

REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L139, 30.4.2004, p.55)

歐洲議會和歐盟理事會 2004 年 4 月 29 日第 853/2004 號規章關於制定動物源性食品之衛生細則

Amended by Commission Regulation (EC) 2074/2005 of 5 December 2005 (L338 p.27) (M1) (第 1 次修訂)
Amended by Commission Regulation (EC) 2076/2005 of 5 December 2005 (L338 p.83) (M2) (第 2 次修訂)
Amended by Commission Regulation (EC) 1662/2006 of 6 November 2006 (L320 p.1) (M3) (第 3 次修訂)
Amended by Council Regulation (EC) No 1791/2006 of 20 November 2006 (L363 p.1) (M4) (第 4 次修訂)
Amended by Commission Regulation (EC) 1243/2007 of 24 October 2007 (L281 p.8) (M5) (第 5 次修訂)
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Amended by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 (L87 p.109) (M7) (第 7 次修訂)
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Amended by Commission Regulation (EC) 633/2014 of 13 June 2014 (L175 p.6) (M16) (第 16 次修訂)
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Appendix to ANNEX III MODEL DOCUMENT TO ACCOMPANY RAW MATERIAL DESTINED FOR THE PRODUCTION OF GELATINE OR COLLAGEN INTENDED FOR HUMAN CONSUMPTION/ 附錄III之附件用於生產供人食用之明膠或膠原蛋白的原料隨附文件範本

原(修正)條文	中譯文(條號請參照原條文)
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 152(4)(b) thereof,	鑒於建立歐洲共同體的條約，特別是其中的第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 European Economic and Social Committee ² ,	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 ,	依據條約第251條規定的程序制定，
Whereas:	茲以：
(1) Pursuant to Regulation (EC) No 852/2004 ⁴ , the European Parliament and the Council laid down general rules for food business operators on the hygiene of foodstuffs.	依據第852/2004號規章，歐洲議會和理事會對食品業者(FBOs)制定關於食品衛生之一般規範。
(2) Certain foodstuffs may present specific hazards to human health, requiring the setting of specific hygiene rules. This is particularly the case for food of animal origin, in which microbiological and chemical hazards have frequently been reported.	某些食材對人類健康可能造成特殊危害，需要建立具體衛生規定。尤其是動物源性的食品，其常被報導含有微生物及化學有害物質。
(3) 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.	在共同農業政策中，對條約附錄I所列產品之生產及上市，已通過許多指令以建立具體的衛生規定。這些衛生規定能減少所關注產品之貿易壁壘，有助於創造內需市場，同

1 OJ C 365 E, 19.12.2000, p. 58.

2 OJ C 155, 29.5.2001, p. 39.

3 Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 288), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 23), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

4 See page 3 of this Official Journal.

	時確保對公眾健康的高度保護。
(4) With regard to public health, these rules contain common principles, in particular in relation to the manufacturers' and competent authorities' responsibilities, structural, operational and hygiene requirements for establishments, procedures for the approval of establishments, requirements for storage and transport and health marks	關於公共衛生，這些規定包含一般原則，特別是關於製造商和權責機關之責任，對廠場之結構、作業和衛生要求，廠場核准之程序，儲存和運輸之要求，以及衛生標記。
(5) These principles constitute a common basis for the hygienic production of food of animal origin, permitting the simplification of the existing directives.	這些原則對於衛生的產製動物源性食品建構了一個共同基礎，以允許既有指令之簡化。
(6) It is desirable to achieve further simplification by applying the same rules wherever appropriate to all products of animal origin.	最好是透過對所有動物源性產品適用相同的規定來達到進一步簡化。
(7) The requirement in Regulation (EC) No 852/2004 whereby food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations must put in place, implement and maintain procedures based on hazard analysis and critical control point (HACCP) principles also permits simplification.	第852/2004號規章中之要求，對於在初級生產和相關作業後進行任何食品生產、加工和分銷階段之FBOs，須基於危害分析與重點管制點(HACCP)原則制定、實施及維持之程序也允許簡化。
(8) Taken together, these elements justify a recasting of the specific hygiene rules contained in existing directives.	總之，這些要素為現有指令中具體衛生規定之重新制定提供了合理依據。
(9) The principal objectives of the recasting are to secure a high level of consumer protection with regard to food safety, in particular by making food business operators throughout the Community subject to the same rules, and to ensure the proper functioning of the internal market in products of animal origin, thus contributing to the achievement of the objectives of the common agricultural policy.	修法的主要目的是為確保消費者食品安全之最高保障，特別是讓全體歐盟FBOs遵守相同規則，以確保國內市場中動物源性產品之正常運作，有助達成共同農業政策目標。
(10) It is necessary to maintain and, where required to ensure consumer protection, to tighten detailed hygiene rules for products of animal origin.	為保障消費者，有必要維持及強化細部的動物源性產品衛生規定。
(11) 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, where small quantities of primary products or of certain types of meat are supplied directly 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.	歐盟法規不應適用於私人自用之初級生產或供私人消費之家庭置備、處理或儲存之食品。此外，當由FBO將所生產的少量初級產品或某些類型肉品，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。
(12) The requirements of Regulation (EC) No 852/2004 are generally sufficient to ensure food safety in establishments carrying out retail activities involving the direct sale or supply of food of animal origin to the final consumer. This Regulation should generally apply to wholesale activities (that is, when a retail establishment carries out operations with a view to supplying food of animal origin to another establishment). Nevertheless, with the exception of the specific temperature requirements laid down in this Regulation, the requirements of Regulation (EC) No 852/2004 should suffice for wholesale activities consisting only of storage or transport.	第852/2004號規章之要求，大致足以確保從事零售活動企業之食品安全，包括直接銷售或供應動物源性食品至最終消費者。本規章應適用於批發活動(即當零售廠商供應動物源性食品給其他廠場所進行之作業)。然而，本規章中除特殊溫度要求外，第852/2004號規章應足以涵蓋僅有倉儲或運輸之批發活動。
(13) Member States should have some discretion to extend or to limit the application of the requirements of this Regulation to retail under national law. However, they may limit their application only if they consider that the requirements of Regulation (EC) No 852/2004 are sufficient to achieve food hygiene objectives and when the supply of	在國內法令下，對於零售部分，會員國應有所裁量權去擴大或限制本規章的適用性。然而，僅有當會員國認為第852/2004號規章的要求足

