試圖影響討論。
9. The procedures for the operation and cooperation of the Scientific Committee and the Scientific Panels shall be laid down in the Authority's internal rules.	科學委員會和科學小組的運作和合作程序應制定於EFSA內部規則中。
These procedures shall relate in particular to:	這些程序應特別論及：
(a) the number of times that a member can serve consecutively on a Scientific Committee or Scientific Panel;	成員可在科學委員會或科學小組中連續任職之次數；
▼ M9	
(b) the number of members in each Scientific Panel but no more than the maximum number provided for in paragraph 5f; ◀M9	每個科學小組之成員數，但不超過第5f段規定的最大數；
(c) the procedure for reimbursing the expenses of members of the Scientific Committee and the Scientific Panels;	科學委員會和科學小組成員報銷費用之程序；
(d) the manner in which tasks and requests for scientific opinions are assigned to the Scientific Committee and the Scientific Panels;	將科學意見的任務和請求分配給科學委員會和科學小組之方式；
(e) the creation and organisation of the working groups of the Scientific Committee and the Scientific Panels, and the possibility of external experts being included in those working groups;	科學委員會和科學小組工作組之創建和組織，以及外部專家被納入這些工作組之可能性；
(f) the possibility of observers being invited to meetings of the Scientific Committee and the Scientific Panels;	觀察員被邀請參加科學委員會和科學小組會議之可能性；
(g) the possibility of organising public hearings.	辦辦公聽會之可能性。
SECTION 3 OPERATION	第 3 節 運作
<i>Article 29</i> Scientific opinions	<i>第29條</i> 科學意見
1. The Authority shall issue a scientific opinion:	EFSA應發表科學意見：
(a) at the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Authority to be consulted;	應執委會在使其使命範圍內任何事項之要求，以及在歐盟立法規定諮詢EFSA之所有情況時；
(b) on its own initiative, on matters falling within its mission.	對其使命範圍內的事務，主動提出。
The European Parliament or a Member State may request the Authority to issue a scientific opinion on matters falling within its mission.	歐洲議會或會員國可要求EFSA就其使命範圍內的事項發表科學意見。
2. Requests referred to in paragraph 1 shall be accompanied by background information explaining the scientific issue to be addressed and the Community interest.	第1段所述的請求應附有背景資訊來說明待解決的科學爭議和歐盟利益。
3. Where Community legislation does not already specify a time limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time limit specified in the requests for opinions, except in duly justified circumstances.	在歐盟立法未對科學意見發表時限有規定時，EFSA應在徵求意見書中所規定時限內發表科學意見，除非有正當理由。
4. Where different requests are made on the same issues or where the request is not in accordance with paragraph 2, or is unclear, the Authority may either refuse, or propose amendments to a request for an opinion in consultation with the institution or Member State(s) that made the request. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.	在對相同爭議有不同請求提出時，或請求未依第2段提出或不明確時，EFSA可以拒絕，或與提出請求之機構或會員國協商對徵求意見的請求進行修改。拒絕的理由應提供給提出請求之機構或會員國。
5. Where the Authority has already delivered a scientific opinion on the specific topic in a request, it may refuse the request if it concludes there are no new scientific elements justifying the re-examination. Justifications	在EFSA已就請求中的特定主題提供了科學意見時，若認為沒有新科學因素證明

for the refusal shall be given to the institution or Member State(s) that made the request.	再次審查之合理性，則可以拒絕該請求。拒絕的理由應提供給提出請求之機構或會員國。
▼ M8	
6. In order to apply this Article, the Commission after consulting the Authority shall adopt:	為適用本條，執委會在諮詢EFSA後應採取：
(a) delegated acts in accordance with Article 57a in order to supplement this Regulation by establishing the procedure to be applied by the Authority to the requests for a scientific opinion;	依第57a條授權法規，以建立EFSA對科學意見請求之適用程序來補充本規章；
(b) implementing acts laying down the guidelines governing the scientific evaluation of substances, products or processes which are subject, under Union legislation, to a system of prior authorisation or entry on a positive list, in particular where Union legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2). ◀M8	制定對管理物質、產品或工序之科學評估指導方針的施行法案，依據歐盟立法，它們須經事先授權或列入正面表列，特別是在歐盟立法規定或授權的情況下，申請人為之目的提交的檔案。那些施行法案應依據第58(2)條所述程序通過。
7. The Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.	EFSA的內部規定應指定對科學意見的格式、解釋背景和發表的要求。
<i>Article 30</i> Diverging scientific opinions	<i>第30條</i> 科學異見
1. The Authority shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.	EFSA應保持警惕，以便及早發現它的科學意見與其他執行類似任務機構發表科學意見間之任何潛在歧異來源。
2. Where the Authority identifies a potential source of divergence, it shall contact the body in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.	在EFSA辨識出潛在歧異來源時，它應與相關機構聯繫來確保共享所有相關科學資訊並用以辨識潛在有爭議的科學問題。
3. Where a substantive divergence over scientific issues has been identified and the body in question is a Community agency or one of the Commission's Scientific Committees, the Authority and the body concerned shall be obliged to cooperate with a view to either resolving the divergence or presenting a joint document to the Commission clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.	在科學問題上發生實質性分歧且有意見機構為歐盟機構或執委會其中的科學委員會時，EFSA和相關機構應有義務合作解決分歧或向執委會提交合署文件來澄清有爭議的科學問題並識別數據中的相關不確定性。該份文件應予公開。
4. Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.	在科學問題上發現實質性分歧且有意見機構為會員國機構時，EFSA和國家機構應有義務合作解決分歧或準備合署文件來澄清有爭議的科學問題並識別數據中的相關不確定性。該份文件應予公開。
<i>Article 31</i> Scientific and technical assistance	<i>第31條</i> 科學和技術援助
1. The Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles which does not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular assistance to the Commission for the establishment or evaluation of technical criteria and also assistance to the Commission in the development of technical guidelines.	EFSA可在執委會要求下就其任務範圍內的任何領域提供科學或技術援助。提供科學和技術援助的任務應包括科學或技術工作，其涉及無需科學委員會或科學小組進行科學評估的已成熟科學或技術原理之應用。此類工作可能包括特別協助執委會建立或評估技術標準，以及協助執委會制定技術指引。
2. Where the Commission refers a request for scientific or technical assistance to the Authority, it shall specify, in agreement with the Authority, the time limit within which the task must be completed.	在執委會向EFSA提出科學或技術援助請求時，應與EFSA達成協議情形下，指定必須完成工作之時限。

<p style="text-align: center;">Article 32 Scientific studies</p> <p>1. Using the best independent scientific resources available, the Authority shall commission scientific studies necessary for the performance of its mission. Such studies shall be commissioned in an open and transparent fashion. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.</p> <p>2. The Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.</p>	<p style="text-align: center;">第32條 科學研究</p> <p>EFSA應委託所必需的科學研究來履行其任務，以使用可用的最佳獨立科學資源。此類研究應以公開和透明的方式進行委託。EFSA應設法避免與會員國或歐盟研究計畫重複，並應通過適當的協調促進合作。</p> <p>EFSA應通知歐洲議會、執委會和會員國其科學研究結果。</p>
<p>▼ M9</p> <p style="text-align: center;">Article 32a Pre-submission advice</p> <p>1. Where Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion, the staff of the Authority shall, at the request of a potential applicant or notifier, provide advice on the rules applicable to, and the content required for, the application or notification, prior to its submission. Such advice provided by the staff of the Authority shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Scientific Panels. The staff of the Authority providing the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice.</p> <p>2. The Authority shall publish general guidance on its website regarding the rules applicable to, and the content required for, applications and notifications, including, where appropriate, general guidance on the design of required studies.</p>	<p style="text-align: center;">第32a條 提交前建議</p> <p>歐盟法律包含對EFSA提供科學產出（包括科學意見）的規定時，EFSA員工對於潛在申請者或通知者的詢問，應在其提交申請或通知前，就申請或通知適用規定和所需的內容提供建議。EFSA員工提供的此類建議應不影響和不承諾後續科學小組所進行之任何申請或通知評估。提供建議的EFSA員工應不得參與與所建議主題之申請或通知直接或間接相關的任何科學或技術準備工作。</p> <p>EFSA應在其網站上發布關於申請和通知適用規定和所需內容的一般指引，在適當情況下，包括所需研究設計的一般指引。</p>
<p style="text-align: center;">Article 32b Notification of studies</p> <p>1. The Authority shall establish and manage a database of studies commissioned or carried out by business operators to support an application or notification in relation to which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion.</p> <p>2. For the purposes of paragraph 1, business operators shall, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.</p> <p>3. For the purposes of paragraph 1, laboratories and other testing facilities located in the Union shall also, without delay, notify the Authority of the title and the scope of any study commissioned by business operators and carried out by such laboratories or other testing facilities to support an application or a notification, its starting and planned completion dates, as well as the name of the business operator who commissioned such a study.</p> <p>This paragraph shall also apply, <i>mutatis mutandis</i>, to laboratories and other testing facilities located in third countries insofar as set out in relevant agreements and arrangements with those third countries, including as referred to in Article 49.</p> <p>4. An application or notification shall not be considered valid or admissible where it is supported by studies that have not been previously notified in accordance with paragraph 2 or 3, unless the applicant or notifier provides a valid justification for the non-notification of such</p>	<p style="text-align: center;">第32b條 研究之通知</p> <p>EFSA應建立和管理由業者委託或辦理的研究資料庫，以支持對於歐盟法律規定EFSA提供科學產出(包括科學意見)有關的申請或通知。</p> <p>就第1段而言，業者應無延遲地將其委託或辦理的任何研究主題和範圍，以及執行該研究的實驗室或檢測機構和其開始和規劃完成日期，通知EFSA以支持申請或通知。</p> <p>就第1段而言，位於歐盟的實驗室和其他檢測機構還應無延遲地將業者委託渠等進行的任何研究主題和範圍、開始和規劃完成日期以及委託研究的業者名稱，通知EFSA以支持申請或通知。</p> <p>只要與那些第三國有相關協議和安排，包括第49條所述的，本段也應準用位於第三國的實驗室和其他檢測機構。</p> <p>若研究的申請或通知先前未依第2或第3段被通知，則其應不被視為有效或可受理，除非申請者或通知者提供了不通知此類研究的正當理由。</p>

