

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

歐洲議會及理事會於 2004 年 4 月 29 日通過有關食品衛生之第 852/2004 號規章

Amended by Commission Regulation (EC) No 1019/2008 of 17 October 2008 (L277 p.7) (M1) (第 1 次修訂)

Amended by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 (L87 p.109) (M2) (第 2 次修訂)

Amended by Commission Regulation (EU) 2021/382 of 3 March 2021 (L74 p.3) (M3) (第3次修訂)

Corrected by Corrigendum, OJ L 226, 25.6.2004, p. 3 (852/2004) (C1) (第 1 次勘誤)

(Based on the consolidation of 24 Mar., 2021) (本譯文係以歐盟公報該規章 2021 年 3 月 24 日合訂版為藍本)

原條文	中譯文
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 Articles 95 and 152(4)(b) thereof,	鑒於建立歐洲共同體(以下簡稱歐盟)的條約，特別是其中的第95條和第152(4)(b)條，
Having regard to the proposal from the Commission ⁽¹⁾ , <small>(1) OJ C 365 E, 19.12.2000, p. 43.</small>	鑒於執委會的提案，
Having regard to the opinion of the European Economic and Social Committee ⁽²⁾ , <small>(2) OJ C 155, 29.5.2001, p. 39.</small>	鑒於歐洲經濟與社會委員會的意見，
Having consulted the Committee of the Regions,	經過與各區域委員會磋商，
Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾ , <small>(3) Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 267), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 1), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.</small>	依據條約第251條規定的程序制定，
Whereas:	茲以：
(1) The pursuit of a high level of protection of human life and health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002 ⁽⁴⁾ . That Regulation also lays down other common principles and definitions for national and Community food law, including the aim of achieving free movement of food within the Community. <small>(4) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1). Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).</small>	如同第178/2002號規章中所制定的，食品法的基本目標之一係為追求人類生命和健康的高度保護。該規章同時規定關於國家和歐盟食品法的其他共同原則及定義，包括達到食品在歐盟境內自由流通的目標。
(2) Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs ⁽⁵⁾ laid down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules. <small>(5) OJ L 175, 19.7.1993, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).</small>	1993年6月14日關於食品(材)衛生的理事會93/43/EEC指令，制定食品(材)衛生的一般規定及符合該等規定的查證程序。
(3) Experience has shown that these rules and procedures constitute a sound basis for ensuring food safety. In the context of the common agricultural policy, many directives have been adopted to establish specific health rules for the production and placing on the market of the products listed in Annex I to the Treaty. These health rules have reduced trade barriers for the products concerned, contributing to the creation of the internal market while ensuring a high level of protection of public health.	由過往經驗顯示，這些規定和程序對確保食品安全建構了良好基礎。在共同農業政策(CAP)下，已採行許多指令作為建立條約附件I所列產品其生產和上市的具體衛生規定。這些衛生規定降低了特定產品的貿易壁壘，有助於內部市場的建立，同時確保對公共衛生的高度保護。
(4) With regard to public health, these rules and procedures contain common principles, in particular in relation to the manufacturers' and competent authorities' responsibilities, structural, operational and	在公共衛生方面，這些規定和程序含有共同原則，特別是關於製造商和主管機關的責任，廠場結構、操

<p>hygiene requirements for establishments, procedures for the approval of establishments, requirements for storage and transport and health marks.</p>	<p>作和衛生要求，廠場核准程序，貯存和運輸要求以及衛生標誌。</p>
<p>(5) These principles constitute a common basis for the hygienic production of all food, including products of animal origin listed in Annex I to the Treaty.</p>	<p>這些原則是所有食品衛生生產的共同基礎，包括列於條約附件I的動物源性產品。</p>
<p>(6) In addition to this common basis, specific hygiene rules are necessary for certain foodstuffs. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ⁽⁶⁾ lays down these rules. <small>(6) See page 22 of this Official Journal.</small></p>	<p>除此共同基礎外，特定的衛生規定對某些食品(材)是必要的。2004年4月29日歐洲議會及理事會第853/2004號規章則制定了動物源性食品的具體衛生規定。</p>
<p>(7) The principal objective of the new general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety.</p>	<p>新的一般和特定衛生規定的主要目的是為確保對消費者食品安全的高度保護。</p>
<p>(8) An integrated approach is necessary to ensure food safety from the place of primary production up to and including placing on the market or export. Every food business operator along the food chain should ensure that food safety is not compromised.</p>	<p>有必要採取一個整合方案以確保從初級生產地直到並包含產品上市或出口的食品安全。食物鏈中的每個食品業者(FBO)都應確保食品安全不受損害。</p>
<p>(9) Community rules should not apply either to primary production for private domestic use, or to the domestic preparation, handling or storage of food for private domestic consumption. Moreover, they should apply only to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation.</p>	<p>歐盟規定不應適用於供私人家用的初級生產，以及供私人消費的家庭製備、處理或貯存的食物。此外，其應僅適用於具特定連續性的活動和一定程度組織之企業體。</p>
<p>(10) Food hazards present at the level of primary production should be identified and adequately controlled to ensure the achievement of the objectives of this Regulation. However, in the case of the direct supply of small quantities of primary products, by the food business operator producing them, to the final consumer or to a local retail establishment, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer.</p>	<p>存在於初級生產的食品危害，應可被鑑定並被充分的控制，以確保達成本規章的目標。然而，當由FBO將所生產的少量初級產品，直接供應給最終消費者或當地零售店時，透過國內法令來保護公眾健康是適當的，特別是因為生產者和消費者之間的密切關係。</p>
<p>(11) The application of hazard analysis and critical control point (HACCP) principles to primary production is not yet generally feasible. However, guides to good practice should encourage the use of appropriate hygiene practices at farm level. Where necessary, specific hygiene rules for primary production should supplement these guides. It is appropriate for the hygiene requirements applicable to primary production and associated operations to differ from those for other operations.</p>	<p>應用危害分析重點控制點(HACCP)原則至初級生產尚未普遍可行。不過，良好作業指引應鼓勵在農場端使用適當的衛生操作。必要時，初級生產的特定衛生規定應補充於這些指引。適用於初級生產及其相關操作的衛生要求與其他作業的衛生要求不同是適恰的。</p>
<p>(12) Food safety is a result of several factors: legislation should lay down minimum hygiene requirements; official controls should be in place to check food business operators' compliance and food business operators should establish and operate food safety programmes and procedures based on the HACCP principles.</p>	<p>食品安全是由許多要素構成的結果：法令應該訂定最低的衛生要求；官方管制應落實檢查FBOs的符合性以及FBOs應建立並執行基於HACCP原則的食品安全方案和程序。</p>
<p>(13) Successful implementation of the procedures based on the HACCP principles will require the full cooperation and commitment of food business employees. To this end, employees should undergo training. The HACCP system is an instrument to help food business</p>	<p>成功實施以HACCP原則為基礎的程序，將需要食品企業員工之全力合作和承諾。為達此目的，員工應經過培訓。HACCP系統是幫助FBOs達</p>

<p>operators attain a higher standard of food safety. The HACCP system should not be regarded as a method of self-regulation and should not replace official controls.</p>	<p>成較高食品安全標準的一項工具。HACCP系統不應被視為一種自主管理的方法，也不應取代官方管制。</p>
<p>(14) While the requirement of establishing procedures based on the HACCP principles should not initially apply to primary production, the feasibility of its extension will be one element of the review that the Commission will carry out following implementation of this Regulation. It is, however, appropriate for Member States to encourage operators at the level of primary production to apply such principles as far as possible.</p>	<p>要求建立以HACCP原則為基礎的程序，初始不應強制施行於初級生產，但其延伸的可行性將是執委會在施行本規章後進行審查的一項要素。然而會員國可適當的鼓勵初級生產業者儘可能的使用該等原則。</p>
<p>(15) The HACCP requirements should take account of the principles contained in the <i>Codex Alimentarius</i>. They should provide sufficient flexibility to be applicable in all situations, including in small businesses. In particular, it is necessary to recognise that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing 'critical limits' does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.</p>	<p>HACCP的要求應考慮包含於食品法典中的原則。其應提供足夠的彈性以適用所有的情況，包括小型企業。特別是，必須要認知到，對某些產業，要鑑定出重要控制點(CCPs)是不可能的，以及在某些情況下，良好衛生規範(GHP)即能取代CCPs的監控。同樣的，建立管制界限(CL)的要求，並不表示每一種情況都有必要固定一個數字作為界限。此外，為了避免對非常小的企業造成過度負擔，文件保存的要求需有彈性。</p>
<p>(16) Flexibility is also appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments. Flexibility is particularly important for regions that are subject to special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty. However, flexibility should not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility should be fully transparent. It should provide, where necessary to resolve disagreements, for discussion within the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002.</p>	<p>在任何食品生產、加工或配銷階段以及對廠場結構上的要求，保有靈活彈性以可以繼續使用傳統方法亦是適當的。保有靈活彈性對於受特殊地理限制的區域是特別重要的，包括條例第299(2)條提及的最偏遠的地區。但是，保有靈活彈性不應該損及食品衛生的目標。此外，因為所有遵照衛生規則所生產的食品，將自由流通銷售於全歐盟地區，允許會員國採行彈性之程序應充分透明。當需要解決歧見時，應提送到依第178/2002號規章所設立的食物鏈和動物衛生常務委員會(SCFAH)進行討論。</p>
<p>(17) The setting of objectives such as pathogen reduction targets or performance standards may guide the implementation of hygiene rules. It is therefore necessary to provide procedures for that purpose. Such objectives would supplement existing food law, such as Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ⁽⁷⁾, which provides for the establishment of maximum tolerances for specific contaminants, and Regulation (EC) No 178/2002, which prohibits the placing on the market of unsafe food and provides a uniform basis for the use of the precautionary principle.</p>	<p>諸如減少病原菌之標的或成效標準等目標設定，可以指導衛生規定的實施。因此有必要為該目的地提供相關程序。此等目標將輔助既有的食品法令，例如1993年2月8日理事會第315/93號規章制定關於食品中污染物質的歐盟程序以建立特定污染物的最大容許量，以及第178/2002號規章，其禁止將不安全的食品流入市場，並對預防性原則的使用提供一致性基礎。</p>
<p>(18) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food</p>	<p>考慮技術和科學的進展，應確保執委會與SCFAH內的會員國間進行緊密和有效的合作。本規章有考慮到</p>

(7) OJ L 37, 13.2.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003.