<p>food of animal origin from a retail establishment to another establishment is a marginal, localised and restricted activity. Such supply should therefore be only a small part of the establishment's business; the establishments supplied should be situated in its immediate vicinity; and the supply should concern only certain types of products or establishments.</p>	<p>以達到食品衛生目標，且當零售商供應動物源性食品至其他廠場為偏遠地方、地區性及有限制性的活動時，方可限制本規章的適用。因此這樣的供應應只屬於廠場商業活動的一小部分；供應的廠場應位在其鄰近區域；且供應應僅涉某類型產品或廠場。</p>
<p>(14) In accordance with Article 10 of the Treaty, Member States are to take all appropriate measures to ensure that food business operators comply with the obligations laid down in this Regulation.</p>	<p>依據本條約第10條規定，會員國需採取所有適當措施以確保FBOs遵循本規章之義務。</p>
<p>(15) The traceability of food is an essential element in ensuring food safety. In addition to complying with the general rules of Regulation (EC) No 178/2002⁵, food business operators responsible for establishments that are subject to approval in accordance with this Regulation should ensure that all products of animal origin that they place on the market bear either a health mark or an identification mark.</p>	<p>食品的可追溯性是確保食品安全的基本要素。除了遵守第178/2002號規章之一般規定，依本規章核准廠場之FBOs應確保他們所有上市的動物源性產品皆有衛生標記或識別標記。</p>
<p>(16) Food imported into the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002 or to satisfy rules that are equivalent to Community rules. This Regulation defines specific hygiene requirements for food of animal origin imported into the Community.</p>	<p>進口到歐盟的食品應符合第178/2002號規章或滿足與歐盟法規等效之要求。本規章規定進口至歐盟動物源性食品之特定衛生要求。</p>
<p>(17) The adoption of this Regulation should not reduce the level of protection provided by the additional guarantees agreed for Finland and Sweden on their accession to the Community and confirmed by Commission Decisions 94/968/EC⁶, 95/50/EC⁷, 95/160/EC⁸, 95/161/EC⁹ and 95/168/EC¹⁰, and Council Decisions 95/409/EC¹¹, 95/410/EC¹² and 95/411/EC¹³. It should establish a procedure for the granting, for a transitional period, of guarantees to any Member State that has an approved national control programme which, for the food of animal origin concerned, is equivalent to those approved for Finland and Sweden. Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents¹⁴ provides for a similar procedure in respect of live animals and hatching eggs.</p>	<p>本規章之採行應不可降低芬蘭和瑞典在加入歐盟時同意且經過執委會決議94/968/EC、95/50/EC、95/160/EC、95/161/EC及95/168/EC等，以及理事會決議95/409/EC、95/410/EC以及95/411/EC等確認的附加保證所規定的保護水準。在過渡期間，應建立一個保證的認可程序，用於認可任何會員國對於已經為相關的動物源性食品建立起經核准的國家控制規畫之保證，該國家控制規畫等同於芬蘭和瑞典所制定的標準。歐洲議會及理事會2003年11月17日頒布第2160/2003號規章關於活動物和種蛋方面控制沙門氏菌和其他特定食源性致病菌之類似程序。</p>
<p>(18) It is appropriate for the structural and hygiene requirements laid down in this Regulation to apply to all types of establishments, including small businesses and mobile slaughterhouses.</p>	<p>本規章所制定的結構與衛生要求適用於各類型廠場，包括小型企業和移動式屠宰場。</p>
<p>(19) Flexibility is 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</p>	<p>在食品任何生產、加工和運輸階段所使用的傳統方法，以及廠場結構相關要求可以保有彈性。對於受地理限制區域，尤其是本條約第</p>

5 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).