studies.	
Where studies have not been previously notified in accordance with paragraph 2 or 3, and where a valid justification has not been provided, an application or notification may be re-submitted, provided that the applicant or notifier notifies to the Authority those studies, in particular their title and their scope, the laboratory or testing facility carrying them out as well as their starting and planned completion dates.	若研究未依第2或第3段被事先通知，且未提供正當理由，申請者或通知者可以重新提交申請或通知，前提是要通知EFSA那些研究執行的實驗室或測試機構，特別是其主要主題和範圍，以及開始和規劃完成日期。
The assessment of the validity or the admissibility of such re-submitted application or notification shall commence six months after the notification of the studies pursuant to the second subparagraph.	對重新提交申請或通知的有效性或可受理性的評估應在根據第2小段通知研究後6個月開始。
5. An application or notification shall not be considered valid or admissible, where studies that have previously been notified in accordance with paragraph 2 or 3 are not included in the application or notification, unless the applicant or notifier provides a valid justification for the non-inclusion of such studies.	若事前依第2或第3段通知的研究未包含在申請或通知中，則該申請或通知應不被視為有效或可受理，除非申請者或通知者提供不包含該研究的正當理由。
Where the studies which have previously been notified in accordance with paragraph 2 or 3 were not included in the application or notification, and where a valid justification has not been provided, an application or notification may be resubmitted, provided that the applicant or notifier submits all the studies that were notified in accordance with paragraph 2 or 3.	若事前依第2或第3段通知的研究未包含在申請或通知中，且未提供正當理由，申請者或通知者可以重新提交申請或通知，但前提是要提交所有依第2或3段通知的研究。
The assessment of the validity or admissibility of such re-submitted application or notification shall commence six months after the submission of the studies pursuant to the second subparagraph.	對重新提交申請或通知的有效性或可受理性的評估應在根據第2小段提交研究後6個月開始。
6. Where the Authority detects, during its risk assessment, that studies notified in accordance with paragraph 2 or 3 are not included in the corresponding application or notification in full, and in the absence of a valid justification of the applicant or notifier to that effect, the applicable time limits within which the Authority is required to deliver its scientific output shall be suspended. That suspension shall end six months after the submission of all data of those studies.	若EFSA在風險評估期間發現依第2或第3段通知的研究未被完整包含在相應的申請或通知中，且申請者或通知者未對此給予正當理由時，應暫停要求EFSA交付其科學成果的適用時限。該暫停應在提交那些研究所有數據後6個月結束。
7. The Authority shall make public the notified information only in cases where it received a corresponding application or notification and after the Authority has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e.	EFSA僅在收到相應的申請或通知並依第38至39e條決定揭露隨附研究後，EFSA應公開通知的資訊。
8. The Authority shall lay down the practical arrangements for implementing the provisions of this Article, including arrangements for requesting and making public the valid justifications in the cases referred to in paragraphs 4, 5 and 6. Those arrangements shall be in accordance with this Regulation and other relevant Union law.	EFSA應制定施行本條規定的實務安排，包括在第4、第5和第6段所述情況下要求和公開正當理由的相關安排。那些安排應符合本規章和其他相關的聯盟法律。
Article 32c Consultation of third parties	第32c條 第三方諮詢
1. Where the relevant Union law provides that an approval or an authorisation, including by means of a notification, may be renewed, the potential applicant or notifier for the renewal shall notify the Authority of the studies it intends to perform for that purpose, including information on how the various studies are to be carried out to ensure compliance with regulatory requirements. Following such notification of studies, the Authority shall launch a consultation of stakeholders and the public on the intended studies for renewal, including on the proposed design of studies. Taking into account the received comments from the stakeholders and the public which are relevant for the risk assessment of the intended renewal, the Authority shall provide advice on the content of the intended renewal application or notification, as well as on the design of the studies. The advice provided by the Authority shall be without prejudice and non-committal as to the subsequent assessment of the applications or notifications for renewal by the Scientific Panels.	若相關歐盟法律規定批准或授權(包括通知方式)可以續期，潛在的續期申請者或通知者應通知EFSA其打算為此目的進行的研究，包括關於如何進行各種研究以確保符合法制要求。EFSA在收到此類研究通知後，應就欲續期的研究(包括提議的研究設計)，向利害關係者和公眾發起諮詢。考慮到從利害關係者和公眾收到的與欲續期風險評估相關的意見，EFSA應就欲續期申請或通知的內容以及研究設計提供意見。EFSA提供的意見應不影響和不承諾科學小組後續對續期申請或通知的評估。

<p>2. The Authority shall consult stakeholders and the public on the basis of the non-confidential version of the application or notification made public by the Authority in accordance with Articles 38 to 39e, and immediately after such disclosure to the public, in order to identify whether other relevant scientific data or studies are available on the subject matter concerned by the application or notification. In duly justified cases, where there is a risk that the results of the public consultation performed in accordance with this paragraph cannot be given proper consideration because of the applicable time limits within which the Authority is required to deliver its scientific output, those time limits may be extended for a maximum period of seven weeks. This paragraph is without prejudice to the Authority's obligations under Article 33 and does not apply to the submission of any supplementary information by the applicants or notifiers during the risk assessment process.</p>	<p>EFSA應以依第38至39e條公開的申請或通知的非機密版本，在向公眾揭露後，立即諮詢利害關係者和公眾，以鑑別是否有其他可獲得關於申請或通知所涉主題相關的科學數據或研究。在有正當理由的情況下，若依本段進行的公眾諮詢結果可能無法得到適恰考量，則那些因要求EFSA交付科學成果的適用時限，可延長至多7週。本段不影響EFSA依第33條所擔負的義務，也不適用於申請者或通知者在風險評估過程中提交的任何補充資訊。</p>
<p>3. The Authority shall lay down the practical arrangements for implementing the procedures referred to in this Article and Article 32a.</p>	<p>EFSA應制定施行本條和第32a條所述程序的實務安排。</p>
<p><i>Article 32d</i> Verification studies</p>	
<p>Without prejudice to the obligation on applicants to demonstrate the safety of a subject matter submitted to a system of authorisation, the Commission, in exceptional circumstances of serious controversies or conflicting results, may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification. ◀M9</p>	<p style="text-align: center;"><i>第32d條</i> 驗證研究</p> <p>在不影響申請者證明提交給授權系統的主題安全性的義務時，執委會在出現嚴重爭議或結果相互矛盾的特殊情況下，可要求EFSA委託進行科學研究，以驗證在風險評估過程中所使用的證據。委託研究可以比需要驗證的證據主題有更廣的範圍。</p>
<p><i>Article 33</i> Collection of data</p>	
<p>1. The Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission. This shall involve in particular the collection of data relating to:</p>	<p>EFSA應在其任務範圍內搜索、收集、整理、分析和彙總相關科學和技術數據。尤其應涵括以下相關數據的蒐集：</p>
<p>(a) food consumption and the exposure of individuals to risks related to the consumption of food;</p>	<p>食品消費和個體對消費食品相關風險的曝露；</p>
<p>(b) incidence and prevalence of biological risk;</p>	<p>生物風險的發生率和流行率；</p>
<p>(c) contaminants in food and feed;</p>	<p>食品和飼料中的污染物；</p>
<p>(d) residues.</p>	<p>殘留物。</p>
<p>2. For the purposes of paragraph 1, the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries or international bodies.</p>	<p>就第1段而言，EFSA應與數據蒐集相關領域的所有組織進行密切合作，包括來自申請國、第三國或國際機構的組織。</p>
<p>3. The Member States shall take the necessary measures to enable the data they collect in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority.</p>	<p>會員國應採取必要措施，將第1和第2段所指領域所收集到的數據傳送給EFSA。</p>
<p>4. The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at Community level.</p>	<p>EFSA應向會員國和執委會提出適當的可以改善其接收和分析數據的技術可比性的建議，以促進歐盟層級的整合。</p>
<p>5. Within one year following the date of entry into force of this Regulation, the Commission shall publish an inventory of data collection systems existing at Community level in the fields within the mission of the Authority.</p>	<p>在本規章生效日起1年內，執委會應公布在EFSA任務範圍內的歐盟層級既有數據收集系統清單。</p>
<p>The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular:</p>	<p>應隨附的報告，適當時藉由提案，應說明特別是：</p>
<p>(a) for each system, the role which should be assigned to the Authority,</p>	<p>對於每個系統，將分配給EFSA的角色，</p>

and any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States;	和為使EFSA能與會員國合作執行其任務可能需要的任何修改或改善；
(b) the shortcomings which should be remedied to enable the Authority to collect and summarise at Community level relevant scientific and technical data in the fields within its mission.	為使EFSA能夠在歐盟層級收集和彙總其任務範圍內的相關科學和技術數據，應予以矯正的缺點。
6. The Authority shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States.	EFSA應將其任務範圍內數據收集的成果遞送給歐洲議會、執委會和會員國。
Article 34 Identification of emerging risks	第34條 新興風險之識別
1. The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission.	EFSA應建立系統化搜索、收集、整理和分析資訊和數據的監測程序，以識別其任務範圍內的新興風險。
2. Where the Authority has information leading it to suspect an emerging serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as a matter of urgency and forward any relevant information in their possession.	在EFSA掌握資訊使其懷疑新出現的嚴重風險時，應要求會員國、其他歐盟機構和執委會提供更多資訊。會員國、相關歐盟機構和執委會應視作緊急事項予以答復並提交所掌握的任何相關資訊。
3. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.	EFSA應使用在執行任務時收到的所有資訊來識別新興風險。
4. The Authority shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.	EFSA應將收集到關於新興風險的評估和資訊提交給歐洲議會、執委會和會員國。
Article 35 Rapid alert system	第35條 快速警示系統
To enable it to perform its task of monitoring the health and nutritional risks of foods as effectively as possible, the Authority shall be the recipient of any messages forwarded via the rapid alert system. It shall analyse the content of such messages with a view to providing the Commission and the Member States with any information required for the purposes of risk analysis.	為使EFSA能盡可能有效地監測食品的健康和營養風險，其應是快速警示系統發送任何訊息的接收者。它應分析此類訊息內容，以便向執委會和會員國提供風險分析所需的任何資訊。
Article 36 Networking of organisations operating in the fields within the Authority's mission	第36條 在EFSA任務領域內運作之組織網絡
1. The Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.	EFSA應促進在其任務範圍內開展業務的歐洲組織網絡。特別是此等網絡目的是在於透過活動協調、資訊交換、制定和實施合作計畫、在EFSA任務範圍內交換專業知識和最佳做法，來促進科學合作框架。
2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of competent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.	管理委員會根據執行長的建議，應草擬一份由會員國所指定主管組織的公開名單，其可以個別或以網絡方式來協助EFSA完成任務。EFSA可將某些工作委託給這些組織，特別是對科學意見、科學和技術支援、數據收集和新興風險識別的準備工作。其中一些工作可以有資格獲得財務支持。
▼ M4 ▼ M8	
3. The Commission is empowered to adopt delegated acts in accordance with Article 57a in order to supplement this Regulation by establishing the	執委會有權依第57a條通過授權法案來補充本規章，以建立將一個研究機構列