Chain and Animal Health. This Regulation takes account of international obligations laid down in the WTO Sanitary and Phytosanitary Agreement and the international food safety standards contained in the <i>Codex Alimentarius</i> .	在WTO/SPS協議中規定的國際義務，以及在食品法典中所包含的國際食品安全標準。
(19) The registration of establishments and the cooperation of food business operators are necessary to allow the competent authorities to perform official controls efficiently.	廠場註冊與FBOs的合作，以使主管機關有效率地完成官方管制是必要的。
(20) The traceability of food and food ingredients along the food chain is an essential element in ensuring food safety. Regulation (EC) No 178/2002 contains rules to ensure the traceability of food and food ingredients and provides a procedure for the adoption of implementing rules to apply these principles in respect of specific sectors.	食物鏈中食品及食品成分的可追溯性是確保食品安全的基本要素。第178/2002號規章包含了確保食品及食品成分可追溯性的規定，並就特定部分所適用的這些原則，提供採用執行規定的程序。
(21) Food imported into the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002 or satisfy rules that are equivalent to Community rules. The present Regulation defines certain specific hygiene requirements for food imported into the Community.	進口到歐盟的食品應符合第178/2002號規章所制定的一般要求或滿足等同於歐盟規定的要求。現有規章明訂進口到歐盟的食品的某些特定衛生要求。
(22) Food exported to third countries from the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002. The present Regulation defines certain specific hygiene requirements for food exported from the Community.	歐盟出口到第3國的食品應符合第178/2002號規章所制定的一般要求。現有規章明訂歐盟出口食品的某些特定衛生要求。
(23) Scientific advice should underpin Community legislation on food hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.	科學建言應用來鞏固歐盟食品衛生的立法。為此，必要時應諮詢歐洲食品安全局(EFSA)。
(24) Since this Regulation replaces Directive 93/43/EEC, the latter should be repealed.	因本規章取代第93/43/EEC號指令，後者將予以廢止。
(25) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow the affected industries time to adapt.	在新的食品衛生立法所有規定生效前，本規章的要求不應適用。新規定自生效到執行之間，提供至少18個月的緩衝期亦是適當的，以使受影響的行業有時間調適。
(26) 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 Commission ⁽⁸⁾ ,	施行本規章的必要措施，應依據1999年6月28日理事會1999/468/EC決議，關於授予執委會執行權力的程序來通過。
<small>(8) OJ L 184, 17.7.1999, p. 23.</small>	
HAVE ADOPTED THIS REGULATION:	已通過本規章：
CHAPTER I GENERAL PROVISIONS	第I章 總則
Article 1 Scope	第1條 適用範圍
1. This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:	本規章對FBOs制定關於食品(材)衛生的一般規定，特別是以下原則：
(a) primary responsibility for food safety rests with the food business	食品安全之主要責任歸屬於FBO；

operator;	
(b) it is necessary to ensure food safety throughout the food chain, starting with primary production;	有必要確保自初級生產開始的整個食物鏈的食品安全；
(c) it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;	對無法在室溫安全貯存的食品，尤其是冷凍食品，維持冷鏈是重要的；
(d) general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;	基於HACCP原則之程序的實施併同良好衛生規範(GHP)的應用，應加諸為FBOs的責任；
(e) guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;	良好操作指引是一種很有用的工具，可幫助食物鏈各階層的FBOs符合食品衛生規定和應用HACCP原則；
(f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment;	有必要建立以科學風險評估為基礎的食品微生物標準及溫度控管要求；
(g) it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard.	有必要確保進口食品至少與歐盟所生產食品之衛生標準相同或等效。
This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.	本規章應適用於食品生產、加工與配銷的所有階段，以及適用於出口，且不得影響與食品衛生相關之更多特定之要求。
2. This Regulation shall not apply to:	本規章不適用於：
(a) primary production for private domestic use;	私人家用的初級生產；
(b) the domestic preparation, handling or storage of food for private domestic consumption;	供私人消費之家庭製備、處理或貯存之食品；
(c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;	由生產者向最終消費者或向直接供應給最終消費者之當地零售店，直接供應之少量初級產品；
(d) collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.	僅因其處理生產明膠或膠原蛋白之原料而歸屬於食品產業定義之集貨中心與鞣皮廠。
3. Member States shall establish, under national law, rules governing the activities referred to in paragraph 2(c). Such national rules shall ensure the achievement of the objectives of this Regulation.	會員國應依國家法律建立管理第2(c)段所敘活動之規定。此類國家規定應確保本規章目標之達成。
Article 2 Definitions	第2條 定義
1. For the purposes of this Regulation:	就本規章制定目的而言：
(a) 'food hygiene', hereinafter called 'hygiene', means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;	食品衛生(以下簡稱衛生)：指在考慮到食品預期用途下，控制危害與確保適合人類食用之必要措施和條件；
(b) 'primary products' means products of primary production including products of the soil, of stock farming, of hunting and fishing;	初級產品：指包括種植、畜牧養殖、狩獵及漁撈等初級生產之產品；
(c) 'establishment' means any unit of a food business;	廠場：指食品企業之任何單位；

<p>(d) 'competent authority' means the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any other authority to which that central authority has delegated that competence; it shall also include, where appropriate, the corresponding authority of a third country;</p>	<p>主管機關：指會員國有能力確保遵循本規章要求的中央機關或經中央機關授權的任何其他機關；在適當情況下，還應包括第三國相對應的機關；</p>
<p>(e) 'equivalent' means, in respect of different systems, capable of meeting the same objectives;</p>	<p>等效：指在不同的系統有能力達到相同的目標；</p>
<p>(f) 'contamination' means the presence or introduction of a hazard;</p>	<p>污染：指一種危害的存在或導入；</p>
<p>(g) 'potable water' means water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption⁽⁹⁾;</p> <p><small>(9) OJ L 330, 5.12.1998, p. 32. Directive as amended by Regulation (EC) No 1882/2003.</small></p>	<p>飲用水：指符合1998年11月3日理事會98/83/EC指令關於供人飲用水品質的最低要求的水；</p>
<p>(h) 'clean seawater' means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food;</p>	<p>潔淨海水：指天然、人工或純淨的海水或微鹹水，不含能直接或間接影響食品衛生安全品質之微生物、有害物質或有毒海洋浮游生物；</p>
<p>(i) 'clean water' means clean seawater and fresh water of a similar quality;</p>	<p>潔淨水：指具相似品質的潔淨海水及淡水；</p>
<p>(j) 'wrapping' means the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself;</p>	<p>內包裝：指將食品放置於直接接觸的包裝材料或容器中，以及指該包裝材料或容器本身；</p>
<p>(k) 'packaging' means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself;</p>	<p>外包裝：指將一個或多個已內包裝的食品(材)放置於第二層容器中，以及指後者的容器本身；</p>
<p>(l) 'hermetically sealed container' means a container that is designed and intended to be secure against the entry of hazards;</p>	<p>密封容器：指經過設計並有效防止危害侵入的容器；</p>
<p>(m) 'processing' means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;</p>	<p>加工：指實質上改變產品最初狀態的任何作業，包括加熱、煙燻、醃漬、熟成、乾燥、鹽漬、萃取、壓擠或這些作業過程的組合；</p>
<p>(n) 'unprocessed products' means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;</p>	<p>未加工產品：指未經加工處理的食品(材)，包括已經被分割、分解、切斷、切片、去骨、切碎、去皮、絞碎、分切、清洗、修整、去殼、研磨、冷藏、冷凍，超低溫冷凍或解凍的產品；</p>
<p>(o) 'processed products' means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.</p>	<p>已加工產品：指經過加工處理之食品(材)。這些產品可能含有製造或賦形所需的組成分。</p>
<p>2. The definitions laid down in Regulation (EC) No 178/2002 shall also apply.</p>	<p>第178/2002號規章中規定的定義亦應適用。</p>
<p>3. In the Annexes to this Regulation the terms 'where necessary', 'where appropriate', 'adequate' and 'sufficient' shall mean respectively where necessary, where appropriate, adequate or sufficient to achieve the objectives of this Regulation.</p>	<p>本規章的附件中，「必要時」、「適當時」、「足夠的」和「充分的」等詞彙，應分別表示在必要時、適當時、足夠的和充分的情況下，實現本規章目標。</p>