6 OJ L 371, 31.12.1994, p. 36.

7 OJ L 53, 9.3.1995, p. 31.

8 OJ L 105, 9.5.1995, p. 40.

9 OJ L 105, 9.5.1995, p. 44.

10 OJ L 109, 16.5.1995, p. 44.

11 OJ L 243, 11.10.1995, p. 21.

12 OJ L 243, 11.10.1995, p. 25.

13 OJ L 243, 11.10.1995, p. 29.

14 OJ L 325, 12.12.2003, p. 1.

<p>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 normally 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 and for the Commission to coordinate the process and take appropriate measures.</p>	<p>299(2)條所指最偏遠地區，保有彈性特別重要。然而，此種彈性不應減損食品衛生目標。此外，因所有依衛生法規生產的食品將在歐盟自由流通，允許會員國採取彈性的程序應充分透明。必要時為解決歧見，應依第178/2002號規章成立食物鏈與動物健康常設委員會，由委員會及執委會討論調和相關程序並採取適當的措施。</p>
<p>(20)The definition of mechanically separated meat (MSM) should be a generic one covering all methods of mechanical separation. Rapid technological developments in this area mean that a flexible definition is appropriate. The technical requirements for MSM should differ, however, depending on a risk assessment of the product resulting from different methods.</p>	<p>機械分離肉(MSM)的定義應泛指使用各種機械分離方法之肉類。此領域快速發展的技術以保有彈性的定義是適當的。然而，對MSM技術的要求應有所差異，取決於不同方法對產品的風險評估。</p>
<p>(21)There are interactions between food business operators, including the animal feed sector, and connections between animal health, animal welfare and public health considerations at all stages of production, processing and distribution. This requires adequate communication between the different stakeholders along the food chain from primary production to retail.</p>	<p>在食品生產、加工及運輸過程的所有階段，FBOs間常有互動關係，包括動物飼料領域，以及動物健康、動物福利和公共衛生之間的連結。自初級生產至零售之食品鏈上所有利害關係人皆需要有充分的溝通與聯繫。</p>
<p>(22)In order to ensure proper inspection of hunted wild game placed on the Community market, bodies of hunted animals and their viscera should be presented for official postmortem inspection at a game-handling establishment. However, to preserve certain hunting traditions without prejudicing food safety, it is appropriate to provide for training for hunters who place wild game on the market for human consumption. This should enable hunters to undertake an initial examination of wild game on the spot. In these circumstances, it is not necessary to require trained hunters to deliver all viscera to the game-handling establishment for post-mortem examination, if they carry out this initial examination and identify no anomalies or hazards. However, Member States should be allowed to establish stricter rules within their territories to take account of specific risks.</p>	<p>為確保對進入歐盟市場之野味進行適當的檢查，其屠體及內臟應由野味廠場進行官方屠後檢查。然而，在同時保留打獵特定傳統且不破壞食品安全的前提下，應針對販售供人食用野味之獵人進行適當的訓練，有助於獵人於現場對獵捕動物做初步檢視。在此情形下，如能執行初步檢視確認無異常或危害，受過訓的獵人即毋需再將所有內臟送交廠場進行屠後檢查。然而，允許各會員國建立更嚴格之國內法規來考量各種特殊風險。</p>
<p>(23)This Regulation should establish criteria for raw milk pending the adoption of new requirements for its placing on the market. These criteria should be trigger values, implying that, in the event of any overshooting, food business operators are to take corrective action and to notify the competent authority. The criteria should not be maximum figures beyond which raw milk cannot be placed on the market. This implies that, in certain circumstances, raw milk not fully meeting the criteria can safely be used for human consumption, if appropriate measures are taken. As regards raw milk and raw cream intended for direct human consumption, it is appropriate to enable each Member State to maintain or establish appropriate health measures to ensure the achievement of the objectives of this Regulation on its territory.</p>	<p>本規章應對延遲通過新上市規定的生乳建立基準，該基準應是觸發啟動值，意味可供FBOs在任何超過該值的狀況下，採取矯正措施並通報主管機關。此基準並非指超出最大值之生乳不得上市，意即在某些條件下，如採取適當的措施，未完全符合基準生乳仍可安全地供人食用。因此對於供人食用之生乳及生乳脂產品，使每一會員國可在其國內維持或建立適當的衛生措施以確保達成本規章目標是適當的。</p>
<p>(24)It is appropriate for the criterion for raw milk used to manufacture dairy products to be three times as high as the criterion for raw milk collected from the farm. The criterion for milk used to manufacture processed dairy products is an absolute value, whereas for raw milk collected from the farm it is an average. Compliance with the</p>	<p>用於產製乳製品的生乳基準值，是自農場收集生乳的3倍是適當的。用於產製乳製品的乳品基準是絕對值，農場收集生乳則為平均值。按</p>

temperature requirements laid down in this Regulation will not halt all bacterial growth during transport and storage.	照本規章的溫度要求，無法杜絕運輸及貯存過程中所有細菌的滋生。
(25)The present recasting means that the existing hygiene rules can be repealed. Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives on food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption ¹⁵ achieves this.	法規重整意指既有的衛生法規可被廢止。像是，歐洲議會及理事會2004年4月21日頒布的2004/41/EC指令廢止了某些關於欲供人食用之動物源性產品的生產和上市之食品衛生和衛生條件的指令。
(26)In addition, the rules of this Regulation on eggs replace those of Council Decision 94/371/EC of 20 June 1994 laying down specific public health conditions for the putting on the market of certain types of eggs ¹⁶ , which the repeal of Annex II to Council Directive 92/118/EEC ¹⁷ renders void.	此外，本規章對禽蛋規定取代理事會1994年6月20日94/371/EC決定對某些類型禽蛋上市之具體公共衛生條件規定，其廢止了對理事會92/118/EEC指令之附錄II。
(27)Scientific advice should underpin Community legislation on food hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.	科學建議應為歐盟食品衛生法規的基礎。為此，應於必要時諮詢歐洲食品安全局(EFSA)。
(28)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 Chain and Animal Health.	考量到科技的發展，於食物鏈與動物健康常設委員會架構下，執委會與會員國間應密切並有效的合作。
(29)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 industries affected time to adapt.	此規章應在所有部分的新食品衛生法規生效後實施。為讓受影響企業有時間調適，從生效後至實施間提供至少18個月的緩衝期也是適當的。
(30)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 ¹⁸ .	執行本規章的必要措施應遵照理事會1999年6月28日1999/468/EC決定制定賦予執委會有關行使執行權力之程序來採認。
HAVE ADOPTED THIS REGULATION:	已通過本規章：
CHAPTER I GENERAL PROVISIONS	第I章 總則
<i>Article 1</i> Scope	第1條 範圍
1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.	本規章制訂關於FBOs生產動物源性食品衛生之具體規定。這些規定補充了第852/2004號規章，應適用於動物源性之未加工及加工產品。
2. Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation.	除非有相反的明確說明，本規章應不適用於同時含有植物源性產品及動物源性加工產品之食品。然而，用來製備此類食品之動物源性加工產品應依本規章要求取得及處理。
3. This Regulation shall not apply in relation to:	本規章應不適用於：

¹⁵ OJ L 157, 30.4.2004, p. 33.

¹⁶ OJ L 168, 2.7.1994, p. 34.

¹⁷ Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/429/EEC (OJ L 62, 15.3.1993, p. 49). Directive as last amended by Commission Regulation (EC) No 445/2004 (OJ L 72, 11.3.2004, p. 60).

¹⁸ OJ L 184, 17.7.1999, p. 23.