<p>criteria for the inclusion of an institute on the list of competent organisations designated by the Member States, the arrangements for setting out harmonised quality requirements and the financial rules governing any financial support. ◀M8</p>	<p>入會員國指定主管組織名單的標準、制定一致品質要求的安排和管理任何財務支持的財務規定。</p>
<p>Other implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the regulatory procedure referred to in Article 58(2). ◀M4</p>	<p>其他適用第1和第2段的施行規定應由執委會在與EFSA諮商後，依第58(2)條所述的法程序來制定。</p>
<p>4. Within one year following the entry into force of this Regulation, the Commission shall publish an inventory of Community systems existing in the fields within the mission of the Authority which make provision for Member States to carry out certain tasks in the field of scientific evaluation, in particular the examination of authorisation dossiers. The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular, for each system, any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States.</p>	<p>在本規章生效後的1年內，執委會應公開在EFSA任務範圍內現有各領域的歐盟系統清單，其為會員國在科學評估領域執行某些工作作成規定，特別是在授權文檔的檢查。應隨附的報告，適當時藉由提案，應說明特別是每個系統可能需要的任何修改或改善，以使EFSA能與會員國合作執行其任務。</p>
<p>SECTION 4 INDEPENDENCE, TRANSPARENCY, CONFIDENTIALITY AND COMMUNICATION</p>	<p>第 4 節 獨立性、透明度、保密和溝通</p>
<p><i>Article 37</i> Independence</p>	<p><i>第37條</i> 獨立性</p>
<p>1. The members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest.</p>	<p>管理委員會成員、諮詢論壇成員和執行長應承諾為公共利益來獨立行事。</p>
<p>For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.</p>	<p>為此，他們應有承諾聲明和利益(迴避)聲明，表明未有任何可能被認為有損其獨立性的利益或任何可能被認為有損其獨立性的直接或間接利益。這些聲明應每年以書面形式簽署。</p>
<p>2. The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence.</p>	<p>科學委員會和科學小組成員應承諾不受任何外部影響來獨立行事。</p>
<p>For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.</p>	<p>為此，他們應有承諾聲明和利益(迴避)聲明，表明未有任何可能被認為有損其獨立性的利益或任何可能被認為有損其獨立性的直接或間接利益。這些聲明應每年以書面形式簽署。</p>
<p>3. The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda.</p>	<p>管理委員會成員、執行長、諮詢論壇成員、科學委員會和科學小組成員以及參與其工作組的外部專家應在每次會議上聲明任何可能被認為有損其與議程項目相關獨立性的利益。</p>
<p><i>Article 38</i> Transparency</p>	<p><i>第38條</i> 透明度</p>
<p>▼M9</p>	
<p>1. The Authority shall carry out its activities with a high level of transparency. It shall in particular make public:</p>	<p>EFSA應以高度透明的方式展開活動。特別是應公開：</p>
<p>(a) agendas, participant lists and minutes of the Management Board, the Advisory Forum, the Scientific Committee and the Scientific Panels and their working groups;</p>	<p>管理委員會、諮詢論壇、科學委員會和科學小組及其工作組的議程、參與者名單和會議紀錄；</p>
<p>(b) all its scientific outputs, including the opinions of the Scientific Committee and the Scientific Panels after adoption, minority opinions and results of consultations performed during the risk assessment process always being included;</p>	<p>所有科學產出，包括在通過後的科學委員會和科學小組意見、少數意見以及應包括在風險評估過程中進行的協商結果；</p>

(c) scientific data, studies and other information supporting applications, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion, taking into account the protection of confidential information and the protection of personal data in accordance with Articles 39 to 39e;	支持申請的科學數據、研究和其他資訊(包括申請者提供的補充資訊)，以及來自歐洲議會、執委會和會員國支持請求科學產出(包括科學意見)的其他科學數據和資訊，依第39至39e條考慮到對機密資訊的保護和個人資料的保護；
(d) the information on which its scientific outputs, including scientific opinions are based, taking into account the protection of confidential information and the protection of personal data in accordance with Articles 39 to 39e;	依第39至39e條考慮到對機密資訊的保護和個人資料的保護，其科學產出(包括科學意見)所依據的資訊；
(e) the annual declarations of interest made by the members of the Management Board, the Executive Director and the members of the Advisory Forum, the Scientific Committee and the Scientific Panels, as well as the members of the working groups, and the declarations of interest made in relation to items on the agendas of meetings;	管理委員會成員、執行長和諮詢論壇、科學委員會和科學小組成員的年度利益聲明，以及工作小組成員和對與會議議程上相關項目所作的利益聲明；
(f) its scientific studies in accordance with Articles 32 and 32d;	依第32和32d條的科學研究；
(g) the annual report of its activities;	其活動的年度報告；
(h) requests from the European Parliament, from the Commission or from a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification;	被歐洲議會、執委會或會員國拒絕或修改的科學意見請求，以及拒絕或修改的理由；
(i) a summary of the advice provided to potential applicants at pre-submission phase pursuant to Articles 32a and 32c.	根據第32a和32c條在提交前階段，提供給潛在申請者的建議彙總。
Information referred to in the first subparagraph shall be made public without delay, with the exception of the information referred to in point (c) thereof, as far as applications are concerned, and in point (i) thereof, which shall be made public without delay once an application has been considered valid or admissible.	第1小段中提及的資訊應無延遲地予以公開，但其中(c)點所指的資訊除外，就相關申請而言，以及(i)點所述的，一旦申請被視為有效或可受理，應無延遲地予以公開。
The information referred to in the second subparagraph shall be made public in a dedicated section of the Authority's website. That dedicated section shall be publicly available and easily accessible. That information shall be available to be downloaded, printed and searched through in an electronic format.	第2小段所指的資訊應在EFSA網站專區公布。該專區應是公開且易於查詢的。該資訊應能以電子格式下載、列印和搜尋。
1a. The disclosure of the information referred to in points (c), (d) and (i) of the first subparagraph of paragraph 1 to the public shall be without prejudice to:	向公眾揭露第1段的第1小段(c)、(d)和(i)點所指的資訊應不妨礙：
(a) any existing rules concerning intellectual property rights which set out limitations on certain uses of the disclosed documents or their content; and	任何關於智財權的現有規定，其規定了對所揭露文件或其內容的某些用途的限制；和
(b) any provisions set out in Union law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations ('data exclusivity rules').	任何歐盟法律中對保護創新者在收集支持相關授權申請的資訊和數據方面投資的規定(數據排他性規定)。
The disclosure to the public of the information referred to in point (c) of the first subparagraph of paragraph 1 shall not be considered to be explicit or implicit permission or licence for the relevant data and information and their content to be used, reproduced, or otherwise exploited in breach of any intellectual property right or data exclusivity rules, and the Union shall not be responsible for its use by third parties. The Authority shall ensure that clear undertakings or signed statements are given to that effect by those who access the relevant information prior to its disclosure. ◀M9	向公眾揭露第1段的第1小段(c)點所指的資訊，不應被視為對相關數據和資訊及其內容在違反任何智財權或數據排他性規定下被使用、複製或以其他利用方式的明示或暗示許可或給證照，且歐盟不應對第三方的使用負責。EFSA應在揭露相關資訊前，確保那些獲知相關資訊者對此做出明確承諾或簽署聲明。
2. The Management Board shall hold its meetings in public unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda, and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.	管理委員會應公開舉行會議，除非按照執行長提議，就議程的具體行政事項另有決定，及可授權消費者代表或其他利害關係者觀察EFSA某些活動的進展。
▼ M9	

<p>3. The Authority shall lay down the practical arrangements for implementing the transparency rules referred to in paragraphs 1, 1a and 2 of this Article, taking into account Articles 39 to 39g and 41.</p>	<p>EFSA應在同時考慮到第39條至第39g條和第41條下，制定施行本條第1、第1a和第2段所述透明度規定的實際安排。</p>
<p>Article 39 Confidentiality</p>	<p>第39條 保密</p>
<p>1. By way of derogation from Article 38, the Authority shall not make public any information for which confidential treatment has been requested under the conditions laid down in this Article.</p>	<p>作為第38條規定的例外，EFSA在本條規定條件下被要求保密處理的任何資訊應不予公開。</p>
<p>2. Upon the request of an applicant, the Authority may grant confidential treatment only with respect to the following items of information where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree:</p>	<p>應申請者要求，若申請者證明揭露此類資訊可能會嚴重損害其利益時，則EFSA僅就關於下列資訊項目給予保密待遇：</p>
<p>(a) the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;</p>	<p>製造或生產過程，包括關於方法和創新面，以及對該過程或方法固有的其他技術和工業規格，但與安全評估相關之資訊除外；</p>
<p>(b) commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;</p>	<p>生產者或進口商與申請者或授權持有人（如適用）之間的商業關聯；</p>
<p>(c) commercial information revealing sourcing, market shares or business strategy of the applicant; and</p>	<p>揭露申請者的上游資源、市佔率或經營策略的商業資訊；和</p>
<p>(d) quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety.</p>	<p>請求標的物的定量組成分，但與安全評估相關之資訊除外。</p>
<p>3. The list of information referred to in paragraph 2 shall be without prejudice to any sectoral Union law.</p>	<p>第2段所述的資訊清單應不影響任何部門的歐盟法律。</p>
<p>4. Notwithstanding paragraphs 2 and 3:</p>	<p>儘管有第2和第3段：</p>
<p>(a) where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the Authority may disclose the information referred to in paragraphs 2 and 3;</p>	<p>若緊急行動對保護人類健康、動物健康或環境是至關重要，在諸如此類緊急情況下，EFSA可揭露第2和第3段所述的資料；</p>
<p>(b) information which forms part of conclusions of scientific outputs, including scientific opinions, delivered by the Authority and which relate to foreseeable effects on human health, animal health or the environment, shall nevertheless be made public.</p>	<p>然而，構成EFSA交付科學成果的部分結論(包括科學意見)資訊，以及與對人類健康、動物健康或環境的可預見影響有關的資訊，應予公開。</p>
<p>Article 39a Confidentiality request</p>	<p>第39a條 保密要求</p>
<p>1. When submitting an application, supporting scientific data and other supplementary information in accordance with Union law, the applicant may request certain parts of the information submitted to be treated as confidential in accordance with Article 39(2) and (3). Such request shall be accompanied by verifiable justification that demonstrates how making public the information concerned significantly harms the interests concerned in accordance with Article 39(2) and (3).</p>	<p>在按照歐盟法律提交1個支持科學數據和其他補充資訊的申請時，申請者可以依第39(2)和(3)條規定對提交資訊的某些部分請求以保密來處理。此類請求應附有可驗證的理由來證明依第39(2)和(3)條公開該等資訊會如何嚴重損害其利益。</p>
<p>2. Where an applicant submits a confidentiality request, it shall provide a non-confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall not include the information the applicant deems confidential on the basis of Article 39(2) and (3) and shall indicate the places where such information has been deleted. The confidential version shall contain all information submitted, including information the applicant deems confidential. Information requested to be treated as confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate the grounds on the basis of which confidentiality is requested for the different pieces of information.</p>	<p>提交保密請求的申請者，若有時，應按照第39f條規定的標準數據格式，提交非保密版本和保密版本。非保密版本不得包含申請者依第39(2)和(3)條認為屬於保密的資訊，並應當註記該資訊被刪除處。保密版本應包含提交的所有資訊，包括申請者認為的機密資訊。保密版本中要求保密的資訊應清楚標記出來。申請者應明確說明對不同資訊要求保密所根據的理由。</p>