CHAPTER II

第II章
食品業者的義務

FOOD BUSINESS OPERATORS' OBLIGATIONS	
<i>Article 3</i> General obligation	第3條 一般義務
Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.	FBOs應確保食品在其控制下生產、加工及流通銷售的所有階段，滿足本規章所制訂關於衛生的要求。
<i>Article 4</i> General and specific hygiene requirements	第4條 一般及特定的衛生要求
1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004.	從事附件I所列之初級生產與相關作業的FBOs，應符合附件I A部份所制定的一般衛生規定以及第853/2004號規章中規定的任何特定要求。
2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004.	從事第1段所述階段後的食品生產、加工與配銷的FBOs，應符合附件II的衛生要求以及第853/2004號規章中規定的任何特定要求。
3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:	FBOs應適當的採行下列特定衛生措施：
(a) compliance with microbiological criteria for foodstuffs;	符合食品(材)的微生物標準；
(b) procedures necessary to meet targets set to achieve the objectives of this Regulation;	為達到本規章目標所必須的程序；
(c) compliance with temperature control requirements for foodstuffs;	符合食品(材)溫度控管的要求；
(d) maintenance of the cold chain;	冷鏈的維持；
(e) sampling and analysis.	取樣和檢驗分析。
▼M2 按：M2僅涉法制審查程序之修正，無涉食品衛生規定。	
4. The criteria, requirements and targets referred to in paragraph 3, and associated sampling and analysis methods shall be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3). ◀M2	第3段所述之標準、要求與目標，以及相關的取樣和分析方法應由執委會制定。旨在通過補充來修訂本規章非關鍵要素的那些措施，應根據第14(3)條所述的法制程序進行審查。
5. When this Regulation, Regulation (EC) No 853/2004 and their implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down in other Community or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.	當本規章、第853/2004號規章及其施行措施未指定取樣或分析方法時，FBOs可使用其他歐盟或國家法規所訂的適當方法，或在沒有這些方法的情況下，可以使用能得到等效結果的方法，那些方法依國際認可的規定或協議經過科學驗證是有效的。
6. Food business operators may use the guides provided for in Articles 7, 8 and 9 as an aid to compliance with their obligations under this Regulation.	FBOs可以使用第7、8、9條所述的指引，來協助達到符合本規章規定之義務。
<i>Article 5</i>	第5條

Hazard analysis and critical control points	危害分析及重要管制點(HACCP)
1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.	FBOs應依HACCP原則落實、執行並維持一個或多個永久的程序。
2. The HACCP principles referred to in paragraph 1 consist of the following:	第1段所指的HACCP原則，包括：
(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;	鑑定任何必須被防止、消除或降低至可接受程度的危害；
(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;	鑑定每一步驟的重要管制點(CCPs)，其管控對防止或消除危害或將其降低至可接受程度至關重要；
(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;	建立CCPs的管制界限，對已識別危害的預防、消弭或降低，可區別為可接受及不可接受；
(d) establishing and implementing effective monitoring procedures at critical control points;	在CCPs建立及執行有效的監控程序；
(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;	當監控顯示CCPs不在管制範圍時，要建立矯正措施；
(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and	建立應定期執行的程序，以確認上述(a)到(e)的措施均有效地運作；及
(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).	建立與食品企業性質、規模相稱的文件及紀錄，以證實上述(a)至(f)的措施有效應用。
When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.	當產品、製程或任何步驟有任何修改時，FBOs應重新審視程序並做必要的修正。
3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.	第1段應只適用於從事附件I所列初級生產與相關作業之後各階段的食品生產、加工與配銷的FBOs。
4. Food business operators shall:	FBOs應：
(a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;	考慮食品企業的性質與規模，以主管機關要求的方式，對主管機關提供符合第1段規定的證據；
(b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;	確保任何按照本條文所制訂程序的文件一直都是最新版本；
(c) retain any other documents and records for an appropriate period.	對任何其他文件與紀錄，保存適當的期限。
5. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c).	本條文的詳細執行安排，可以依據第14(2)條所述之程序來訂定。該安排可能有助於某些FBOs實施本條文以符合第1段的要求，特別是通過規定使用HACCP原則應用指引中的程序。該安排亦可指定FBOs應依據第4(c)段保留文件與紀錄的期限。

<p style="text-align: center;"><i>Article 6</i> Official controls, registration and approval</p>	<p style="text-align: center;">第6條 官方管制、註冊與核可</p>
<p>1. Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.</p>	<p>FBOs應依據其他適用的歐盟法規與主管機關合作，若無，則依國家法規。</p>
<p>2. In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.</p>	<p>特別是，每個FBO應對在其控制之下的每個廠場所進行任何階段的食物生產、加工及配銷，以相應的主管機關要求方式進行通報，以便主管機關對每個這樣的廠場進行註冊。</p>
<p>Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.</p>	<p>FBOs亦應確保主管機關對其廠場掌握最新資訊，包括通報生產活動的任何顯著改變及現有廠場的關閉。</p>
<p>3. However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:</p>	<p>然而，當廠場依下列條件需要主管機關核准的情況下，FBOs應確保廠場經主管機關至少1次現場訪查：</p>
<p>(a) under the national law of the Member State in which the establishment is located;</p>	<p>依據廠場所在會員國的國家法律；</p>
<p>(b) under Regulation (EC) No 853/2004; or</p>	<p>依據第853/2004號規章； 或</p>
<p>▼M2 (c) by a decision adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3). ◀M2</p>	<p>通過執員會的決定。應根據第14(3)條所述的法制審查程序，採行旨在修訂本規章非關鍵要素的措施。</p>
<p>Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.</p>	<p>如(a)段所述在國家法律下，任何會員國需要核可某個位於其領土的廠場時，應通知執委會及其他會員國該等相關國家規定。</p>
<p style="text-align: center;"><i>CHAPTER III</i> GUIDES TO GOOD PRACTICE</p>	<p style="text-align: center;">第三章 良好作業指引</p>
<p style="text-align: center;"><i>Article 7</i> Development, dissemination and use of guides</p>	<p style="text-align: center;">第7條 指引的制定、推廣及使用</p>
<p>Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP principles in accordance with Article 8. Community guides shall be developed in accordance with Article 9.</p>	<p>會員國應鼓勵依據第8條制定食品衛生及HACCP原則應用之國家衛生良好作業指引。歐盟指引則應依據第9條制定。</p>
<p>The dissemination and use of both national and Community guides shall be encouraged. Nevertheless, food business operators may use these guides on a voluntary basis.</p>	<p>應鼓勵推廣和使用國家與歐盟指引。然而，FBOs可基於自願來使用這些指引。</p>
<p style="text-align: center;"><i>Article 8</i> National guides</p>	<p style="text-align: center;">第8條 國家指引</p>

1. When national guides to good practice are developed, they shall be developed and disseminated by food business sectors:	制定國家良好作業指引時，應由食品相關產業制定及推廣：
(a) in consultation with representatives of parties whose interests may be substantially affected, such as competent authorities and consumer groups;	與其權益可能受影響的利害團體代表協商，例如相關主管機關與消費者團體；
(b) having regard to relevant codes of practice of the <i>Codex Alimentarius</i> ; and	考慮到食品法典中相關的操作規範； 及
(c) when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.	涉及附件I所列之初級生產與相關作業時，參考附件I B部分所訂的建議。
2. National guides may be developed under the aegis of a national standards institute referred to in Annex II to Directive 98/34/EC ⁽¹⁰⁾ . <small>(10) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, p. 37). Directive as last amended by the 2003 Act of Accession.</small>	國家指引可在98/34/EC指令附件II所提及的國家標準協會支持下來制定。
3. Member States shall assess national guides in order to ensure that:	會員國應評估國家指引以確保：
(a) they have been developed in accordance with paragraph 1;	其依據第1段所制定；
(b) their contents are practicable for the sectors to which they refer; and	其內容對所涉及的產業是可行的； 及
(c) they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.	其適合作為符合第3、4和5條各環節產業及所涵括食品(材)的指引。
4. Member States shall forward to the Commission national guides complying with the requirements of paragraph 3. The Commission shall set up and run a registration system for such guides and make it available to Member States.	會員國應向執委會遞送符合第3段要求的國家指引。執委會應建立並運作此類指引之登記系統，並使其可被會員國取得。
5. Guides to good practice drawn up pursuant to Directive 93/43/EEC shall continue to apply after the entry into force of this Regulation, provided that they are compatible with its objectives.	在本規章正式生效後，依據93/43/EEC指令制定的良好作業指引，其符合本規章目標，應繼續適用。
<i>Article 9</i> Community guides	第9條 歐盟指引
1. Before Community guides to good practice for hygiene or for the application of the HACCP principles are developed, the Commission shall consult the Committee referred to in Article 14. The objective of this consultation shall be to consider the case for such guides, their scope and subject matter.	在制定歐盟食品衛生或HACCP原則應用之良好作業指引前，執委會應與第14條所述之委員會協商。協商之目的應考慮此指引的案例、範圍與主題。
2. When Community guides are prepared, the Commission shall ensure that they are developed and disseminated:	當歐盟指引編寫完成時，執委會應確認其制定及推廣：
(a) by or in consultation with appropriate representatives of European food business sectors, including SMEs, and other interested parties, such as consumer groups;	透過歐洲合適的食品企業代表協商，包括小中型企業與其他權益團體，例如消費者團體；
(b) in collaboration with parties whose interests may be substantially affected, including competent authorities;	與其權益可能受影響之利害團體合作，包括相關主管機關；
(c) having regard to relevant codes of practice of the <i>Codex Alimentarius</i> ; and	考慮到食品法典中相關的操作規範； 及
(d) when they concern primary production and those associated	涉及附件I所列初級生產和相關作業時，參照附件I B部分所載的建

operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.	議。
3. The Committee referred to in Article 14 shall assess draft Community guides in order to ensure that:	第14條所述之委員會應評估歐盟指引草案以確認：
(a) they have been developed in accordance with paragraph 2;	其係依據第2段所制定；
(b) their contents are practicable for the sectors to which they refer throughout the Community; and	該指引內容對於其產業在整個歐盟是確實可行的； 及
(c) they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.	其適合作為符合第3、4和5條各環節產業及所涵括食品(材)的指引。
4. The Commission shall invite the Committee referred to in Article 14 periodically to review any Community guides prepared in accordance with this Article, in cooperation with the bodies mentioned in paragraph 2.	執委會應與第2段所述之團體合作，定期邀請第14條所述之委員會審查依據本條文編寫的任何歐盟指引。
The aim of this review shall be to ensure that the guides remain practicable and to take account of technological and scientific developments.	此審查目的應確保指引維持確實可行並考慮到技術與科學上之發展。
5. The titles and references of Community guides prepared in accordance with this Article shall be published in the C series of the Official Journal of the European Union.	依據本條文所編寫的歐盟指引之標題及參考資料應於歐盟官方期刊之C系列上公布。
CHAPTER IV IMPORTS AND EXPORTS	第四章 進口和出口
<i>Article 10</i> Imports	<i>第10條</i> 進口
As regards the hygiene of imported food, the relevant requirements of food law referred to in Article 11 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.	關於進口食品之衛生，參照第178/2002號規章第11條中相關食品法律之要求，應包括本規章第3條到第6條之要求。
<i>Article 11</i> Exports	<i>第11條</i> 出口
As regards the hygiene of exported or re-exported food, the relevant requirements of food law referred to in Article 12 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.	關於出口或再出口食品之衛生，參照第178/2002號規章第12條中相關食品法律之要求，應包括本規章第3條到第6條之要求。
CHAPTER V FINAL PROVISIONS	第五章 最終規定
▼M2	
<i>Article 12</i>	<i>第12條</i>
Transitional measures of general scope designed to amend non-essential elements of this Regulation, inter alia, by supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).	旨在修訂本規章非關鍵要素的一般範圍的過渡措施，除其他外，通過補充新的非關鍵要素，特別是本規章所規定的進一步規定，應根據第14(3)條所述的法制審查程序。

<p>Other implementing or transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 14(2). ◀M2</p>	<p>其他執行或過渡措施可採用依據第14(2)條所述的法制程序。</p>
<p><i>Article 13</i> Amendment and adaptation of Annexes I and II</p>	<p><i>第13條</i> 附件 I 與 II 之修正與改編</p>
<p>▼M2</p>	
<p>1. Annexes I and II may be adapted or updated by the Commission taking into account: ◀M2</p>	<p>執委會在考慮到下列因素後，可改編或更新附件 I 與 II：</p>
<p>(a) the need to revise the recommendations set out in Annex I, Part B, paragraph 2;</p>	<p>修正附件 I B 部分第 2 段所載建議的需要；</p>
<p>(b) the experience gained from the implementation of HACCP based systems pursuant to Article 5;</p>	<p>依第 5 條實施基於 HACCP 系統所獲得的經驗；</p>
<p>(c) technological developments and their practical consequences and consumer expectations with regard to food composition;</p>	<p>關於食品技術之發展與實踐結果，及消費者對食品組成分的期待；</p>
<p>(d) scientific advice, particularly new risk assessments;</p>	<p>科學建議，特別是新的風險評估；</p>
<p>(e) microbiological and temperature criteria for foodstuffs.</p>	<p>食品(材)之微生物與溫度標準；</p>
<p>▼M2</p>	
<p>Those measures, designed to amend non-essential elements of this Regulation, <i>inter alia</i>, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).</p>	<p>應依據第 14(3) 條所述法制審查程序，除其他外，進行補充旨在修訂本規章非關鍵要素的那些措施。</p>
<p>2. Derogations from Annexes I and II may be granted by the Commission, in particular to facilitate the implementation of Article 5 for small businesses, taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of this Regulation. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3). ◀M2</p>	<p>考慮相關風險因素，執委會可批准排除附件 I 與 II 規定，特別是為了使小型企業對第 5 條之實施變得容易，但此種排除不可影響達到本規章的目標。應根據第 14(3) 條所述的法制審查程序，採用旨在通過補充而修訂本規章非關鍵要素的那些措施。</p>
<p>3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7 of this Article, national measures adapting the requirements laid down in Annex II.</p>	<p>會員國可在不損害本規章目標下，依據本條文第 4 到 7 段規定，採行改編附件 II 所制定要求的國家措施。</p>
<p>4. (a) The national measures referred to in paragraph 3 shall have the aim of:</p>	<p>在第 3 段所指的國家措施應符合下列目的：</p>
<p>(i) enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food; or</p>	<p>促使可繼續利用傳統方法於各階段的食品生產、加工處理或配銷。 或</p>
<p>(ii) accommodating the needs of food businesses situated in regions that are subject to special geographical constraints.</p>	<p>滿足地理環境受限制之食品企業的需要。</p>
<p>(b) In other cases, they shall apply only to the construction, layout and equipment of establishments.</p>	<p>在其他狀況下，應只適用於廠場之建築、配置與設備。</p>
<p>5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. The notification shall:</p>	<p>任何希望採用第 3 段所指之國家措施的會員國，應通知執委會與其他會員國。其通知應：</p>
<p>(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation</p>	<p>對於會員國認為需被改編之措施與其改編該措施之本質，提供詳細描</p>

sought;	述；
(b) describe the foodstuffs and establishments concerned;	描述關切之食品(材)和廠場；
(c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation; and	闡述改編的原因，包含提供相關執行之風險分析及任何採取之措施以確保其改編不會有損達成本規章的目標； 和
(d) give any other relevant information.	提供任何有關的資訊。
6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of the adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 14(1). The Commission may decide, in accordance with the procedure referred to in Article 14(2), whether the envisaged measures may be implemented, subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraph 1 or 2.	其他會員國應於接到第5點所指之通知後，在3個月的時間內提出意見給執委會。在有第4(b)條修正的情形下，會員國可以要求將時間延長至4個月。當執委會收到1個或多個會員國書面評論意見時，將與第14(1)條所提及的委員會內的會員國進行磋商。執委會依據第14(2)條程序可以判決擬議中的措施是否可以實施，前提條件是做出適當的修正是必要的。在適當的情形下，執委會可以依據第1或2段規定對一般措施提出建議。
7. A Member State may adopt national measures adapting the requirements of Annex II only:	會員國只可於以下情況，採取改編附件II要求的國家措施：
(a) in compliance with a decision adopted in accordance with paragraph 6; or	符合依據第6點要求所採用的決定； 或
(b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6.	假使，依照第6點規定的期限1個月後，執委會還未通知會員國其接到書面意見或其擬提出依第6段要求所採用之決定。
<i>Article 14</i> Committee procedure	<i>第14條</i> 委員會程序
1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.	執委會應得到SCFCAH的協助。
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. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.	鑒於第8條的規定，在制定本段的參考時，第1999/468/EC號決議中第5條與第7條應予適用。第1999/468/EC號決議中第5(6)條規定期限應限定為3個月。
▼ <u>M2</u>	
3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. ◀ <u>M2</u>	鑒於第8條的規定，在制定本段的參考時，第1999/468/EC號決議中第5a(1)到(4)條與第7條應予適用。
<i>Article 15</i> Consultation of the European Food Safety Authority	<i>第15條</i> 向歐洲食品安全局(EFSA)諮詢
The Commission shall consult the European Food Safety Authority on any	就屬於本規章範圍內可能對公共衛