(a) primary production for private domestic use;	供私人自用之初級生產。
(b) the domestic preparation, handling or storage of food for private domestic consumption;	私人自用之家庭製備、處理或儲藏之食品。
(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;	由生產者少量直接提供給最終消費者或對象為最終消費者的當地零售店之初級產品。
▼ M24	
(d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer; ◀M24	由生產者在農場少量屠宰後直接供應給最終消費者或對象為最終消費者的當地零售店之禽兔肉類產品。
(e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.	由獵人少量直接供應給最終消費者或對象為最終消費者的當地零售店之野味或其肉。
4. Member States shall establish, according to national law, rules governing the activities and persons referred to in paragraph 3(c), (d) and (e). Such national rules shall ensure the achievement of the objectives of this Regulation.	會員國應依國家法律訂定關於第3(c)、(d)與(e)款所述活動及人員之管理規定。此等國內規定應確保達到本規章之目標。
5. (a) Unless expressly indicated to the contrary, this Regulation shall not apply to retail.	除非有相反的明確說明，本規章應不適用於零售。
(b) However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment, unless:	然而，本規章應適用於向其他廠場供應動物源性食品之零售作業，除非：
(i) the operations consist only of storage or transport, in which case the specific temperature requirements laid down in Annex III shall nevertheless apply;	作業方式僅包括儲存或運輸，不過這類作業仍應符合附錄III所規定之特定溫度要求；
or	或
(ii) the supply of food of animal origin from the retail establishment is to other retail establishments only and, in accordance with national law, is a marginal, localised and restricted activity.	僅自零售廠場供應動物源性食品給其它零售廠場，且依國家法律，是屬偏僻的、當地性的及受限制的活動。
(c) Member States may adopt national measures to apply the requirements of this Regulation to retail establishments situated on their territory to which it would not apply pursuant to subparagraphs (a) or (b).	會員國對於不適用(a)或(b)款之國內零售廠場，可採行國家措施來符合本規章要求。
6. This Regulation shall apply without prejudice to:	本規章應在不違反以下規定下實施：
(a) relevant animal and public health rules, including more stringent rules laid down for the prevention, control and eradication of certain transmissible spongiform encephalopathies;	相關動物與公共衛生規定，包括為預防、控制及撲滅某些傳染性海綿狀腦病而制定之更嚴格規定；
(b) animal welfare requirements;	動物福利要求；
and	和
(c) requirements concerning the identification of animals and the traceability of products of animal origin.	關於動物識別和動物源性產品可追溯性之要求。
Article 2 Definitions	第2條 定義

The following definitions shall apply for the purposes of this Regulation:	下列定義適用於本規章：
1. the definitions laid down in Regulation (EC) No 178/2002;	第178/2002號規章中規定之定義；
2. the definitions laid down in Regulation (EC) No 852/2004;	第852/2004號規章中規定之定義；
3. the definitions laid down in Annex I;	附錄 I 中規定之定義；
and	和
4. any technical definitions contained in Annexes II and III.	附錄 II 和 III 中之任何技術定義。
CHAPTER II FOOD BUSINESS OPERATORS' OBLIGATIONS	第二章 食品業者(FBOs)的義務
<i>Article 3</i> General obligations	第3條 一般義務
1. Food business operators shall comply with the relevant provisions of Annexes II and III.	FBOs應遵守附錄 II 和 III 之相關規定。
▼ M21	
2. Food business operators shall not use any substance other than potable water or, when Regulation (EC) No 852/2004 or this Regulation permits its use, clean water, to remove surface contamination from products of animal origin, unless use of the substance has been approved by the Commission. For that purpose the Commission is empowered to adopt delegated acts in accordance with Article 11a supplementing this Regulation. Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of this Regulation. ◀ M21	FBOs不得使用除了飲用水，或第852/2004號規章和本規章所允許使用之潔淨水以外的其他物質，來清除動物源性產品表面之污染物，除非該物質經執委會核可使用。執委會為此目的有權依第11a條通過授權法案來補充本規章。FBOs亦應遵守在相同程序下可能採行的任何使用條件。核可物質的使用應不影響遵守本規章要求之FBO責任。
<i>Article 4</i> Registration and approval of establishments	第4條 廠場登記和核准
1. Food business operators shall place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments:	FBOs應僅能將在下列廠場製備及處理之動物源性產品投放至歐盟市場：
(a) that meet the relevant requirements of Regulation (EC) No 852/2004, those of Annexes II and III of this Regulation and other relevant requirements of food law;	符合第852/2004號規章、本規章附錄 II 和 III 的相關要求及食品法規之其它相關要求；
and	且
(b) that the competent authority has registered or, where required in accordance with paragraph 2, approved.	權責機關已登記或依第2項要求核准。
2. Without prejudice to Article 6(3) of Regulation (EC) No 852/2004, establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them in accordance with paragraph 3 of this Article, with the exception of establishments carrying out only:	在不違反第852/2004號規章第6(3)條規定下，廠場不得對本規章附錄 III 之動物源性產品進行營運，除非權責機關依本條第3項核准生產，但僅從事下列作業之廠場除外：
(a) primary production;	初級生產；
(b) transport operations;	運輸作業；