<p style="text-align: center;">Article 39b Decision on confidentiality</p>	<p style="text-align: center;">第39b條 保密決定</p>
<p>1. The Authority shall:</p> <p>(a) make public the non-confidential version of the application as submitted by the applicant without delay once that application has been considered valid or admissible;</p> <p>(b) proceed, without delay, to a concrete and individual examination of the confidentiality request in accordance with this Article;</p> <p>(c) inform the applicant in writing of its intention to disclose information and the reasons for that, before the Authority formally takes a decision on the confidentiality request. If the applicant disagrees with the assessment of the Authority, the applicant may state its views or withdraw its application within two weeks of the date on which it was notified of the Authority's position;</p> <p>(d) adopt a reasoned decision on the confidentiality request, taking into account the observations of the applicant, within 10 weeks of the date of receipt of the confidentiality request with respect to applications and without delay in the case of supplementary data and information; notify the applicant of its decision and provide information on the right to submit a confirmatory application in accordance with paragraph 2; and inform the Commission and the Member States, where appropriate, of its decision; and</p> <p>(e) make public any additional data and information for which the confidentiality request has not been accepted as justified at the earliest two weeks after the notification of its decision to the applicant has taken place pursuant to point (d).</p>	<p>EFSA應：</p> <p>一旦申請被認為有效或受理，無延遲地公開申請者所提交的非機密版本申請資料；</p> <p>依本條規定對保密請求進行無延遲地具體且個別的審查；</p> <p>在EFSA正式就保密請求作出決定前，以書面通知申請者其揭露資訊的意圖及原因。若申請者不同意EFSA的評估結果，申請者可在被通知EFSA立場之日起2週內陳述意見或撤銷申請；</p> <p>在收到保密請求申請之日起10週內，考慮到申請者的觀點，對保密請求作出合理的決定，且在補充數據和資訊的情況下不得拖延；將決定通知申請者並提供依第2段提交確認申請的有關權利之資訊；並適當時將決定通知執委會和會員國；和</p> <p>在按(d)點向申請者發出決定通知後的首2週，公開其保密請求未被接受為正當理由的任何其他數據和資訊。</p>
<p>2. Within two weeks of the notification of the Authority's decision on the confidentiality request to the applicant pursuant to paragraph 1, the applicant may submit a confirmatory application asking the Authority to reconsider its decision. The confirmatory application shall have suspensive effect. The Authority shall examine the grounds for the confirmatory application and shall adopt a reasoned decision on that confirmatory application. It shall notify the applicant of that decision within three weeks of submitting the confirmatory application and shall include in that notification information on the available remedies, namely an action before the Court of Justice of the European Union (the 'Court of Justice') against the Authority pursuant to paragraph 3. The Authority shall make public any additional data and information for which the confidentiality request has not been accepted by the Authority as justified, at the earliest two weeks after the notification of the Authority's reasoned decision on the confirmatory application to the applicant has taken place pursuant to this paragraph.</p>	<p>在依據第1段向申請者通知EFSA對保密請求的決定後的2週內，申請者可提交確認申請，要求EFSA重新考慮其決定。確認申請應具暫停效力。EFSA應審查確認申請所根據的理由，並應對該確認申請作出合理的決定。它應在提交確認申請後3週內將決定通知申請者，並應涵括可利用的補救措施資訊，即依第3段向歐盟法院（法院）對EFSA提出訴訟。EFSA應在依據本段對申請者確認申請作出合理決定的通知後首2週內，公開保密請求未被EFSA接受為正當理由的任何其他數據和資訊。</p>
<p>3. Decisions taken by the Authority pursuant to this Article may be subject to an action before the Court of Justice, under the conditions laid down in Articles 263 and 278 of the Treaty on the Functioning of the European Union (TFEU) respectively.</p>	<p>分別在依歐盟運作條約（TFEU）第263條和第278條規定的條件下，EFSA依據本條所作出的決定可能會在法院提起訴訟。</p>
<p style="text-align: center;">Article 39c Review of confidentiality</p>	<p style="text-align: center;">第39c條 保密審查</p>
<p>Before the Authority issues its scientific outputs, including scientific opinions, it shall review whether information that has been previously accepted as confidential may nevertheless be made public in accordance with point (b) of Article 39(4). Should that be the case, the Authority shall follow the procedure laid down in Article 39b, which shall apply <i>mutatis mutandis</i>.</p>	<p>在EFSA發布其科學成果（包括科學意見）前，它應審查以前被視為保密資訊是否仍可依據第39(4)條(b)點進行公開。在這種情況下，EFSA應遵循第39b條規定的程序，該程序應予準用。</p>
<p style="text-align: center;">Article 39d Obligations with regard to confidentiality</p>	<p style="text-align: center;">第39d條 保密義務</p>

<p>1. The Authority shall make available, upon request, to the Commission and the Member States all information in its possession relating to an application or to a request by the European Parliament, by the Commission or by the Member States for a scientific output, including a scientific opinion, unless otherwise indicated in Union law.</p>	<p>EFSA應依請求向執委會和會員國提供其擁有的與申請相關的或與歐洲議會、執委會或會員國提出科學產出要求相關的所有資訊，包括科學意見，除非歐盟法律另有規定。</p>
<p>2. The Commission and the Member States shall take the necessary measures so that information received by them under Union law for which confidential treatment has been requested is not made public until a decision on the confidentiality request has been taken by the Authority and has become final. The Commission and the Member States shall also take the necessary measures so that information for which confidential treatment has been accepted by the Authority is not made public.</p>	<p>執委會和會員國應採取必要措施，使他們依據歐盟法律收到要求保密處理的資訊，在EFSA對保密請求作出決定並成為最終決定之前不會公開。執委會和會員國還應採取必要措施，使EFSA所接受保密處理的資訊不會被公開。</p>
<p>3. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of information as granted by the Authority in accordance with Articles 39 to 39e. The application shall be considered withdrawn as of the moment the written request to that effect is received by the competent body that had received the original application. Where the withdrawal of the application takes place before a final decision on the confidentiality request has been adopted by the Authority pursuant to, where appropriate, Article 39b(1) or (2), the Commission, the Member States and the Authority, shall not make public the information for which confidentiality has been requested.</p>	<p>若申請者撤銷或已撤回申請，EFSA、執委會和會員國應尊重EFSA依據第39至39e條授予資訊的機密性。自收到原始申請的主管機構收到書面請求時，該申請應被視為撤回。在EFSA依據第39b(1)或(2)條酌情通過保密請求的最終決定之前撤回申請時，執委會、會員國和EFSA不得公開要求保密的資訊。</p>
<p>4. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of the obligation of professional secrecy pursuant to Article 339 TFEU.</p>	<p>管理委員會成員、執行長、科學委員會和科學小組成員以及參與其工作組的外部專家、諮詢論壇成員和EFSA員工，即使在卸任後，應遵守TFEU第339條專業保密義務的要求。</p>
<p>5. The Authority shall lay down in consultation with the Commission the practical arrangements for implementing the confidentiality rules laid down in Articles 39, 39a, 39b, 39e and in this Article, including arrangements concerning the submission and treatment of confidentiality requests with respect to information to be made public under Article 38, and taking into account Articles 39f and 39g. As regards Article 39b(2), the Authority shall ensure that appropriate separation of tasks is applied for the assessment of confirmatory applications.</p>	<p>EFSA應與執委會協商，制定施行第39條、第39a條、第39b條、第39e條和本條中規定的保密規則的實務安排，包括在考慮到第39f條和第39g條，關於保密請求的提交和處理要依第38條公開。關於第39b(2)條，EFSA應確保在評估確認申請時做適當的工作區別。</p>
<p><i>Article 39e</i> Protection of personal data</p>	<p><i>第39e條</i> 個人資料保護</p>
<p>1. With respect to requests for scientific outputs, including scientific opinions under Union law, the Authority shall always make public:</p>	<p>關於科學產出的請求，包括依歐盟法請求的科學意見，EFSA應永予公開：</p>
<p>(a) the name and address of the applicant;</p>	<p>申請者姓名和地址；</p>
<p>(b) the names of authors of published or publicly available studies supporting such requests; and</p>	<p>支持此類請求的已發表或可公開取得研究的作者姓名；和</p>
<p>(c) the names of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any other ad hoc group meeting on the subject matter.</p>	<p>科學委員會和科學小組會議、其工作組和任何其他對該主題專案小組會議中的所有參與者和觀察員姓名。</p>
<p>2. Notwithstanding paragraph 1, disclosure of names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information shall be deemed to significantly harm the privacy and the integrity of those natural persons and shall not be made publicly available unless otherwise specified in Regulations (EU) 2016/679²⁸ and (EU) 2018/1725²⁹ of the European Parliament and of the Council.</p>	<p>儘管有第1段的規定，揭露參與脊椎動物試驗或獲取毒理學資訊的自然人的姓名和地址，應視為嚴重損害這些自然人的隱私和完整性，除非歐洲議會和理事會(EU) 2016/679和(EU) 2018/1725規章另有規定，否則應不可公開。</p>

²⁸ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p.1) / 關於在處理個人數據和此類數據的自由流通方面之個人資料保護