<p>matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing criteria, requirements or targets in accordance with Article 4(4).</p>	<p>生產生重大影響的任何事項，特別是依據第4(4)條提出標準、要求或目標之前，執委會應諮詢EFSA。</p>
<p><i>Article 16</i> Report to the European Parliament and the Council</p>	<p>第16條 向歐洲議會與理事會報告</p>
<p>1. The Commission shall, not later than 20 May 2009, submit a report to the European Parliament and the Council.</p>	<p>執委會應於2009年5月20日前向歐洲議會和理事會提交1份報告。</p>
<p>2. The report shall, in particular, review the experience gained from the application of this Regulation and consider whether it would be desirable and practicable to provide for the extension of the requirements of Article 5 to food business operators carrying out primary production and those associated operations listed in Annex I.</p>	<p>該報告應特別評論從實施本規章所獲得的經驗，並考慮將第5條的要求延伸到附件1所列的初級生產和相關作業的FBOs是否可取和可行。</p>
<p>3. The Commission shall, if appropriate, accompany the report with relevant proposals.</p>	<p>如合適，執委會應在報告中附上相關建議。</p>
<p><i>Article 17</i> Repeal</p>	<p>第17條 廢止</p>
<p>1. Directive 93/43/EEC shall be repealed with effect from the date of application of this Regulation.</p>	<p>於本規章生效後，應廢止第93/43/EEC號指令。</p>
<p>2. References to the repealed Directive shall be construed as being made to this Regulation.</p>	<p>廢止指令的參考文件應做為本規章的參考文件。</p>
<p>3. However, decisions adopted pursuant to Articles 3(3) and 10 of Directive 93/43/EEC shall remain in force pending their replacement by decisions adopted in accordance with this Regulation or Regulation (EC) No 178/2002. Pending the setting of the criteria or requirements referred to in Article 4(3)(a) to (e) of this Regulation, Member States may maintain any national rules establishing such criteria or requirements that they had adopted in accordance with Directive 93/43/EEC.</p>	<p>然而，依照第93/43/EEC號指令第3(3)條與第10條所採用的決議在替代方案出來前仍然有效，該替代方案是依據本規章或第178/2002號規章所作的決議。依本規章第4(3)(a)到(e)條要求設定之標準和要求未決之前，會員國可以維持他們依據第93/43/EEC號指令所建立之國家規定，例如標準或要求。</p>
<p>4. Pending the application of new Community legislation laying down rules for official controls on food, Member States shall take all appropriate measures to ensure the fulfilment of the obligations laid down in or under this Regulation.</p>	<p>關於官方管制在食品方面的新歐盟法規尚未生效前，會員國應採取適當之措施來確保履行本規章規定的義務。</p>
<p><i>Article 18</i> Entry into force</p>	<p>第18條 生效</p>
<p>This Regulation shall enter into force on the 20th day after that of its publication in the Official Journal of the European Union.</p>	<p>本規章應在歐盟官方公報刊登後第20天生效。</p>
<p>It shall apply 18 months after the date on which all of the following acts have entered into force:</p>	<p>其應在所有下列法案生效日起18個月後適用：</p>
<p>(a) Regulation (EC) No 853/2004;</p>	<p>第853/2004號規章；</p>
<p>(b) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ⁽¹¹⁾; and</p>	<p>2004年4月29日歐洲議會及理事會第854/2004號規章對於供人食用的動物源性產品執行官方管制的組織所制定的特定規定； 及</p>

(11) See page 83 of this Official Journal.			
(c) Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption ⁽¹²⁾ . <small>(12) OJ L 157, 30.4.2004, p. 33.</small>		2004年4月21日歐洲議會和理事會第2004/41/EC號指令廢除了某些關於食品衛生和衛生條件的指令，其用於生產和上市某些供人食用的動物源性產品。	
However, it shall apply no earlier than 1 January 2006.		本規章應於2006年1月1日後適用。	
This Regulation shall be binding in its entirety and directly applicable in all Member States.		本規章應完整並直接適用於所有會員國。	
Done at Strasbourg, 29 April 2004.		制定於2004年4月29日在斯特拉斯堡。	
For the European Parliament The President P. COX	For the Council The President P. M. McDOWELL	歐洲議會議長	理事會主席

<i>ANNEX I</i> PRIMARY PRODUCTION	<i>附件 I</i> 初級生產
PART A: GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS	Part A：初級生產和相關作業的衛生規定
I. Scope	I. 範圍
1. This Annex applies to primary production and the following associated operations:	本附件適用於初級生產和下列相關作業：
(a) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;	對初級產品於產地的運輸、貯存與處理，而這些作業不會實質改變產品原有性質；
(b) the transport of live animals, where this is necessary to achieve the objectives of this Regulation; and	在為符合本規章目的所必須的情況下，對活體動物的運輸； 及
(c) in the case of products of plant origin, fishery products and wild game, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.	針對植物性產品、漁產品和野味的初級產品，將其從產地運送到廠場的運輸作業，而其不會實質改變產品原有性質。
II. Hygiene provisions	II. 衛生規定
2. As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.	考慮到初級產品隨後會進行的任何加工過程，FBOs要儘可能地確保初級產品免於污染。
3. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including:	儘管第2段規範了一般責任，FBOs要遵守適用的歐盟和國家對初級生產及其相關作業危害管制的立法規定，包括：
(a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste; and	控制來自空氣、土壤、水、飼料、肥料、獸藥產品、植物防護性產品與生物滅製劑以及廢棄物的貯存、處理和丟棄的污染所採取的措施； 及
(b) measures relating to animal health and welfare and plant health that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.	關於會影響人類健康的動物衛生、福利與植物衛生的措施，包括對監控與管制人畜共通傳染病與傳染媒介的方案。
4. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:	FBOs飼養、收穫或捕獵動物或生產初級動物性產品時，應採取適當措施，適當的有：
(a) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner;	對任何使用於初級生產和作業的相關設施(場所)，包括用來儲存和處理飼料的設施，保持清潔，必要時，在清潔後以適當的方式對這些設施(場所)進行消毒；
(b) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels;	對設備、容器、條板箱、車輛和船隻，保持清潔及以適當的方式在清潔後進行必要的消毒；
(c) as far as possible to ensure the cleanliness of animals going to	儘可能確保即將屠宰動物的清潔，

slaughter and, where necessary, production animals;	必要時，包括生產動物的清潔；
(d) to use potable water, or clean water, whenever necessary to prevent contamination;	每當進行防止污染作業時(譯注：意指清洗程序)，使用飲用水或乾淨水；
(e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;	確保處理食品(材)的員工保持良好健康狀態並經過衛生風險的培訓；
(f) as far as possible to prevent animals and pests from causing contamination;	儘可能防止由動物及害蟲所引起的污染；
(g) to store and handle waste and hazardous substances so as to prevent contamination;	儲存和處理廢棄物與有害物質，以防止污染；
(h) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the competent authority;	防止經由食品將傳染性疾病引進和散播給人類，包括當引進新動物所採行的預防措施及向主管機關通報類此可疑疾病的爆發；
(i) to take account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health; and	考慮到對取自動物的樣本或其他對人類健康很重要的樣本所進行任何相關分析的結果； 及
(j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.	依相關法令要求，正確地使用飼料添加物和獸藥產品。
5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:	生產或收穫植物產品的FBOs，應採取適當措施，適當的有：
(a) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;	對設施(場所)、設備、容器、條板箱、車輛和船隻，保持清潔及以適當的方式在清潔後進行必要的消毒；
(b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products;	必要時，確保植物性產品在衛生條件下生產、運輸與貯存，以及確保其清潔度；
(c) to use potable water, or clean water, whenever necessary to prevent contamination;	每當進行防止污染作業時，使用飲用水或乾淨水；
(d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;	確保處理食品(材)的員工保持良好健康狀態並經過衛生風險危害的培訓；
(e) as far as possible to prevent animals and pests from causing contamination;	儘可能防止由動物及害蟲所引起的污染；
(f) to store and handle wastes and hazardous substances so as to prevent contamination;	儲存和處理廢棄物與有害物質，以防止污染；
(g) to take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health; and	考慮到對取自植物的樣本或其他對人類健康很重要的樣本所進行任何相關分析的結果； 及
(h) to use plant protection products and biocides correctly, as required by the relevant legislation.	依相關法令要求，正確地使用植物防護性產品與生物滅製劑。
▼M3	
5a. Equipment, conveyances and/or containers used for the harvesting, transport or storage of one of the substances or products causing	被用於收穫、運輸或儲存有關第(EU) 1169/2011號規章附件II所列

allergies or intolerances, referred to in Annex II to Regulation (EU) No 1169/2011, shall not be used for the harvesting, transport or storage of any food not containing that substance or product, unless the equipment, conveyances and/or containers have been cleaned and checked at least for the absence of any visible debris of that substance or product. ◀M3

之任一引起過敏或不耐受物質或產品之設備、交通工具和/或容器，應不得用於收穫、運輸或儲存不含該等物質或產品的任何食品，除非這些設備、交通工具和/或容器已經過清潔和檢查，至少沒有可見的任何該物質或產品殘留物。

6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

當官方管制時鑑別到問題而被通知時，FBOs應採行適當的補救措施。

III. Record-keeping

III. 紀錄保存

7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request.

FBOs應依據企業性質和規模，以適當的方式在適當的時間內保存和保留與控制危害的措施相關的紀錄。FBOs應配合主管機關及應收貨業者的要求，提供這些紀錄中的相關訊息。

8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:

飼養動物或生產初級動物性產品的FBOs，特別應保存以下紀錄：

(a) the nature and origin of feed fed to the animals;

餵飼動物的飼料性質與來源；

(b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods;

施用之動物用藥品或其他治療處方、施藥日期與停藥期；

(c) the occurrence of diseases that may affect the safety of products of animal origin;

可能影響動物源性產品安全之疾病的發生；

(d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health;
and

對取自動物的樣本或其他用於診斷目的的樣本，所進行任何對人類健康很重要的分析結果；
及

(e) any relevant reports on checks carried out on animals or products of animal origin.

任何對動物或動物源性產品所執行檢查的相關報告。

9. Food business operators producing or harvesting plant products are, in particular, to keep records on:

生產或採收植物性產品的FBOs，特別應保存以下紀錄：

(a) any use of plant protection products and biocides;

任何植物防護性產品與生物滅製劑的使用；

(b) any occurrence of pests or diseases that may affect the safety of products of plant origin;
and

任何可能影響植物性產品安全性之害蟲或疾病的事件；
及

(c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.

對取自植物的樣本或其他對人類健康很重要的樣本，所進行任何分析的結果。

10. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.