(c) the storage of products not requiring temperature-controlled storage conditions;	毋需控管貯存溫度之倉儲產品；
or	或
(d) retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b).	非本規章第1(5)(b)條適用之零售作業。
3. An establishment subject to approval in accordance with paragraph 2 shall not operate unless the competent authority has, in accordance with Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption ¹⁹ :	依第2款核准之廠場不得進行營運，除非權責機關已依歐洲議會及理事會2004年4月29日制定之第854/2004號規章關於欲供人食用動物源性產品之官方管制具體規定執行下列事項：
(a) granted the establishment approval to operate following an on-site visit;	經現場訪查後核准廠場營運；
or	或
(b) provided the establishment with conditional approval.	給予廠場有條件的核准。
4. Food business operators shall cooperate with the competent authorities in accordance with Regulation (EC) No 854/2004. In particular, food business operators shall ensure that an establishment ceases to operate if the competent authority withdraws its approval or, in the case of conditional approval, fails to prolong it or to grant full approval.	FBOs應依第854/2004號規章與權責機關合作。特別是，當權責機關撤銷核准，或在有條件核准情形下無法獲得展延或得到完整核准時，FBOs應確實配合停止營運。
5. This Article shall not prevent an establishment from placing food on the market between the date of application of this Regulation and the first subsequent inspection by the competent authority, if the establishment:	本條不應禁止廠場在本規章實施之日至權責機關首次接續檢查之間的食物上市，如果廠場：
(a) is subject to approval in accordance with paragraph 2 and placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation;	依第2項獲得核准且依本規章實施前的歐盟法規將動物源性產品上市；
or	或
(b) is of a type in respect of which there was no requirement for approval before the application of this Regulation.	屬於本規章實施前無需核准之類別。
Article 5	第5條
Health and identification marking	健康和識別標記
1. Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has either:	FBOs應不得將依據第4(2)條核准廠場中處理之動物源性產品上市，除非該產品已符合下列任一情形：
(a) a health mark applied in accordance with Regulation (EC) No 854/2004;	具有符合第854/2004號規章之健康標記；
or	或
(b) when that Regulation does not provide for the application of a health mark, an identification mark applied in accordance with Annex II, Section I, of this Regulation.	當法規未規定使用健康標記時，使用符合本規章附錄II第I節之識別標記。
2. Food business operators may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with this Regulation in establishments meeting the requirements of Article 4.	FBOs只有在動物源性產品產製於符合本規章第4條要求之廠場時，可於該產品上使用識別標記。

¹⁹ See page 83 of this Official Journal.

<p>3. Food business operators may not remove a health mark applied in accordance with Regulation (EC) No 854/2004 from meat unless they cut or process it or work upon it in another manner.</p>	<p>FBOs不可移除依第854/2004號規章標示在肉類產品上的健康標記，除非會對肉品進行分切或加工或以其他方式之處理。</p>
<p><i>Article 6</i> Products of animal origin from outside the Community</p>	<p><i>第6條</i> 來自歐盟以外的動物源性產品</p>
<p>1. Food business operators importing products of animal origin from third countries shall ensure that importation takes place only if:</p>	<p>自第三國進口動物源性產品之FBOs應確保僅在下列條件下進口：</p>
<p>(a) the third country of dispatch appears on a list, drawn up in accordance with Article 11 of Regulation (EC) No 854/2004, of third countries from which imports of that product are permitted;</p>	<p>發貨的第三國，是來自依第854/2004號規章第11條制定允許進口該項產品之第三國名單；</p>
<p>(b) (i) the establishment from which that product was dispatched, and in which it was obtained or prepared, appears on a list, drawn up in accordance with Article 12 of Regulation (EC) No 854/2004, of establishments from which imports of that product are permitted, when applicable,</p>	<p>適用時，集散貨及獲得或製備該產品的廠場，是來自依第854/2004號規章第12條制定允許進口該項產品之廠場名單，</p>
<p>(ii) in the case of fresh meat, minced meat, meat preparations, meat products and MSM, the product was manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with Article 12 of Regulation (EC) No 854/2004 or in approved Community establishments,</p>	<p>如果是鮮肉、碎肉、肉類製品、肉類產品及MSM，產品要產製於肉類源自依第854/2004號規章第12條制定及更新之屠宰場及分切工廠或核准的歐盟廠場名單，</p>
<p>and</p>	<p>且</p>
<p>(iii) in the case of live bivalve molluscs, echinoderms, tunicates and marine gastropods, the production area appears on a list drawn up in accordance with Article 13 of that Regulation, when applicable;</p>	<p>適用時，如果是活雙枚貝類、棘皮動物、被囊類動物和海洋腹足類動物，是來自依該規章第13條制定之生產區域名單；</p>
<p>(c) the product satisfies:</p>	<p>產品要符合：</p>
<p>(i) the requirements of this Regulation, including the requirements of Article 5 on health and identification marking;</p>	<p>本規章要求，包括第5條對健康和識別標記之規定；</p>
<p>(ii) the requirements of Regulation (EC) No 852/2004;</p>	<p>第852/2004號規章之規定；</p>
<p>and</p>	<p>和</p>
<p>(iii) any import conditions laid down in accordance with Community legislation governing import controls for products of animal origin,</p>	<p>依歐盟法規管理動物源性產品進口控管之任何進口條件，</p>
<p>and</p>	<p>以及</p>
<p>(d) the requirements of Article 14 of Regulation (EC) No 854/2004 concerning certificates and documents are satisfied, when applicable.</p>	<p>適用時，應符合第854/2004號規章第14條關於證書與文件之要求。</p>
<p>2. By way of derogation from paragraph 1, the importation of fishery products may also take place in accordance with the special provisions laid down in Article 15 of Regulation (EC) No 854/2004.</p>	<p>水產品的進口如無法符合第1項規定，也可依第854/2004號規章第15條之特別條款辦理。</p>
<p>3. Food business operators importing products of animal origin shall ensure that:</p>	<p>進口動物源性產品的FBOs應確保：</p>
<p>(a) products are made available for control upon importation in accordance with Directive 97/78/EC²⁰;</p>	<p>產品於進口時可依97/78/EC指令規定進行控管；</p>

²⁰ Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9). Directive amended by the 2003 Act of Accession.