<p>3. Regulations (EU) 2016/679 and (EU) 2018/1725 shall apply to the processing of personal data carried out pursuant to this Regulation. Any personal data made public pursuant to Article 38 of this Regulation and this Article shall only be used to ensure the transparency of the risk assessment under this Regulation and shall not be further processed in a manner that is incompatible with these purposes, in accordance with point (b) of Article 5(1) of Regulation (EU) 2016/679 and point (b) of Article 4(1) of Regulation (EU) 2018/1725, as the case may be.</p>	<p>(EU) 2016/679和(EU) 2018/1725規章應適用於依本規章進行的個人數據處理。任何依本規章第38條和本條規定公開的個人數據，應僅用於確保在本規章下風險評估的透明度，且應不得用於與這些目的不符的進一步處理用途，依(EU) 2016/679規章第5(1)條(b)點和(EU) 2018/1725規章第4(1)條(b)點，可視情況而定。</p>
<p><i>Article 39f</i> Standard data formats</p>	<p><i>第39f條</i> 標準數據格式</p>
<p>1. For the purposes of point (c) of Article 38(1) and in order to ensure the efficient processing of requests to the Authority for a scientific output, standard data formats shall be adopted in accordance with paragraph 2 of this Article to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union law. Those standard data formats shall:</p>	<p>為第38(1)條(c)點的目的，並為確保向EFSA提出科學產出請求的有效處理，標準數據格式應按本條第2段規定，以允許文件的提交、搜索、複製和印刷，同時確保符合歐盟法律規定中的法制要求。那些標準數據格式應：</p>
<p>(a) not be based on proprietary standards;</p>	<p>非基於具所有權的標準；</p>
<p>(b) ensure interoperability with existing data submission approaches to the extent possible;</p>	<p>盡可能地確保與現有數據提交方法有互通性；</p>
<p>(c) be user-friendly and adapted for the use by small and medium-sized enterprises.</p>	<p>具易使用性並適合中小型企業使用。</p>
<p>2. For the adoption of standard data formats referred to in paragraph 1, the following procedure shall be followed:</p>	<p>為採用第1段所述的標準數據格式，應遵循以下程序：</p>
<p>(a) the Authority shall draw up draft standard data formats for the purposes of the different authorisation procedures and relevant requests for a scientific output by the European Parliament, by the Commission and by the Member States;</p>	<p>EFSA應為不同的授權程序和歐洲議會、執委會和會員國對科學產出的相關要求制定標準數據格式草案；</p>
<p>(b) the Commission shall, taking into account the applicable requirements in the different authorisation procedures and other legal frameworks and following any necessary adaptations, adopt, by means of implementing acts, standard data formats. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2);</p>	<p>執委會應考慮到不同授權程序和其他法律框架中的適用要求，並在進行任何必要的調整後，通過施行法案採用標準數據格式。施行法案應依第58(2)條規定的程序通過；</p>
<p>(c) the Authority shall make the standard data formats, as adopted, available on its website;</p>	<p>EFSA應在其網站上提供所採用的標準數據格式；</p>
<p>(d) where standard data formats have been adopted pursuant to this Article, applications as well as requests for a scientific output, including a scientific opinion by the European Parliament, by the Commission and by the Member States, shall only be submitted in accordance with those standard data formats.</p>	<p>在依本條採用標準數據格式時，申請和科學產出請求，包括歐洲議會、執委會和會員國提出的科學意見請求，應僅能以依那些標準數據格式進行提交。</p>
<p><i>Article 39g</i> Information systems</p>	<p><i>第39g條</i> 資訊系統</p>
<p>The information systems operated by the Authority to store its data, including confidential and personal data shall be designed in a way that guarantees that any access to it is fully auditable and that the highest standards of security appropriate to the security risks at stake are attained, taking into account Articles 39 to 39f. ◀M9</p>	<p>EFSA為存檔其數據(包括保密和個人數據)所運作的資訊系統，應以保證對任何存取是完全可稽查並在考慮到第39條至第39f條規定下，達到與所涉保密風險相應的最高安全標準的方式來設計。</p>
<p><i>Article 40</i> Communications from the Authority</p>	<p><i>第40條</i> 來自EFSA的溝通</p>

29 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p.39)/ 關於在歐盟機構、團體、辦公室和機構處理個人數據以及此類數據自由流通之個人資料保護

1. The Authority shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions.	EFSA應在不影響執委會溝通其風險管理決策的能力下，主動在其任務範圍的領域內進行溝通。
2. The Authority shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Authority shall develop and disseminate information material for the general public.	EFSA應確保向公眾和任何利害關係者快速地提供客觀、可靠和易於取得的資訊，特別是有關工作結果的資訊。為了達到這些目標，EFSA應開發和廣宣對一般公眾的資訊素材。
3. The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.	EFSA應與執委會和會員國密切合作，以促進風險溝通過程中必要的關聯性。
▼ M9	
The Authority shall make public all scientific outputs including the scientific opinions issued by it and supporting scientific data and other information in accordance with Articles 38 to 39e. ◀M9	EFSA應依第38條至第39e條規定公開所有科學產出，包括所發表的科學意見和科學支持數據和其他資訊。
4. The Authority shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.	EFSA應確保與會員國的主管機構和其他利害關係者就公開資訊宣傳活動進行適當的合作。
▼ M1	
<i>Article 41</i> Access to documents	
▼ M9	
1. Notwithstanding the rules on confidentiality provided for in Articles 39 to 39d of this Regulation, Regulation (EC) No 1049/2001 of the European Parliament and of the Council ³⁰ shall apply to documents held by the Authority.	儘管本規章第39條至第39d條規定了保密規定，但歐洲議會和理事會第(EC) 1049/2001號規章應適用於EFSA所持有的文件。
Where environmental information is concerned, Regulation (EC) No 1367/2006 of the European Parliament and of the Council ³¹ shall also apply. Directive 2003/4/EC of the European Parliament and of the Council ³² shall apply to environmental information held by Member States, notwithstanding the rules on confidentiality provided for in Articles 39 to 39d of this Regulation.	在環境資訊受關注時，歐洲議會和理事會第(EC) 1367/2006號規章也應適用。儘管本規章第39條至第39d條規定了保密規定，但歐洲議會和理事會2003/4/EC指令應適用於會員國所擁有的環境資訊。
2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006 by 27 March 2020, ensuring as wide access as possible to documents in its possession. ◀M9	管理委員會應在2020年3月27日前通過施行第(EC) 1049/2001號規章和第(EC) 1367/2006號規章第6條和第7條的實務安排，以確保盡可能廣泛地獲取可擁有的文件。
3. Decisions taken by the Authority pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the EC Treaty respectively. ◀M1	EFSA依第(EC) 1049/2001號規章第8條所作的決定，可分別在歐盟條約第195條和第230條規定的條件下，構成向監察員投訴或向法院提起訴訟的標的。
<i>Article 42</i> Consumers, producers and other interested parties	
The Authority shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties.	EFSA應與消費者代表、生產者代表、加工業者和任何其他利害關係者建立有效的聯繫。
SECTION 5	
第 5 節	

30 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p.43)/ 關於公眾獲取歐洲議會、理事會和執委會文件之規定

31 Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p.13)/ 關於在環境問題上獲取資訊、公眾參與決策和訴諸司法的奧胡斯公約的規定對歐盟機構和團體的適用

32 Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p.26)/ 關於公眾獲取環境資訊和廢除理事會90/313/EEC指令

FINANCIAL PROVISIONS	財務條款
<p><i>Article 43</i> Adoption of the Authority's budget</p>	<p><i>第43條</i> EFSA預算之通過</p>
<p>1. The revenues of the Authority shall consist of a contribution from the Community and, from any State with which the Community has concluded the agreements referred to in Article 49, and charges for publications, conferences, training and any other similar activities provided by the Authority.</p>	<p>EFSA的收入應包括來自歐盟和與歐盟締結第49條所述協定的任何國家的捐款，以及來自EFSA的出版物、會議、培訓和其他任何類似活動的費用。</p>
<p>2. The expenditure of the Authority shall include the staff, administrative, infrastructure and operational expenses, and expenses resulting from contracts entered into with third parties or resulting from the financial support referred to in Article 36.</p>	<p>EFSA的支出應包括人員、行政、基礎設施和營運費用，以及因與第三方簽訂合約或因第36條所述的財政支持而產生的費用。</p>
<p>▼ M1</p>	
<p>3. The Executive Director shall draw up, in good time before the date referred to in paragraph 5, a draft statement of estimates of the Authority's revenue and expenditure for the following financial year and shall forward it to the Management Board, together with the establishment plan.</p>	<p>執行長應在第5段所述之日期前，適時擬定EFSA下一個財政年度的收支概算報表草案，並與擬定計畫一同提交給管理委員會。</p>
<p>4. Revenue and expenditure shall be in balance.</p>	<p>收支應達平衡。</p>
<p>5. Each year the Management Board, on the basis of a draft statement of estimates of revenue and expenditure, shall produce a statement of estimates of revenue and expenditure of the Authority for the following financial year. This statement of estimates, which shall include a draft establishment plan together with the provisional work programmes, shall be forwarded by 31 March at the latest by the Management Board to the Commission and to the countries with which the Community has concluded agreements in accordance with Article 49.</p>	<p>管理委員會應每年以收支概算報表草案，編制EFSA下一個財政年度的收支概算報表。這份應包括一份擬定計畫及暫定工作計畫的概算報表，最遲應由管理委員會在3月31日前提交給執委會和依第49條與歐盟已簽訂協議的國家。</p>
<p>6. The statement of estimates shall be forwarded by the Commission to the European Parliament and the Council (hereinafter referred to as the budgetary authority) together with the preliminary draft general budget of the European Union.</p>	<p>概算報表應由執委會連同歐盟總預算的初稿一起提交給歐洲議會和理事會（以下簡稱預算機關）。</p>
<p>7. On the basis of the statement of estimates, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.</p>	<p>在預算報表的基礎上，執委會應在歐盟總預算初稿中輸入它認為建立計畫必要的概算數和應計入總預算的補貼金額，其應依條約第272條向預算機關提交。</p>
<p>8. The budgetary authority shall authorise the appropriations for the subsidy to the Authority.</p>	<p>預算機關應授權對EFSA補貼的撥款。</p>
<p>The budgetary authority shall adopt the establishment plan for the Authority.</p>	<p>預算機關應通過EFSA所建立計畫。</p>
<p>9. The budget shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.</p>	<p>預算應由管理委員會通過。它應在最終通過歐盟總預算後成為定案。適當時，應作相應調整。</p>
<p>10. The Management Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of the budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.</p>	<p>管理委員會應盡快通知預算機關其預計實施任何可能對預算金額產生重大財務影響的項目，特別是任何與財產有關的項目，例如租賃或購買建物。它應將此事通知執委會。</p>
<p>Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of six weeks from the date of notification of the project.</p>	<p>在預算機關的分支部門已通知其欲提出的意見時，它應在項目通知之日起6週內將其意見遞送給管理委員會。</p>
<p><i>Article 44</i> Implementation of the Authority's budget</p>	<p><i>第44條</i> EFSA預算之執行</p>
<p>1. The Executive Director shall implement the Authority's budget.</p>	<p>執行長應執行EFSA的預算。</p>