FBOs可以由獸醫、農業專家與農場技師等其他人員協助來保存紀錄。

PART B: RECOMMENDATIONS FOR GUIDES TO GOOD HYGIENE PRACTICE

Part B：良好衛生作業指引的建議

1. National and Community guides referred to in Articles 7 to 9 of this Regulation should contain guidance on good hygiene practice for the

本規章第7條到第9條所指的國家及歐盟指引，應包含對初級生產及其

control of hazards in primary production and associated operations.	相關作業進行危害管控的良好衛生作業指引。
2. Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations and actions to control hazards, including relevant measures set out in Community and national legislation or national and Community programmes. Examples of such hazards and measures may include:	良好衛生作業指引應包括適當的危害資訊，這些危害可能在初級生產與相關作業中發生，以及控制危害方法的資訊，包括在歐盟與國家法規或方案中所制定的相關措施。此類危害及措施的例子可以包括：
(a) the control of contamination such as mycotoxins, heavy metals and radioactive material;	污染的管控，如黴菌毒素、重金屬和放射性物質；
(b) the use of water, organic waste and fertilisers;	水、有機廢棄物和肥料的使用；
(c) the correct and appropriate use of plant protection products and biocides and their traceability;	植物防護性產品與生物滅製劑正確及適當的使用，以及其可追溯性；
(d) the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;	動物用藥品和飼料添加物正確及適當的使用，以及其可追溯性；
(e) the preparation, storage, use and traceability of feed;	飼料的製備、貯存、使用和可追溯性；
(f) the proper disposal of dead animals, waste and litter;	死動物、廢棄物和垃圾的妥善處理；
(g) protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;	對防止經由食品傳播傳染性疾病給人類的防護措施，以及任何通報主管機關的義務；
(h) procedures, practices and methods to ensure that food is produced, handled, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;	確保食品在適當之衛生條件下生產、處理、包裝、儲存與運輸的程序、作業及方法，包括有效的清洗及病媒防治等；
(i) measures relating to the cleanliness of slaughter and production animals;	屠體和生產動物清潔相關的措施；
(j) measures relating to record-keeping.	與紀錄保存相關的措施。

<p style="text-align: center;"><i>ANNEX II</i></p> <p style="text-align: center;">GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS (EXCEPT WHEN ANNEX I APPLIES)</p>	<p style="text-align: center;"><i>附件 II</i></p> <p style="text-align: center;">對所有食品業者的一般衛生要求 (適用附件 I 之初級生產者除外)</p>
<p>▼M3</p>	
<p>INTRODUCTION</p>	<p>前言</p>
<p>Chapters V, Va, VI, VII, VIII, IX, X, XI, Xla and XII apply to all stages of production, processing and distribution of food. The remaining Chapters apply as follows:</p>	<p>第 V、Va、VI、VII、VIII、IX、X、XI、Xia 及 XII 章適用於所有食品生產、加工與配銷等階段，而其他章則適用如下：</p>
<p>— Chapter I applies to all food premises, except premises to which Chapter III applies,</p>	<p>— 除第 III 章所適用的場所外，第 I 章適用於所有食品營業場所</p>
<p>— Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies,</p>	<p>— 除第 III 章所適用的用餐區及場所外，第 II 章適用於所有食品製備、處理或加工的空間</p>
<p>— Chapter III applies to those premises listed in the heading to that Chapter,</p>	<p>— 第 III 章適用於列於此章標題的那些場所</p>
<p>— Chapter IV applies to all transportation. ◀M3</p>	<p>— 第 IV 章適用於所有的運輸過程。</p>
<p style="text-align: center;">CHAPTER I</p> <p style="text-align: center;">General requirements for food premises (other than those specified in chapter III)</p>	<p style="text-align: center;">第 I 章</p> <p style="text-align: center;">食品營業場所的一般要求 (第 III 章所列場所除外)</p>
<p>1. Food premises are to be kept clean and maintained in good repair and condition.</p>	<p>食品營業場所須保持乾淨，並維持良好的維修和狀況。</p>
<p>2. The layout, design, construction, siting and size of food premises are to:</p>	<p>食品營業場所的配置、設計、結構、選址和規模須：</p>
<p>(a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;</p>	<p>允許適當的維護、清潔及/或消毒，以避免或減少空氣媒介的污染，並提供足夠的作業空間，以准許所有操作過程皆能衛生的執行；</p>
<p>(b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;</p>	<p>要防止污垢的積聚、與有毒材料的接觸、微粒掉落到食品中和在表面形成凝結水或不良黴菌；</p>
<p>(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control; and</p>	<p>允許食品良好衛生規範，包括對污染的防護措施，尤其是病媒防治；及</p>
<p>(d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.</p>	<p>必要時，提供適合的控溫處理及足夠空間的儲存條件以維持食品(材)在適當的溫度，必要時並設計對該等溫度進行監控及記錄。</p>
<p>3. An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.</p>	<p>須有足量的沖水廁所並連結有效的排水系統。廁所不可直接開向食品處理作業的空間。</p>
<p>4. An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for</p>	<p>須有足量的、設於適當的位置並指定用於洗手的洗手槽。洗手槽應供配流動的熱水與冷水、清潔手部及衛生烘乾的用具。必要時，清洗食</p>

washing food are to be separate from the hand-washing facility.	品的設施與洗手的設施須要區別開來。
5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.	須有合適和充分的自然或機械通風方式。要避免機械氣流由污染區流到清潔區。通風系統也須在結構上可確保過濾器和其他需要清潔或更換的部件易於處理。
6. Sanitary conveniences are to have adequate natural or mechanical ventilation.	衛生便利設備須有適當的自然或機器通風。
7. Food premises are to have adequate natural and/or artificial lighting.	食品營業場所須有充足的自然及/或人工照明。
8. Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.	排水設施須能達到預期目的。其設計與結構應避免發生污染的風險。在排水管道完全或部分開放的地方，要設計成可確保廢棄物不會從污染區流向或流入清潔區，特別是那些可能對最終消費者造成高風險的食品處理區。
9. Where necessary, adequate changing facilities for personnel are to be provided.	必要時，提供員工足夠的更衣設施。
10. Cleaning agents and disinfectants are not to be stored in areas where food is handled.	清潔劑與消毒劑不能存放在食品製備處理區域。
CHAPTER II Specific requirements in rooms where foodstuffs are prepared, treated or processed (excluding dining areas and those premises specified in chapter III)	第二章 食品(材)前製、處理或加工處所的特殊要求 (第三章所指的用餐區及場所除外)
1. In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular:	在食品前製、處理或加工處所(除第三章所指的用餐區及場所外，但包括存放運輸工具的場所)，其設計與廠房配置須允許實施食品良好衛生規範，包括在作業之間及期間，對污染所做的防護措施。尤其是：
(a) floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;	地板表面應維持在良好狀態，並易於清洗及必要的消毒。其需要使用不可滲透、不具吸附力、耐洗和無毒的材料，除非FBOs能使主管機關滿意其使用其他材質也是適切的。在適當情況下，地板須有足夠的地面引流設備；
(b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;	牆面應維持在良好狀態，並易於清洗及必要的消毒。其需要使用不可滲透、不具吸附力、耐洗和無毒的材料，並要求有一定高度的光滑表面以供作業，除非FBOs能使主管機關滿意其使用其他材質也是適切的；
(c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the	天花板(或在沒有天花板情形下，為屋頂的內面)和頂部固定裝置，應在結構及設計上能防止污垢的積聚並減少凝結水、不良黴菌的生長以及

<p>growth of undesirable mould and the shedding of particles;</p>	<p>微粒脫落；</p>
<p>(d) windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;</p>	<p>窗戶與其他開口設備，應在結構上能防止污垢的積聚。那些對外開啟的設備，必要時，需加裝容易拆卸清洗的防蟲紗窗。因開啟窗戶可能導致污染，在生產過程，窗戶必須保持緊閉並固定；</p>
<p>(e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and nonabsorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate; and</p>	<p>門須易於清洗及必要的消毒。其需要使用具光滑且不吸水的表面，除非FBOs能使主管機關滿意其使用其他材質也是適切的； 及</p>
<p>(f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.</p>	<p>食品處理區域的表面(包括設備的表面)，尤其與食品接觸的設備，須保持在良好的狀態且易於清洗及必要的消毒。其需要使用光滑、可清洗的耐腐蝕和無毒的材料，除非FBOs能使主管機關滿意其使用其他材質也是適切的。</p>
<p>2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.</p>	<p>必要時，應提供足夠的設施，以供清洗、消毒及貯存工作器具和設備。這些設施應在結構上能為耐腐蝕材料、易於清潔並能供應足夠的熱水與冷水。</p>
<p>3. Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and be kept clean and, where necessary, disinfected.</p>	<p>必要時，應對清洗食品制定適當的規定。每個提供清洗食品的洗滌槽或其他相似設施，須有充足的熱水和/或冷水供應以符合第七章的要求，並保持乾淨及必要的消毒。</p>
<p>CHAPTER III Requirements for movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), premises used primarily as a private dwelling-house but where foods are regularly prepared for placing on the market and vending machines</p>	<p>第三章 移動式及/或臨時性場所(諸如棚架、市場攤位、移動餐車)、定期調製食品販售的私人住宅場所及自動販賣機的要求</p>
<p>1. Premises and vending machines are, so far as is reasonably practicable, to be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contamination, in particular by animals and pests.</p>	<p>場所與自動販賣機，在合理可行的安裝、設計、建構並保持清潔及維持良好修復及狀態，以避免污染的風險，特別是動物及害蟲的污染。</p>
<p>2. In particular, where necessary:</p>	<p>必要時，特別是：</p>
<p>(a) appropriate facilities are to be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);</p>	<p>可利用適當的設施來維持足夠的個人衛生(包括洗手及乾手設施、衛生的廁間布置及更衣設施)；</p>
<p>(b) surfaces in contact with food are to be in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate;</p>	<p>與食品接觸的表面須是在良好的狀態並易於清洗及必要的消毒。其需要使用光滑、可清洗的耐腐蝕和無毒的材料，除非FBOs能使主管機關滿意其使用其他材質也是適切的；</p>