(b) importation complies with the requirements of Directive 2002/99/EC ²¹ ; and	進口符合2002/99/EC指令之要求； 且
(c) operations under their control that take place after importation are carried out in accordance with the requirements of Annex III.	進口後在其控制下的作業，要依附錄III之要求來執行。
4. Food business operators importing food containing both products of plant origin and processed products of animal origin shall ensure that the processed products of animal origin contained in such food satisfy the requirements of paragraphs 1 to 3. They must be able to demonstrate that they have done so (for example, through appropriate documentation or certification, which need not be in the format specified in paragraph 1(d)).	進口同時含植物源性產品與動物源性加工產品之食品的FBOs，應確保此食品中的動物源性加工產品符合第1至3項之要求。FBOs必須能提供證明其符合性(例如，透過適當的文件或證書，毋需依第1(d)項規定的格式)。
CHAPTER III TRADE	第三章 貿易
<i>Article 7</i> Documents	第7條 文件
1. When required in accordance with Annex II or III, food business operators shall ensure that certificates or other documents accompany consignments of products of animal origin.	當附錄II或III有要求時，FBOs應確保動物源性產品隨貨附有證書或其他文件。
2. In accordance with the procedure referred to in Article 12(2):	依第12(2)條所述之程序：
(a) model documents may be established; and	可建立模板文件； 且
(b) provision may be made for the use of electronic documents.	可制定使用電子文件之條款。
<i>Article 8</i> Special guarantees	第8條 特別擔保
1. Food business operators intending to place the following food of animal origin on the market in Sweden or Finland shall comply with the rules set out in paragraph 2 in respect of salmonella:	略(有關動物源性食品投放瑞典或芬蘭市場之沙門氏菌規定)
(a) meat from bovine and porcine animals, including minced meat but excluding meat preparations and MSM;	
(b) meat from poultry of the following species: domestic fowl, turkeys, guinea-fowl, ducks and geese, including minced meat but excluding meat preparations and MSM;	
and	
(c) eggs.	
2. (a) In the case of meat from bovine and porcine animals and meat from poultry, samples of consignments shall have been taken in the dispatching establishment and been subjected to a microbiological test with negative results in accordance with Community legislation.	略(有關牛、豬及禽肉類微生物檢驗，應在集散貨品廠場取樣之規定)
(b) In the case of eggs, packing centres shall provide a guarantee that consignments originate from flocks that have been subjected to a microbiological test with negative results in accordance with Community legislation.	略(有關蛋包裝場應保證貨物來自微生物檢驗陰性雞群之規定)

²¹ Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).

<p>(c) In the case of meat from bovine and porcine animals, the test provided for in subparagraph (a) need not be carried out for consignments intended for an establishment for the purposes of pasteurisation, sterilisation or treatment having a similar effect. In the case of eggs, the test provided for in subparagraph (b) need not be carried out for consignments intended for the manufacture of processed products by a process that guarantees the elimination of salmonella.</p>	<p>略(有關後續有殺滅菌工序之牛豬肉及蛋，得免前述(a)&(b)款之微生物檢驗)</p>
<p>(d) The tests provided for in subparagraphs (a) and (b) need not be carried out for foodstuffs originating in an establishment that is subject to a control programme recognised, in respect of the food of animal origin concerned and in accordance with the procedure referred to in Article 12(2), as equivalent to that approved for Sweden and Finland.</p>	<p>略</p>
<p>(e) In the case of meat from bovine and porcine animals and meat from poultry, a trade document or certificate conforming to a model laid down by Community legislation shall accompany the food and state that:</p> <p>(i) the checks referred to in subparagraph (a) have been carried out with negative results; or (ii) the meat is intended for one of the purposes referred to in subparagraph (c); or (iii) the meat comes from an establishment covered by subparagraph (d).</p>	<p>略</p>
<p>(f) In the case of eggs, a certificate stating that the tests referred to in subparagraph (b) have been carried out with negative results, or that the eggs are destined to be used in the manner referred to in subparagraph (c), must accompany consignments.</p>	<p>略</p>
<p>▼ M7 ▼ M21</p>	
<p>3.(a) The Commission is empowered to adopt delegated acts in accordance with Article 11a amending paragraphs 1 and 2 of this Article in order to update the requirements set out in those paragraphs, taking into account changes in Member States' control programmes or the adoption of microbiological criteria in accordance with Regulation (EC) No 852/2004. ◀ M21</p>	<p>略(執委會依第11a條被授權修正前2項規定)</p>
<p>(b) In accordance with the regulatory procedure referred to in Article 12(2), the rules laid down in paragraph 2 of this Article in respect of any of the foodstuffs referred to in paragraph 1 of this Article may be extended, in whole or in part, to any Member State, or any region of a Member State, that has a control programme recognised as equivalent to that approved for Sweden and Finland in respect of the food of animal origin concerned. ◀ M7</p>	<p>略(每個會員國、瑞典及芬蘭間，控制計畫的採認)</p>
<p>4. For the purposes of this Article, 'control programme' means a control programme approved in accordance with Regulation (EC) No 2160/2003.</p>	<p>就本條目的而言，「控制計畫」係指依第2160/2003號規章核准之控制計畫。</p>
<p>CHAPTER IV FINAL PROVISIONS</p>	
<p>第四章 最後條款</p>	
<p>▼ M21</p>	
<p>Article 9 Implementing measures and transitional measures ◀ M21</p>	<p>第9條 執行措施和過渡措施</p>