<p>2. By 1 March at the latest following each financial year, the Authority's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of the general Financial Regulation.</p>	<p>最遲在每個財政年度之後的3月1日前，EFSA的會計官員應將暫定帳戶連同該財政年度的預算和財務管理報告一起傳送至執委會的會計官員。執委會的會計官員依一般財務法規第128條，應合併機構和分權機構的暫定帳戶。</p>
<p>3. By 31 March at the latest following each financial year, the Commission's accounting officer shall forward the Authority's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for the financial year shall also be forwarded to the European Parliament and the Council.</p>	<p>最遲在每個財政年度之後的3月31日前，執委會的會計官員應將EFSA的暫定帳戶連同該財政年度的預算和財務管理報告一起提交給審計院。財政年度的預算和財務管理報告也應提交給歐洲議會和理事會。</p>
<p>4. On receipt of the Court of Auditors' observations on the Authority's provisional accounts under Article 129 of the general Financial Regulation, the Executive Director shall draw up the Authority's final accounts under his own responsibility and submit them to the Management Board for an opinion.</p>	<p>在收到審計院依一般財務法規第129條對EFSA暫定帳戶提出的意見後，執行長應自行負責編制EFSA的決算數，並將其提交管理委員會徵求意見。</p>
<p>5. The Management Board shall deliver an opinion on the Authority's final accounts.</p>	<p>管理委員會應就EFSA決算數發表意見。</p>
<p>6. The Executive Director shall, by 1 July at the latest following each financial year, forward the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.</p>	<p>執行長應在每個財政年度最遲於7月1日前，將決算數及管理委員會的意見提交給歐洲議會、理事會、執委會和審計院。</p>
<p>7. The final accounts shall be published.</p>	<p>決算數應予公開。</p>
<p>8. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September at the latest. He shall also send this reply to the Management Board.</p>	<p>執行長最遲應在9月30日前對審計院的查察提交答復。他還應將此答復遞送給管理委員會。</p>
<p>9. The Executive Director shall submit to the European Parliament, at the latter's request, all information necessary for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 146(3) of the general Financial Regulation.</p>	<p>依一般財務法規第146(3)條規定，執行長應依據歐洲議會的要求，向歐洲議會提交順利執行有關財政年度的解除列管程序所需的所有資訊。</p>
<p>10. The European Parliament, on a recommendation from the Council acting by a qualified majority, shall, before 30 April of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N. ◀M1</p>	<p>歐洲議會應基於理事會以特定多數決的建議，在N+2年4月30日前，對執行長就N年預算的執行情況解除列管。</p>
<p><i>Article 45</i> Fees received by the Authority</p>	<p><i>第45條</i> EFSA收取的費用</p>
<p>Within three years following the date of entry into force of this Regulation and after consulting the Authority, the Member States and the interested parties, the Commission shall publish a report on the feasibility and advisability of presenting a legislative proposal under the co-decision procedure and in accordance with the Treaty and for other services provided by the Authority.</p>	<p>在本規章生效日起3年內，並在與EFSA、會員國和利害關係者協商後，執委會應依據條約和EFSA提供的其他服務，公布1份在共同決定程序下，關於提出立法提案的可行性和可取性的報告。</p>
<p>SECTION 6 GENERAL PROVISIONS</p>	<p>第 6 節 通用條款</p>
<p><i>Article 46</i> Legal personality and privileges</p>	<p><i>第46條</i> 法人資格和特權</p>
<p>1. The Authority shall have legal personality. In all Member States it shall enjoy the widest powers granted by law to legal persons. In particular, it may acquire and dispose of movable and immovable property and institute legal proceedings.</p>	<p>EFSA應具有法人資格。在所有會員國中，它應享有法律賦予法人最廣泛的權力。特別是，它可以取得和處分動產和不動產，並提起法律訴訟。</p>
<p>2. The Protocol on the privileges and immunities of the European Communities shall apply to the Authority.</p>	<p>對歐盟體系的特權和豁免議定書應適用於EFSA。</p>

<p style="text-align: center;">Article 47 Liability</p>	<p style="text-align: center;">第47條 職責</p>
<p>1. The contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority.</p>	<p>EFSA的合約責任應受有關合約適用的法律管轄。歐盟體系法院應有權依據EFSA簽訂的合約中所包含的任何仲裁條款作出判決。</p>
<p>2. In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.</p>	<p>在非合約責任的情況下，EFSA應依據會員國法律共同通則，賠償其或其僱員在履行職責時造成的任何損害。法院對與此類損害賠償有關的任何爭議具有管轄權。</p>
<p>3. The personal liability of its servants towards the Authority shall be governed by the relevant provisions applying to the staff of the Authority.</p>	<p>僱員對EFSA擔負的個人責任應適用於EFSA員工的相關規定。</p>
<p style="text-align: center;">Article 48 Staff</p>	<p style="text-align: center;">第48條 職員</p>
<p>1. The staff of the Authority shall be subject to the rules and regulations applicable to officials and other staff of the European Communities.</p>	<p>EFSA員工應遵守適用於歐盟官員和其他員工的規定和規章。</p>
<p>2. In respect of its staff, the Authority shall exercise the powers which have been devolved to the appointing authority.</p>	<p>關於其員工，EFSA應行使已移交給指定機關的權力。</p>
<p style="text-align: center;">Article 49 Participation of third countries</p>	<p style="text-align: center;">第49條 第三國之參與</p>
<p>The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation.</p>	<p>EFSA應向已與歐盟簽訂協議的國家開放參與，以藉由在本規章所涵蓋領域內通過和適用歐盟立法。</p>
<p>Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries will participate in the Authority's work, including provisions relating to participation in the networks operated by the Authority, inclusion in the list of competent organisations to which certain tasks may be entrusted by the Authority, financial contributions and staff.</p>	<p>應在那些協定的相關規定下作出安排，特別在具體化這些國家將參與EFSA工作的性質、程度和方式，包括參與EFSA營運網絡有關的規定、列入EFSA可委託某些工作的主管組織名單、財政捐助和職員。</p>
<p style="text-align: center;">CHAPTER IV RAPID ALERT SYSTEM, CRISIS MANAGEMENT AND EMERGENCIES</p>	<p style="text-align: center;">第四章 快速警示系統、危機管理和緊急事件</p>
<p style="text-align: center;">SECTION 1 RAPID ALERT SYSTEM</p>	<p style="text-align: center;">第 1 節 快速警示系統</p>
<p style="text-align: center;">Article 50 Rapid alert system</p>	<p style="text-align: center;">第50條 快速警示系統</p>
<p>1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network. The Commission shall be responsible for managing the network.</p>	<p>特此建立一個快速警示系統，用來通知食品或飼料對人類健康造成的直接或間接風險的網絡。它應涉及會員國、執委會和EFSA。會員國、執委會和EFSA應各指定一個聯絡窗口，其應是網絡的成員。執委會應負責管理網絡。</p>
<p>2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network.</p>	<p>網絡成員有任何資訊關於存在來自食品或飼料對人類健康有直接或間接嚴重風險時，應立即將此資訊透過快速警示系統通知執委會。執委會應立即將此資訊傳送給網絡成員。</p>
<p>The Authority may supplement the notification with any scientific or</p>	<p>EFSA可以用任何科學或技術資訊來補充</p>

technical information, which will facilitate rapid, appropriate risk management action by the Member States.	通知，其將有助於會員國促進迅速、適當的風險管理行動。
3. Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:	在不影響其他歐盟立法的情況下，會員國應立即於快速警示系統通知執委會：
(a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;	他們所採行目的在於限制上市或強制自市場回收或召回的食品或飼料，以保護人類健康並需要迅速行動的任何措施；
(b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;	與專業經營者達成的任何建議或協議，其目的是在自願或強制性的基礎上，考慮到對人類健康的嚴重威脅，為防止、限制或對上市或最終使用的食品或飼料施加特定條件，需要迅速採取行動；
(c) any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.	在歐盟境內邊境管制站的主管機關，對與人類健康有直接或間接風險相關的批次、貨櫃或貨物的食品或飼料的任何拒絕。
The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.	通知應附有發出通知之會員國主管機關所採取行動理由的詳細解釋。其後應適時以補充資訊方式來追蹤，特別是在通知所依據的措施被修改或撤銷的情況。
The Commission shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs.	執委會應將依據第1和第2小段收到的通知和補充資訊立即傳送給網絡成員。
Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin.	在歐盟境內邊境管制站的主管機關拒絕一批次、貨櫃或貨物時，執委會應立即通知歐盟境內的所有邊境管制站及第三來源國。
4. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information.	在食品或飼料已依照快速警示系統發送通知給第三國時，執委會應向第三國提供適當的資訊。
5. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network.	會員國應在接收到快速警示系統傳輸的通知和補充資訊後，立即通知執委會已採取的行動或採取的措施。執委會應立即將此資訊傳送給網絡成員。
6. Participation in the rapid alert system may be opened up to applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.	在歐盟與那些國家或國際組織間的協議的基礎上，按照那些協議中規定的程序，可以對申請國、第三國或國際組織開放參與快速警示系統。後者應以互惠為基礎並應包括等同於歐盟適用的保密措施。
Article 51 Implementing measures	第51條 施行措施
The measures for implementing Article 50 shall be adopted by the Commission, after discussion with the Authority, in accordance with the procedure referred to in Article 58(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information.	施行第50條的措施應由執委會依第58(2)條所述的程序，在與EFSA討論後通過。這些措施應特別規定適用於傳送通知和補充資訊的具體條件和程序。
Article 52 Confidentiality rules for the rapid alert system	第52條 對快速警示系統之保密規定
1. Information, available to the members of the network, relating to a risk to human health posed by food and feed shall in general be available	網絡成員可獲得關於食品和飼料對人類健康造成風險的資訊，一般應按照第10

<p>to the public in accordance with the information principle provided for in Article 10. In general, the public shall have access to information on product identification, the nature of the risk and the measure taken.</p>	<p>條規定的資訊原則向公眾開放。一般而言，公眾應可取得有關產品識別、風險性質和所採取措施的資訊。</p>
<p>However, the members of the network shall take steps to ensure that members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public, if circumstances so require, in order to protect human health.</p>	<p>但是，網絡成員應採取確保其員工不得揭露為本節目的而獲得資訊的作為，這些資訊就其性質而言有正當理由視為職業機密，若情況需要，除了為保護人類健康必須公開的資訊外。</p>
<p>2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.</p>	<p>職業機密的保護不應妨礙向主管機關通報與食品和飼料領域市場監督和執法活動的有效性相關的資訊。接收涵括職業機密資訊的主管機關應確保符合第1段規定的保護。</p>
<p>SECTION 2 EMERGENCIES</p>	<p>第 2 節 緊急事件</p>
<p><i>Article 53</i> Emergency measures for food and feed of Community origin or imported from a third country</p>	<p><i>第53條</i> 對歐盟原產或從第三國進口的食品和飼料之應急措施</p>
<p>1. Where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, acting in accordance with the procedure provided for in Article 58(2) on its own initiative or at the request of a Member State, shall immediately adopt one or more of the following measures, depending on the gravity of the situation:</p>	<p>源自歐盟或從第三國進口的食品或飼料很明顯可能對人類健康、動物健康或環境構成嚴重風險，並且該類風險無法藉由受影響會員國採取措施得到令人滿意的控制，執委會依第58(2)條規定的程序主動或應會員國要求，應視情況的嚴重性，立即採行以下一項或多項措施：</p>
<p>(a) in the case of food or feed of Community origin:</p>	<p>對於源自歐盟的食品或飼料：</p>
<p>(i) suspension of the placing on the market or use of the food in question;</p>	<p>暫停有問題食品的上市或使用；</p>
<p>(ii) suspension of the placing on the market or use of the feed in question;</p>	<p>暫停有問題飼料的上市或使用；</p>
<p>(iii) laying down special conditions for the food or feed in question;</p>	<p>對有問題食品或飼料制定特殊條件；</p>
<p>(iv) any other appropriate interim measure;</p>	<p>任何其他適當的暫行措施；</p>
<p>(b) in the case of food or feed imported from a third country:</p>	<p>對於從第三國進口的食品或飼料：</p>
<p>(i) suspension of imports of the food or feed in question from all or part of the third country concerned and, where applicable, from the third country of transit;</p>	<p>暫停從有關的第三國全部或部分地區，以及在適用情況下，從第三過境國進口有問題食品或飼料；</p>
<p>(ii) laying down special conditions for the food or feed in question from all or part of the third country concerned;</p>	<p>對來自第三國全部或部分有問題食品或飼料制定特殊條件；</p>
<p>(iii) any other appropriate interim measure.</p>	<p>任何其他適當的暫行措施。</p>
<p>2. However, in emergencies, the Commission may provisionally adopt the measures referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.</p>	<p>但是，在緊急情況下，執委會可在與受影響會員國協商並通知其他會員國後，暫時採行第1段所述的措施。</p>
<p>As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 58(2), and the reasons for the Commission's decision shall be made public without delay.</p>	<p>應盡快，並至多在10個工作日內，所採取的措施應依第58(2)條所述的程序確認、修改、撤銷或延長，並無延遲地將執委會所作決定的理由予以公開。</p>
<p><i>Article 54</i> Other emergency measures</p>	<p><i>第54條</i> 其他應急措施</p>
<p>1. Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim</p>	<p>在會員國正式通知執委會需要採取緊急措施，且在執委會未依第53條採取行動時，該會員國可以採取暫行保護措施。</p>