(c) adequate provision is to be made for the cleaning and, where necessary, disinfecting of working utensils and equipment;	必要時，應對清洗及消毒工作器具及設備制定適當的規定；
(d) where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically;	當食品(材)清洗是食品企業作業的一部分時，要制定適切的規定以保證衛生；
(e) an adequate supply of hot and/or cold potable water is to be available;	要有可充分供應的熱水和/或冷飲用水；
(f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) are to be available;	要有足夠的安排和/或設施來衛生的貯存及處置有害和/或不可食用物質和廢棄物(無論是液體或固體)；
(g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions are to be available;	要有足夠的設施和/或安排來維護並監控食品在適合的溫度條件下；
(h) foodstuffs are to be so placed as to avoid the risk of contamination so far as is reasonably practicable.	合理可行的食品(材)置放方式以避免污染發生的風險。
CHAPTER IV Transport	第IV章 運輸
1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.	被用來運輸食品(材)的運輸工具和/或貨櫃必須保持清潔並維持良好的維護狀態，以保護食品(材)受到污染，及必要時在設計及結構上是允許適當的清洗和/或消毒。
2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination.	車輛和/或貨櫃內的容器不可用來裝載運輸食品(材)以外的任何物品，以避免可能導致的污染。
3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.	當運輸工具和/或貨櫃被用來運送食品(材)以外的貨品或同時運送不同的食品(材)時，必要時，應對產品進行有效的隔離。
4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked 'for foodstuffs only'.	液體、顆粒狀或粉末型態等散裝食品(材)，可以容器及/或貨櫃/槽車來裝載運輸。這些容器上應以清晰可見和不可磨滅的方式，及1種或多種歐盟文字進行標記，表明它們用於運輸食品(材)，或者被標記「僅用於食品(材)」。
5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.	當運輸工具和/或貨櫃用於運送非食品(材)或不同的食品(材)時，在每次裝載之間要有效的清潔以避免污染的風險。
6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination.	運輸工具和/或貨櫃中的食品(材)應妥為置放及防護，以使污染風險降至最低。
7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored.	必要時，用於運輸食品(材)的工具和/或貨櫃，須能夠在適當的溫度下保持食品(材)，並允許監測這些溫度。

<p style="text-align: center;">CHAPTER V Equipment requirements</p>	<p style="text-align: center;">第V章 設備的要求</p>
<p>1. All articles, fittings and equipment with which food comes into contact are to:</p>	<p>與食品接觸的所有物品、配件和設備，應：</p>
<p>(a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;</p>	<p>可被有效的清潔及必要的消毒。要以適當的頻率進行清潔及消毒以避免任何污染風險；</p>
<p>(b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;</p>	<p>具良好的結構、材質，並保持在良好的運作、修復及環境狀態，以使任何污染風險降至最低；</p>
<p>(c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected; and</p>	<p>除不可重複使用的容器及包裝，具良好的結構、材質，並保持在良好的運作、修復及環境狀態，以確保其保持清潔及必要的消毒；及</p>
<p>(d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.</p>	<p>以允許對設備和周圍區域進行充分清潔的方式進行安裝。</p>
<p>2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives.</p>	<p>必要時，在設備上可裝置任何適當的控制設施，以保證實現本規章的目標。</p>
<p>3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice.</p>	<p>當添加化學添加物來防止設備及容器的腐蝕時，將依良好作業規範來使用。</p>
<p>▼M3</p>	
<p style="text-align: center;">CHAPTER Va Redistribution of food</p>	<p style="text-align: center;">第Va章 食物再分銷</p>
<p>Food business operators may redistribute food for the purpose of food donation subject to the following conditions:</p>	<p>FBOs可在符合下列條件下，以捐贈食品目的再分銷食物：</p>
<p>(1) Food business operators shall routinely check if food under their responsibility is not injurious to health and is fit for human consumption in accordance with Article 14(2) of Regulation (EC) No 178/2002. If the check carried out is satisfactory, food business operators may redistribute food in accordance with point (2):</p>	<p>依據第178/2002號規章第14(2)條規定，FBOs應定期檢查其負責的食品是否健康無害且適合人類食用。若檢查結果令人滿意，FBOs可以依第2點進行食物再分配：</p>
<p>— for food for which a 'use by' date is applied in accordance with Article 24 of Regulation (EU) No 1169/2011, before the expiry of that date,</p>	<p>依據第1169/2011號規章第24條規定具「使用截止」日期的食品，在該日期過期前，</p>
<p>— for food for which a date of minimum durability is applied in accordance with Article 2(2)(r) of Regulation (EU) No 1169/2011, up to and after that date, or</p>	<p>依據第1169/2011號規章第2(2)(r)條規定具最低保存期的食品，直到該日期及之後，或</p>
<p>— for food for which a date of minimum durability is not required in accordance with point 1(d) of Annex X to Regulation (EU) No 1169/2011, at any time provided.</p>	<p>依據第1169/2011號規章附錄X第1(d)點規定不需有保存期的食品，可隨時提供。</p>
<p>(2) Food business operators handling food referred to in point 1, shall assess if food is not injurious to health and fit for human consumption by taking into account at least the following:</p>	<p>處理第1點所述食品的FBOs，應至少考慮以下因素來評估食品是否對健康無害且適合人類食用：</p>
<p>— the date of minimum durability or the 'use by' date, ensuring sufficient remaining shelf-life left to allow for the safe redistribution</p>	<p>最低保存期或「使用截止」日期，確保有足夠剩餘的期限，以允許安</p>

<p>and use by the final consumer,</p> <p>— the integrity of the packaging, when applicable,</p> <p>— the proper storage and transport conditions, including applicable temperature requirements,</p> <p>— the date of freezing in accordance with point 2(b) of Section IV of Annex II to Regulation (EC) No 853/2004 of the European Parliament and of the Council, when applicable,</p> <p>— the organoleptic conditions,</p> <p>— the assurance of traceability in accordance with Commission Implementing Regulation (EU) No 931/2011⁽¹³⁾, in case of products of animal origin. ◀M3</p>	<p>全的再分銷以供最終消費者使用，</p> <p>包裝的完整性，如適用，</p> <p>適當的儲存和運輸條件，包括適用的溫度要求，</p> <p>依據歐洲議會和理事會第853/2004號規章附件II第IV節第2(b)點凍結日期，如適用，</p> <p>官能條件</p> <p>對於動物源性產品，依據執委會實施第931/2011號規章保證可追溯性。</p>
<p>(13) Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin (OJ L 242, 20.9.2011, p. 2).</p>	
<p>CHAPTER VI</p> <p>Food waste</p>	<p>第VI章</p> <p>食品廢棄物</p>
<p>1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.</p>	<p>食品廢棄物、非食用副產品與其他垃圾須儘快從食品存在的房間中移除，以避免其堆積。</p>
<p>2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.</p>	<p>食品廢棄物、非食用副產品與其他垃圾須存放在可封閉的容器中，除非FBOs能向主管機關證明其使用其他類型的容器或排放系統是適當的。這些容器須具有適當的結構、保持良好狀態、易於清洗及必要的消毒。</p>
<p>3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.</p>	<p>應對食品廢棄物、非食用副產品與其他垃圾制定適當的規定。廢料庫房的設計及管理應能確保其保持清潔及，必要時，沒有動物及害蟲出沒。</p>
<p>4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.</p>	<p>所有廢棄物應依據適用的歐盟法規，以衛生及友善環境的方式進行清除，並不會構成直接或間接的污染來源。</p>
<p>CHAPTER VII</p> <p>Water supply</p>	<p>第VII章</p> <p>水的供應</p>
<p>1. (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;</p>	<p>須有足夠的飲用水供應，在必要使用時，應確保食品(材)不受污染；</p>
<p>▼M1</p>	
<p>(b) Clean water may be used with whole fishery products.</p>	<p>乾淨水可被用於全部的漁產品。</p>