<p style="text-align: center;">Article 10 Amendment and adaptation of Annexes II and III</p>	<p style="text-align: center;">第10條 附錄 II 和 III 的修正和改編</p>
<p>▼ M21</p>	
<p>1. The Commission is empowered to adopt delegated acts in accordance with Article 11a amending Annexes II and III. The amendments shall have the aim of ensuring and facilitating the achievement of the objectives of this Regulation, taking into account the relevant risk factors, and shall be justified on the basis of:</p>	<p>執委會有權依第11a條通過授權法案來修正附錄 II 和 III。其修正應具有確保和促進實現本法規目標之目的，同時考慮到相關風險因素，並應基於下列理由：</p>
<p>(a) the experience gained by food business operators and/or competent authorities, in particular on the implementation of HACCP-based systems pursuant to Article 5;</p>	<p>FBOs及/或權責機關所獲得的經驗，特別是依照第5條實施以HACCP為基礎的系統；</p>
<p>(b) the experience gained by the Commission, in particular on the outcome of its audits;</p>	<p>執委會所獲得的經驗，特別是其稽核的成果；</p>
<p>(c) technological developments and their practical consequences, and consumer expectations with regard to food composition;</p>	<p>科技發展和其實務應用，以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>食品的微生物與溫度基準；</p>
<p>(f) changes in patterns of consumption.</p>	<p>消費型態的改變。</p>
<p>The amendments referred to in the first subparagraph shall concern:</p>	<p>第1項所述之修正，應考慮到：</p>
<p>(a) the requirements on the identification marking of products of animal origin;</p>	<p>動物源性產品之識別標記的要求；</p>
<p>(b) the objectives of HACCP-based procedures;</p>	<p>基於HACCP程序的目標；</p>
<p>(c) the requirements on the food chain information;</p>	<p>食物鏈資訊的要求；</p>
<p>(d) the specific hygiene requirements for the premises, including means of transport, where products of animal origin are produced, handled, processed, stored or distributed;</p>	<p>對動物源性產品進行生產、處理、加工、貯存或分銷的場所，包括運輸工具之具體衛生要求；</p>
<p>(e) the specific hygiene requirements for the operations involving the production, handling, processing, storage, transport or distribution of products of animal origin;</p>	<p>對涉及動物源性產品生產、處理、加工、貯存、運輸或分銷各項作業之具體衛生要求；</p>
<p>(f) the rules for the transport of meat while it is warm;</p>	<p>溫體肉類的運輸規定；</p>
<p>(g) the health standards or checks, where there is scientific evidence indicating that they are necessary to protect public health;</p>	<p>有科學證據指出對公共衛生是必要的衛生標準或查核；</p>
<p>(h) the extension of Annex III, Section VII, Chapter IX, to live bivalve molluscs other than pectinidae;</p>	<p>附錄 III 第 VII 節 第 IX 章擴展到除海扇蛤科外的活雙枚貝類；</p>
<p>(i) the criteria for determining when epidemiological data indicate that a fishing ground does not present a health hazard with regard to the presence of parasites and, consequently, for determining when the competent authority may authorise food business operators not to freeze fishery products in accordance with Annex III, Section VIII, Chapter III, Part D;</p>	<p>依附錄 III 第 VIII 節 第 III 章 D 部分，對流行病學數據是指漁場不代表有存在寄生蟲衛生危害，以及因此權責機關可以准許FBOs不凍結漁產品的判定時點的基準；</p>
<p>(j) the additional health standards for live bivalve molluscs in cooperation with the relevant Union Reference Laboratory, including:</p>	<p>與相關歐盟參考試驗室合作制定額外的活雙枚貝類衛生標準，包括：</p>
<p>(i) limit values and analysis methods for other marine biotoxins;</p>	<p>其他海洋生物毒素之限量值和分析方法；</p>
<p>(ii) virus testing procedures and virological standards; and</p>	<p>病毒測試程序和病毒學標準；及</p>
<p>(iii) sampling plans and the methods and analytical tolerances to be</p>	<p>取樣計畫和適用於確認衛生標準符</p>

applied to check compliance with the health standards.	合性的方法和分析容許差。
2. The Commission is empowered to adopt delegated acts in accordance with Article 11a in order to supplement this Regulation by granting derogations from Annex II and III, taking into account the relevant risk factors and provided that such derogations do not affect the achievement of the following objectives of this Regulation:	執委會有權依第11a條通過授權法案，允許附錄II和III的豁免來補充本規章，同時考量到相關風險因子及確認此等豁免並不得影響本規章下列目標之達成：
(a) to facilitate the fulfilment, by small businesses, of the requirements laid down in the Annexes;	促進小型企業履行附錄中的要求；
(b) to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food;	使傳統方法能續使用在食品生產、加工或分銷的任何階段；
(c) to accommodate the needs of food businesses situated in regions that are subject to special geographic constraints;	支持位處於特殊地理限制區域的食品企業之需求；
(d) to facilitate the work of establishments producing raw material which is intended for the production of highly refined food products and which has undergone a treatment ensuring its safety. ◀M21	促進那些生產欲供作產製高度精煉食品並經過安全性確認處理的原料的廠場之工作。
3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 8, national measures adapting the requirements laid down in Annex III.	在不違背本規章目標達成下，會員國可依據第4至8項採行國內措施以調和附錄III中的要求。
4. (a) The national measures referred to in paragraph 3 shall have the aim of:	依據第3項所述之國內措施應具有以下目的：
(i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food;	使傳統方法能續使用在食品生產、加工或分銷的任何階段；
or	或
(ii) accommodating the needs of food businesses situated in regions that are subject to special geographic constraints.	支持位處於特殊地理限制區域的食品企業之需求。
(b) In other cases, they shall apply only to the construction, layout and equipment of establishments.	在其他狀況，它們應只適用於廠場的建築、配置和設備。
5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each notification shall:	任何希望參採第3項所述國內措施的會員國，應通知執委會和其他會員國。每項通知應：
(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;	提供該會員國認為需要調和的要求與尋求調和的本質之詳細說明；
(b) describe the foodstuffs and establishments concerned;	描述涉及的食材和廠場；
(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;	闡述調和的理由，包括在相關情形下，提供所執行危害分析的總結及為確保調和不會損害本規章目標所採取的任何措施；
and	和
(d) give any other relevant information.	提供其他任何相關資訊。
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 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 12(1). The Commission may decide, in accordance with the procedure referred to in Article 12(2), whether the	其他會員國應於收到第5項之通知後3個月內，向執委會提交書面意見。應任何會員國請求，對於第4(b)項所致調整的期限應延長至4個月。(餘略，執委會後續依第12條辦理的行政程序)