protective measures. In this event, it shall immediately inform the other Member States and the Commission.	在此情況，應立即通知其他會員國和執委會。
2. Within 10 working days, the Commission shall put the matter before the Committee set up in Article 58(1) in accordance with the procedure provided for in Article 58(2) with a view to the extension, amendment or abrogation of the national interim protective measures.	在10個工作日內，執委會應按照第58(2)條規定的程序，將此事件提交給第58(1)規定設立的委員會，以期國家暫行保護措施的延長、修改或廢除。
3. The Member State may maintain its national interim protective measures until the Community measures have been adopted.	會員國可以維持其國家暫行保護措施，直到歐盟措施被採用。
SECTION 3 CRISIS MANAGEMENT	第 3 節 危機管理
<i>Article 55</i> General plan for crisis management	<i>第55條</i> 對危機管理之總體計畫
1. The Commission shall draw up, in close cooperation with the Authority and the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as 'the general plan').	執委會應與EFSA和會員國密切合作，制定食品和飼料安全領域的危機管理總體計畫(以下簡稱總體計畫)。
2. The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54.	總體計畫應詳細說明源自食品和飼料對人類健康造成直接或間接風險情境的類型，該風險不可能由現有規定來預防、消除或降低到可接受程度，或不能僅經由適用第53條和第54條得到充分管理。
The general plan shall also specify the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.	總體計畫還應指定管理危機所需的實務程序，包括適用的透明度原則和溝通策略。
<i>Article 56</i> Crisis unit	<i>第56條</i> 危機處理小組
1. Without prejudice to its role of ensuring the application of Community law, where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 53 and 54, it shall immediately notify the Member States and the Authority.	在不影響確保歐盟法律適用角色的情況下，執委會鑑別了源自食品和飼料對人類健康構成嚴重直接或間接風險的情境，且現有規定無法預防、消除或降低，或不能僅經由適用第53條和第54條得到充分管理的風險時，應立即通知會員國和EFSA。
2. The Commission shall set up a crisis unit immediately, in which the Authority shall participate, and provide scientific and technical assistance if necessary.	執委會應立即成立危機處理小組，EFSA應參與該小組，並在必要時提供科學和技術支援。
<i>Article 57</i> Tasks of the crisis unit	<i>第57條</i> 危機處理小組之任務
1. The crisis unit shall be responsible for collecting and evaluating all relevant information and identifying the options available to prevent, eliminate or reduce to an acceptable level the risk to human health as effectively and rapidly as possible.	危機處理小組應負責收集和評估所有相關資訊，並鑑別可用於儘可能有效和迅速地預防、消除或降低人類健康風險至可接受程度的選項。
2. The crisis unit may request the assistance of any public or private person whose expertise it deems necessary to manage the crisis effectively.	危機處理小組可以請求其認為有效管理危機所需專業知識的任何公部門或私企業人員的協助。
3. The crisis unit shall keep the public informed of the risks involved and the measures taken.	危機處理小組應讓公眾知悉涉及的風險和所採取的措施。
CHAPTER V PROCEDURES AND FINAL PROVISIONS	第 V 章 程序和最終條款
▼ M8	
SECTION 1	第 1 節

<p>EXERCISE OF THE DELEGATION, COMMITTEE AND MEDIATION PROCEDURES</p>	<p>行使授權、委員會和調解程序</p>
<p><i>Article 57a</i> Exercise of the delegation</p>	<p><i>第57a條</i> 行使授權</p>
<p>1. The power to adopt delegated acts is conferred upon the Commission subject to the conditions laid down in this Article.</p>	<p>在符合本條規定的條件下，授予執委會通過授權法案的權力。</p>
<p>2. The power to adopt delegated acts referred to in Article 28(4), Article 29(6) and Article 36(3) shall be conferred on the Commission for a period of five years from 26 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before 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.</p>	<p>第28(4)條、第29(6)條和第36(3)條所述的授權法案的權力應授予執委會，自2019年7月26日起為期5年。執委會應至遲在5年任期結束前9個月擬定1份關於授權的報告。權力授權應被默認延長相同期限，除非歐洲議會或理事會在每個任期結束前不遲於3個月反對此類延長。</p>
<p>3. The delegation of power referred to in Article 28(4), Article 29(6) and Article 36(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 power specified in that decision. It shall take effect the day following the publication of the decision in the <i>Official Journal of the European Union</i> or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.</p>	<p>歐洲議會或理事會可隨時撤銷第28(4)條、第29(6)條和第36(3)條所述的權力授權。撤銷決定應在該決定中指定授權終止日。它應在該決定在歐盟官方公報公布後的次日或其中指定較晚日期生效。它應不影響任何已經生效之授權法案的有效性。</p>
<p>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-Making³³.</p>	<p>在通過授權法案前，執委會應依據2016年4月13日關於更佳立法的機構間協議中所規定的原則，諮詢每個會員國指定的專家。</p>
<p>5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.</p>	<p>一旦通過授權法案，執委會應同步通知歐洲議會和理事會。</p>
<p>6. A delegated act adopted pursuant to Article 28(4), Article 29(6) and Article 36(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and 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.</p>	<p>依據第28(4)條、第29(6)條和第36(3)條通過的授權法案，應僅在歐洲議會或理事會兩者在收到通知2個月期間內沒有表示反對，或在該期限屆滿之前，歐洲議會和理事會均通知執委會他們不會反對的情況下才生效。該期限應在歐洲議會或理事會的倡議下延長2個月。</p>
<p>◀M8</p>	
<p><i>Article 58</i> Committee</p>	<p><i>第58條</i> 委員會</p>
<p>▼M5</p>	
<p>1. The Commission shall be assisted by a Standing Committee on Plants, Animals, Food and Feed, hereinafter referred to as the 'Committee'. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council³⁴. The Committee shall be organised in sections to deal with all relevant matters.</p>	<p>執委會應獲植物、動物、食品和飼料常設委員會(以下簡稱委員會)的支持。該委員會應是歐洲議會和理事會在第(EU)182/2011號規章所指的委員會。委員會應按部門來組織處理所有相關事務。</p>
<p>All references in Union law to the Standing Committee on the Food Chain and Animal Health shall be construed as references to the Committee referred to in the first subparagraph. ◀M5</p>	<p>歐盟法律中對食物鏈和動物健康常設委員會的所有引用應可理解為在第1小段所述的委員會。</p>
<p>▼M4</p>	
<p>2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.</p>	<p>在引用本段時，考慮其中第8條的規定，1999/468/EC 決定的第5條和第7條應適用。</p>
<p>The period laid down in Article 5(6) of Decision 1999/468/EC shall be set</p>	<p>在1999/468/EC決定第5(6)條中規定的</p>

³³ OJ L 123, 12.5.2016, p.1.

³⁴ 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 the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13)/ 制訂有關會員國管轄執委會行使執行權力的機制之規定和一般原則

at three months. ◀M4	期限應設定為3個月。
▼ M8 ◀M8	
<i>Article 59</i> Functions assigned to the Committee	<i>第59條</i> 授予委員會之職能
The Committee shall carry out the functions assigned to it by this Regulation and by other relevant Community provisions, in the cases and conditions provided for in those provisions. It may also examine any issue falling under those provisions, either at the initiative of the Chairman or at the written request of one of its members.	委員會應在那些條款規定的情況和條件下履行本規章和其他相關歐盟條款所賦予的職能。它還可以依主席的倡議或其成員之一的書面請求下，審查屬於那些規定的任何問題。
<i>Article 60</i> Mediation procedure	<i>第60條</i> 調解程序
1. Without prejudice to the application of other Community provisions, where a Member State is of the opinion that a measure taken by another Member State in the field of food safety is either incompatible with this Regulation or is likely to affect the functioning of the internal market, it shall refer the matter to the Commission, which will immediately inform the other Member State concerned.	在不影響其他歐盟規定適用的情況下，當一個會員國認為另一個會員國在食品安全領域採取的措施與本規章不符或可能影響內部市場的運作時，它應將此事項提交到執委會，執委會將立即通知其他受影響的會員國。
2. The two Member States concerned and the Commission shall make every effort to solve the problem. If agreement cannot be reached, the Commission may request an opinion on any relevant contentious scientific issue from the Authority. The terms of that request and the time limit within which the Authority is requested to give its opinion shall be established by mutual agreement between the Commission and the Authority, after consulting the two Member States concerned.	2個受影響的會員國和執委會將盡一切努力來解決問題。若無法達成協議，執委會可就任何相關的有爭議的科學問題，請求EFSA的意見。該請求的條款和要求EFSA發表意見的時限，應由執委會和EFSA在與2個有關會員國協商後設定。
SECTION 2 FINAL PROVISIONS	第 2 節 最終條款
▼ M9	
<i>Article 61</i> Review clause	<i>第61條</i> 條款審查
1. The Commission shall ensure the regular review of the application of this Regulation.	執委會應確保定期審查本規章的適用情況。
2. By 28 March 2026, and every five years thereafter, the Commission shall evaluate the Authority's performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines. That evaluation shall also cover the impact of Article 32a on the functioning of the Authority with particular attention to the relevant workload and mobilisation of staff, and to any shifts in the allocation of the Authority's resources that may have taken place, at the expense of activities of public interest. That evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification.	截至2026年3月28日，以及此後每5年，執委會應依據執委會指引去評估EFSA在其目標、授權、任務、程序和地點方面的表現。該評估還應涵蓋第32a條對EFSA運作的影響，特別關注在相關的工作量和職員的調動，以及在EFSA資源分配可能發生的任何變化，其係以公共利益的活動為代價。該評價應解決修改EFSA任務的可能需要以及任何此類修改的財務影響。
3. In the evaluation referred to in paragraph 2, the Commission shall also evaluate whether the organisational framework of the Authority needs to be further updated with regard to decisions on requests for confidentiality and confirmatory applications, namely by setting up a specific Board of Appeal or by other appropriate means.	在第2段所述的評估中，執委會還應評估EFSA的組織框架是否需要進一步更新關於保密和確認申請請求的決定，即通過設立一個特定的上訴委員會或其他適當的手段。
4. Where the Commission considers that the continued operation of the Authority is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose that the relevant provisions of this Regulation be amended accordingly or repealed.	在執委會認為EFSA繼續在指定的目標、授權和任務方面的運作不再合理時，它可以建議對本規章有關規定作相應地修改或廢止。
5. The Commission shall report to the European Parliament, to the Council and to the Management Board on the findings of its reviews and	執委會應向歐洲議會、理事會和管理委員會報告其依本條審查和評估的結果。