<p>Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing.</p>	<p>乾淨海水可被用於活雙枚貝類軟體動物、棘皮動物、被囊類動物和海生腹足類動物；乾淨水也可被用於外部清洗。</p>
<p>When clean water is used, adequate facilities and procedures are to be available for its supply to ensure that such use is not a source of contamination for the foodstuff. ◀M1</p>	<p>當使用乾淨水時，應有足夠的設施和程序進行供應，以確保這種使用不會成為食品污染的來源。 <small>(按：依據食物鏈和動物衛生常務委員提供意見，考慮當食品業者已制定並實施基於HACCP原則的控制程序，以確保它不是污染源，那麼使用清潔水就不會對公共衛生構成風險。爰對此節作M1修正。)</small></p>
<p>2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems.</p>	<p>當使用非飲用水，例如：用於消防設施，蒸氣產生、冷藏及其他相似目的時，其須為獨立可妥善識別的流通系統。非飲用水不可與飲用水系統連結或允許回流到飲用水系統。</p>
<p>3. Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.</p>	<p>使用於加工過程或產品成份的循環水，不可存在污染的風險。其須與飲用水標準相同，除非主管機關認為該水質不會影響最終食品的健康安全性。</p>
<p>4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.</p>	<p>直接接觸食品或可能造成食品污染的冰塊應製自飲用水，或用於冷藏全漁產品的冰塊應產製自乾淨水。其製造、處理及儲存皆應在防止遭受污染的條件下進行。</p>
<p>5. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.</p>	<p>直接接觸食品的蒸氣，不可含任何危害健康或可能造成食品污染的物質。</p>
<p>6. Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.</p>	<p>在食品(材)在密封容器中施以熱處理的情形下，應確保使用於冷卻容器的水不會是食品的污染來源。</p>
<p>CHAPTER VIII Personal hygiene</p>	<p>第八章 個人衛生</p>
<p>1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.</p>	<p>在食品處理區工作的每位員工須保持高度的個人清潔並穿戴合適、乾淨及，必要時，具防護性的衣物。</p>
<p>2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.</p>	<p>如果有任何直接或間接污染的可能性，可能經由食品傳播疾病的感染者或帶原者或如患有感染傷口、皮膚感染、膿瘡或腹瀉的員工，不得以任何身份獲准處理食品或進入任何食品處理區。 任何此類受影響和受僱的食品企業員工及其可能與食品接觸的人，應立即向FBO報告疾病或症狀，如其可能原因。</p>
<p>CHAPTER IX Provisions applicable to foodstuffs</p>	<p>第九章 適用於食品(材)的規定</p>

<p>1. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.</p>	<p>除活體動物外，若已知或可合理預測到遭到寄生蟲、病原菌或有毒物質污染，即使在FBO採取衛生地應用正常的揀選和/或準備或加工程序後，已降解或外來物質達安全程度，FBO不應接受使用這些原料或成分，或任何其他材料於加工產品中，最終產品也不適合供人類食用。</p>
<p>2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</p>	<p>食品企業所儲放的原物料和所有添加物須保存在經適當設計的環境條件下，以防止有害的變質並保護其不受污染。</p>
<p>3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.</p>	<p>在整個生產、加工或配銷過程，食品須被完整的保護免受到任何污染，該污染可能導致食品不適合人類食用、有害健康或受到這種污染的食品不可能再用來消費。</p>
<p>4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).</p>	<p>要應用適當的程序來控制害蟲。應用適當的程序也可預防畜養動物進入食品製備、處理或儲存的地方(或，主管機關在特殊情況下允許，以防止畜養動物進入所導致的污染)。</p>
<p>5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage.</p>	<p>可能會支持病原性微生物繁殖或形成毒素的原物料、成分、半成品和成品，不得保存在可能導致健康風險的溫度下。冷鏈不可被中斷。然而，在不會導致健康風險下，允許一段有限的期間在溫度控制之外，以包容食品在製備、運輸、貯存、展示和供應等處理期間的實際需要。從事製造、處理和包裝已加工食品(材)的食品企業應具有合適的房間、夠大足以將原物料與加工材料分開儲放並有足夠的獨立凍庫。</p>
<p>6. Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.</p>	<p>當食品(材)須在冷藏溫度下保持或供應時，其應在熱處理階段之後儘可能快速地完成冷卻，或在施加熱處理的最後製備階段達到不會導致健康風險的溫度。</p>
<p>7. The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins in the foods. During thawing, foods are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.</p>	<p>食品(材)的解凍須使用使病原性微生物生長或毒素形成降至最低的方式。在解凍期間，應確定食品所處的溫度不會導致健康風險。在解凍過程中可能對健康造成危害風險的流出液應充分排去。在解凍後，食品應在使病原性微生物生長或毒素形成風險最小化的方式下處理。</p>
<p>8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.</p>	<p>危險和/或不可食用的物質，包括動物飼料，必須適當的標識並單獨儲存在安全的容器中。</p>

<p>▼M3</p> <p>9. Equipment, conveyances and/or containers used for the processing, handling, transport or storage of one of the substances or products causing allergies or intolerances, referred to in Annex II to Regulation (EU) No 1169/2011, shall not be used for the processing, handling, transport or storage of any food, not containing that substance or product, unless the equipment, conveyances and/or containers have been cleaned and checked at least for the absence of any visible debris of that substance or product. ◀M3</p>	<p>用於加工、處理、運輸或儲存引起過敏或不耐受的物質或產品之一的設備、交通工具和/或容器，如第1169/2011號規章附件II所述，不得用於加工、處理、運輸或儲存不含該物質或產品的任何食品，除非設備、交通工具和/或容器已清潔並至少檢查未有任何可見該物質或產品的殘留。</p>
<p style="text-align: center;">CHAPTER X Provisions applicable to the wrapping and packaging of foodstuffs</p>	<p style="text-align: center;">第X章 適用於食品(材)內外包裝的規定</p>
<p>1. Material used for wrapping and packaging are not to be a source of contamination.</p>	<p>內外包材不得成為污染來源。</p>
<p>2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.</p>	<p>內包材的儲存方式應確保它們不會受到污染的風險。</p>
<p>3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.</p>	<p>內外包裝的作業應在避免產品污染的情形下執行。在適當的，特別是在罐頭和玻璃罐的情況下，應確認容器結構的完整性和其清潔度。</p>
<p>4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.</p>	<p>重複使用於食品(材)的內外包材，應易於清洗與必要的消毒。</p>
<p style="text-align: center;">CHAPTER XI Heat treatment</p>	<p style="text-align: center;">第XI章 熱處理</p>
<p>The following requirements apply only to food placed on the market in hermetically sealed containers:</p>	<p>下列要求僅適用於市面上密封容器中的食品：</p>
<p>1. any heat treatment process used to process an unprocessed product or to process further a processed product is:</p> <p>(a) to raise every party of the product treated to a given temperature for a given period of time; and</p>	<p>用於處理未加工產品或進一步處理已加工產品的任何熱處理過程是：</p> <p>在指定的時間內使產品每一部分達到指定的溫度； 及</p>
<p>(b) to prevent the product from becoming contaminated during the process;</p>	<p>防止產品在加工過程被污染。</p>
<p>2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;</p>	<p>為確保所採用的加工程序能達到預期目標，FBOs須定期檢查主要相關參數(特別是溫度、壓力、密封情形和微生物)，包括通過使用自動裝置；</p>
<p>3. the process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).</p>	<p>所使用的加工程序應符合國際公認的標準(例如：巴氏殺菌，超高溫滅菌或殺菌)。</p>
<p>▼M3</p> <p style="text-align: center;">CHAPTER XIa Food Safety Culture</p>	<p style="text-align: center;">CHAPTER XIa 食品安全文化</p>

1. Food business operators shall establish, maintain and provide evidence of an appropriate food safety culture by fulfilling the following requirements:	FBOs應藉由滿足下列要求，來建立、保持並提供適當的食品安全文化的證據：
(a) commitment of the management, in accordance with point 2, and all employees to the safe production and distribution of food;	依據第2點，管理階層和所有員工對安全食品的生產和配銷做出承諾；
(b) leadership towards the production of safe food and to engage all employees in food safety practices;	領導生產安全食品並使所有員工參與食品安全活動；
(c) awareness of food safety hazards and of the importance of food safety and hygiene by all employees in the business;	企業所有員工對食品安全危害以及食品安全和衛生重要性的意識；
(d) open and clear communication between all employees in the business, within an activity and between consecutive activities, including communication of deviations and expectations;	企業所有員工之間、活動內和連續活動之間的公開和清晰的溝通，包括偏差和期望的溝通；
(e) availability of sufficient resources to ensure the safe and hygienic handling of food.	有足夠的資源來確保安全和衛生的處理食品。
2. Management commitment shall include:	管理承諾應包括：
(a) ensuring that roles and responsibilities are clearly communicated within each activity of the food business;	確保在食品企業的每項活動中明確界定角色和職責；
(b) maintaining the integrity of the food hygiene system when changes are planned and implemented;	在規劃和實施變更措施時，保持食品衛生系統的完整性；
(c) verifying that controls are being performed timely and efficiently and documentation is up to date;	驗證是否及時有效地執行了控制並且文件是最新的；
(d) ensuring that the appropriate training and supervision are in place for personnel;	確保對人員進行適當的培訓和監督；
(e) ensuring compliance with relevant regulatory requirements;	確保符合相關法規要求；
(f) encouraging continual improvement of the food safety management system of the business, where appropriate, taking into account developments in science, technology and best practices.	鼓勵持續改進企業的食品安全管理體系，在適當的情況下，考慮到科學、技術和最佳實踐的發展。
3. The implementation of the food safety culture shall take account of the nature and size of the food business. ◀M3	食品安全文化的實施應當考慮食品企業性質和規模。
CHAPTER XII Training	第XII章 培訓
Food business operators are to ensure:	FBOs要確保：
1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;	食品處理人員在與其工作內容相關的食品衛生事務受到監督、指導和/或培訓；
2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and	那些負責制定和維持本規章第5(1)條所述程序或負責操作相關指引的員工，已接受充分的HACCP原則應用培訓； 及
3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.	在特定食品領域工作人員，遵守國家法律對於培訓計畫的任何要求。