evaluations under this Article. Those findings shall be made public.	那些調查結果應予公開。
<p>Article 61a Fact-finding missions</p>	<p>第61a條 事實調查任務</p>
<p>Commission experts shall perform fact-finding missions in Member States to assess the application, by laboratories and by other testing facilities, of the relevant standards for carrying out tests and studies submitted to the Authority as part of an application, as well as compliance with the notification obligation set out in Article 32b(3), by 28 March 2025. By that date, Commission experts shall also perform fact-finding missions to assess the application of those standards by laboratories and other testing facilities located in third countries insofar as set out in relevant agreements and arrangements with those third countries, including as referred to in Article 49.</p>	<p>執委會專家應在會員國執行事實調查任務，以評估實驗室和其他測試機構所提的申請，對作為申請的一部分提交給EFSA的執行測試和研究的相關標準，以及在2025年3月28日之前遵守第32b(3)條規定的通知義務。到那時，執委會專家還應與那些第三國的相關協議和安排規定的範圍內完成事實調查任務，以評估位於第三國的實驗室和其他測試機構對那些標準的應用情況，包括第49條所提及的。</p>
<p>Non-compliance identified during those fact-finding missions shall be brought to the attention of the Commission, Member States, the Authority as well as the assessed laboratories and other testing facilities. The Commission, the Authority and Member States shall ensure the appropriate follow-up to such identified non-compliance.</p>	<p>在事實調查期間發現的違規行為應提請執委會、會員國、EFSA以及評估的實驗室和其他測試機構注意。執委會、EFSA和會員國應確保對已確定的違規行為採取適當的後續行動。</p>
<p>The outcome of these fact-finding missions shall be presented in an overview report. On the basis of that report, the Commission shall submit a legislative proposal, if appropriate, as regards, in particular, any necessary control procedures, including audits. ◀M9</p>	<p>這些事實調查結果應在概述報告中呈現。在該報告的基礎上，執委會應在適當的情況下提交立法提案，特別是關於任何必要的控制程序，包括稽核。</p>
<p>Article 62 References to the European Food Safety Authority and to the Standing Committee on the Food Chain and Animal Health</p>	<p>第62條 對於EFSA和食物鏈和動物健康常設委員會之引用</p>
<p>1. Every reference in Community legislation to the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Veterinary Committee, the Scientific Committee on Pesticides, the Scientific Committee on Plants and the Scientific Steering Committee shall be replaced by a reference to the European Food Safety Authority.</p>	<p>歐盟立法中對食品科學委員會、動物營養科學委員會、獸醫科學委員會、農藥科學委員會、植物科學委員會和科學指導委員會的每個引用都應以EFSA所取代。</p>
<p>2. Every reference in Community legislation to the Standing Committee on Foodstuffs, the Standing Committee for Feedingstuffs and the Standing Veterinary Committee shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.</p>	<p>歐盟立法中對食品常設委員會、飼料常設委員會和獸醫常設委員會的每個引用都應以食物鏈和動物健康常設委員會所取代。</p>
<p>Every reference to the Standing Committee on Plant Health in Community legislation based upon and including Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC and 91/414/EEC relating to plant protection products and the setting of maximum residue levels shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.</p>	<p>基於並包括與植物保護產品和最大殘留量設定有關的76/895/EEC、86/362/EEC、86/363/EEC、90/642/EEC和91/414/EEC等指令的歐盟立法中植物健康常設委員會的每個引用，應被食物鏈和動物健康常設委員會所取代。</p>
<p>3. For the purpose of paragraphs 1 and 2, 'Community legislation' shall mean all Community Regulations, Directives and Decisions.</p>	<p>就第1段和第2段而言，「歐盟立法」是指所有歐盟規章、指令和決定。</p>
<p>4. Decisions 68/361/EEC, 69/414/EEC and 70/372/EEC are hereby repealed.</p>	<p>68/361/EEC、69/414/EEC和70/372/EEC等決定特此廢止。</p>
<p>Article 63 Competence of the European Agency for the Evaluation of Medicinal Products</p>	<p>第63條 對藥品評估的歐洲機構之權限</p>
<p>This Regulation shall be without prejudice to the competence conferred on the European Agency for the Evaluation of Medicinal Products by Regulation (EEC) No 2309/93, Regulation (EEC) No 2377/90, Council Directive 75/319/EEC³⁵ and Council Directive 81/851/EEC³⁶.</p>	<p>本法規應不影響由第(EEC) 2309/93號規章、第(EEC) 2377/90號規章、理事會75/319/EEC指令和理事會81/851/EEC</p>

35 OJ L 147, 9.6.1975, p. 13. Directive amended by Directive 2001/83/EC of the European Parliament and of the Council (OJ L 311, 28.11.2001, p.67).

		指令所授予歐洲藥品評估機構的權責。
Article 64 Commencement of the Authority's operation	第64條 EFSA運作之起始	
The Authority shall commence its operations on 1 January 2002.		EFSA應於2002年1月1日開始運作。
Article 65 Entry into force	第65條 生效	
This Regulation shall enter into force on the 20th day following that of its publication in the <i>Official Journal of the European Communities</i> .		本規章應在於歐盟官方公報公布後的第20天生效。
Articles 11 and 12 and Articles 14 to 20 shall apply from 1 January 2005.		第11條和第12條以及第14條至第20條自2005年1月1日起適用。
Articles 29, 56, 57 and 60 and Article 62(1) shall apply as from the date of appointment of the members of the Scientific Committee and of the Scientific Panels which shall be announced by means of a notice in the 'C' series of the Official Journal.		第29條、第56條、第57條和第60條以及第62(1)條應自科學委員會和科學小組成員(應以官方公報C系列通知方式予以宣告)任命之日起適用。
This Regulation shall be binding in its entirety and directly applicable in all Member States.		本規章應具有整體約束性且直接適用於所有會員國。

譯註：歷次制修訂層級及說明

(M0) Regulation (EC) No 178/2002 Done at Brussels, 28 January 2002.

<i>For the European Parliament</i> The President P. COX	<i>For the Council</i> The President J. PIQUE I CAMPS	本規章制訂總說明之譯文詳見第2-9頁。
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(M1) Regulation (EC) No 1642/2003 Done at Brussels, 22 July 2003.

<i>For the European Parliament</i> The President P. Cox	<i>For the Council</i> The President G. Alemanno	EFSA 應符合及適用 Council Reg. (EC, Euratom) No 1605/2002 及 Reg (EC) No 1049/2001 規定，因此對 Reg (EC) No 178/2002 進行相應修正。
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(M2) Commission Regulation (EC) No 575/2006 Done at Brussels, 7 April 2006.

<i>For the Commission</i> Markos KYPRIANOU Member of the Commission		EFSA為了應對亦屬食物鏈安全重要一環節的植物健康領域有越來越多的科學意見請求(對植物健康風險進行科學評估)，正式要求執委會建立1個新的常設科學小組(植物健康科學小組)，以處理與植物健康相關的，如昆蟲學、真菌學、病毒學、細菌學、植物學、農學、植物檢疫和植物病害流行病學等各個領域的廣泛專業知識。因此對Reg (EC) No 178/2002進行相應修正(修改名稱Panel on plant health, plant protection products and their residues)。
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(M3) Commission Regulation (EC) No 202/2008 Done at Brussels, 4 March 2008.

<i>For the Commission</i> Androulla VASSILIOU Member of the Commission		EFSA於2007年9月12日向執委會提交請求，由於在維生素和礦物質之食品添加劑、調味劑、加工助劑、酶和與食品接觸材料等領域大量科學意見的授權審核工作，要求建立2個新科學小組'the Panel on food additives and nutrient sources added to food' and 'the Panel on food contact materials, enzymes, flavourings and processing aids'，但後續被M6修正。
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(M4) Regulation (EC) No 596/2009 Done at Brussels, 18 June 2009.

<i>For the European Parliament</i> The President H.-G. PÖTTERING	<i>For the Council</i> The President Š. FÜLE	Decision 2006/512/EC修正Council Decision 1999/468/EC關於賦予執委會依據條約第251條規定程序來通過執行權力的相關審查法制程序，因為此目的所做的修訂是技術性的，且僅涉及執委會程序，因此不需要會員國對相關指令進行轉換。
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(M5) Regulation (EU) No 652/2014 Done at Brussels, 15 May 2014.

<i>For the European Parliament</i> The President M. SCHULZ	<i>For the Council</i> The President D. KOURKOULAS	歐盟應為確保正確實施歐盟法律和確保法律適應科學、技術和社會發展所必需的技術、科學、協調和交流活動，以及提高官方控制的有效性和效率的項目提供資金，制定與食物鏈、動植物健康、動物福利和植物生殖材料相關的支出管理規定，共有4篇、3個附錄及1個執委會關於批准獸醫和植物檢疫計畫程序的聲明。
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(M6) Commission Regulation (EU) 2017/228 Done at Brussels, 9 February 2017.

<i>For the Commission</i> The President Jean-Claude JUNCKER		Reg (EC) No 178/2002第28條設立了10個科學小組，預估技術和科學發展的變化主要影響各小組的工作量，EFSA於2016年2月3日向執委會提交3個小組重新命名及任務調整之請求：'Panel on food additives and flavourings'(ANS Panel)、'Panel on nutrition, novel foods and food allergens'(NDA Panel)和'Panel on food contact materials, enzymes and processing aids'(CEF Panel)，因此進行相應修正。
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(M7) Regulation (EU) 2017/745 Done at Strasbourg, 5 April 2017.

<i>For the European Parliament</i> The President A. TAJANI	<i>For the Council</i> The President I. BORG	關於醫療器械管理框架有本專責法規管理(共10章，123條，17個附件)，因此修訂Reg (EC) No 178/2002，將醫療器械排除在食品範圍之外。
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(M8) Regulation (EU) 2019/1243 Done at Brussels, 20 June 2019.

<i>For the European Parliament The President A. TAJANI</i>	<i>For the Council The President G. CIAMBA</i>	依據歐盟運作條約第290條和第291條，修改授權法案的法制程序，因此，有關法律行為應作相應修正。
(M9) Regulation (EU) 2019/1381 Done at Brussels, 20 June 2019.		
<i>For the European Parliament The President A. TAJANI</i>	<i>For the Council The President G. CIAMBA</i>	在2018年對一般食品法的適用性檢查(REFIT)評估發現，風險溝通總體上被認為不夠有效，這會影響消費者對風險分析過程結果的信心，故有必要確保在整個風險分析(風險評估、風險管理和風險溝通)過程中進行透明、持續和包容性的風險溝通，以促進所有利害關係者之間的參與式和公開對話，確保在風險分析過程中考慮到公共利益的普遍性以及準確性、全面性、透明度、一致性和問責制。因此，對Reg (EC) No 178/2002在風險溝通面向進行總體性規定的增修訂。

by SW