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 of this Article.	
7. A Member State may adopt national measures adapting the requirements of Annex III only:	會員國可採行經調和附錄III要求的國內措施，只有在：
(a) in compliance with a decision adopted in accordance with paragraph 6;	符合依第6段要求採納之決定；
(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;	依第6項所述期限後1個月，若執委會未通知會員國關於他所收到的書面意見或欲依第6項提出採行一項決定；
or	或
(c) in accordance with paragraph 8.	依據第8項。
8. A Member State may, of its own initiative and subject to the general provisions of the Treaty, maintain or establish national rules:	會員國可自行發起並依照本條約的一般條款，來維持或制定國內規定，關於：
(a) prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption;	禁止或限制欲供人直接食用的生乳或生乳油於國內上市販售；
or	或
(b) permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses, provided that this does not prejudice the achievement of the objectives of this Regulation.	略(在不影響食安條件下，對於不符合衛生規定的生乳之處理規定)
Article 11 Specific decisions	第11條 具體決定
▼ M21	
Without prejudice to the general application of Article 9 and Article 10(1), the Commission may lay down the following measures by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 12(2):	在不違反第9條和第10(1)條一般適用的情況下，執委會可經由實施法案來制定下列措施。那些實施法案應按照第12(2)條所述的程序審議採行：
←M21	
2. to specify, in respect of MSM, which calcium content is not significantly higher than that of minced meat;	關於MSM，指出其鈣含量並不顯著比較肉高；
3. to lay down other treatments that may be applied in a processing establishment to live bivalve molluscs from class B or C production areas that have not been submitted to purification or relaying;	制定可適用於對來自沒有經過純化或中繼處理的B或C級生產區的活雙枚貝類加工廠場進行其他處理；
4. to specify recognised testing methods for marine biotoxins;	指定認可的海洋生物毒素檢驗方法；
▼ M21	
←M21	
9. to lay down freshness criteria and limits with regard to histamine and	制定關於水產品組織胺及總揮發性

total volatile nitrogen for fisheries products;	氮之鮮度基準及管制值；
10.to permit the use for the manufacture of certain dairy products of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards its plate count and somatic cell count;	允許使用不符合附錄III第IX節中關於平板菌數及體細胞數規定基準的生乳來製造某些乳產品；
11.without prejudice to Directive 96/23/EC ²² , to fix a maximum permitted value for the combined total of residues of antibiotic substances in raw milk;	在不違反96/23/EC指令的前提下，訂定生乳中抗生素殘留物總量的最大允許值；
and	及
12.to approve equivalent processes for the production of gelatine or collagen.	批准生產明膠或膠原蛋白的等效工法。
▼ M21	
Article 11a Exercise of the delegation	第11a條 行使授權
1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	授予執委會在符合本條規定下之通過授權法案之權力。
2. The power to adopt delegated acts referred to in Article 3(2), Article 8(3)(a) and Article 10(1) and (2) 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.	自2019年7月26日起5年期間，執委會有權通過在第3(2)條、第8(3)(a)條和第10(1)及(2)條中所述的授權法案。在5年期限結束前至少9個月，執委會應提交關於授權權力的報告。權力授予應被默認延長相同期限，除非在每個期限結束前至少3個月，歐洲議會或理事會反對此等延長。
3. The delegation of powers referred to in Article 3(2), Article 8(3)(a) and Article 10(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the <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.	在第3(2)條、第8(3)(a)條和第10(1)及(2)條中所述的授權，可由歐洲議會或理事會在任何時點撤銷。撤銷決定應在該決定中敘明授權終止日期，並應在公布於歐盟官方公報後次日或指定較晚日期生效。其不應影響任何已生效授權法案之有效性。
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ²³ .	在通過授權法案前，執委會應遵照2016年4月13日關於更加立法之機構間協議所訂原則，來諮詢各會員國指定的專家。
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	一旦通過授權法案，執委會應同時通知歐洲議會和理事會。
6. A delegated act adopted pursuant to Article 3(2), Article 8(3)(a) and Article 10(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or 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 the Council. ◀M21	據第3(2)條、第8(3)(a)條和第10(1)及(2)條通過的授權法案，應僅在法案通知歐洲議會和理事會2個月內，歐洲議會或理事會未表示反對，或在屆期前，歐洲議會和理事會均通知執委會不反對的情形下生效。該期限應在歐洲議會或理事會提議下延長2個月。

²² Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10). Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
²³ OJ L 123, 12.5.2016, p. 1.

<p style="text-align: center;">Article 12 Committee procedure</p>	<p style="text-align: center;">第12條 委員會程序</p>
<p>1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.</p>	<p>執委會應獲食物鏈與動物健康常務委員會的協助。</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>當參用本項時，1999/468/EC決定之第5和7條規定應適用，並考量其中第8條的條文。</p>
<p>The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.</p>	<p>1999/468/EC決定的第5(6)條中規定的期限應設定為3個月。</p>
<p>▼ M21</p>	
<p>← M21</p>	
<p style="text-align: center;">Article 13 Consultation of the European Food Safety Authority</p>	<p style="text-align: center;">第13條 諮詢歐洲食品安全局(EFSA)</p>
<p>The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing to extend Annex III, Section III, to other animal species.</p>	<p>執委會應向EFSA諮詢關於本規章適用範圍內任何可能對公共衛生有顯著影響的事務，特別是對在計劃擴大附錄III第III節的適用範圍之前的其他動物種類。</p>
<p style="text-align: center;">Article 14 Report to the European Parliament and to the Council</p>	<p style="text-align: center;">第14條 向歐洲議會和理事會報告</p>
<p>1. The Commission shall, not later than 20 May 2009, submit a report to the European Parliament and the Council reviewing the experience gained from the implementation of this Regulation.</p>	<p>執委會至遲應於2009年5月20日前向歐洲議會和理事會提交一份報告去審查實施本規章所獲得的經驗。</p>
<p>2. The Commission shall, if appropriate, accompany the report with relevant proposals.</p>	<p>如適當，執委會應隨報告附上相關提案。</p>
<p style="text-align: center;">Article 15</p>	<p style="text-align: center;">第15條</p>
<p>This Regulation shall enter into force on the 20th day after that of its publication in the <i>Official Journal of the European Union</i>.</p>	<p>本規章自其公布於歐盟官方公報後第20日生效。</p>
<p>It shall apply 18 months after the date on which all of the following acts have entered into force:</p>	<p>它應自下列所有法規生效日起18個月後適用：</p>
<p>(a) Regulation (EC) No 852/2004;</p>	<p>第852/2004號規章；</p>
<p>(b) Regulation (EC) No 854/2004;</p>	<p>第854/2004號規章；</p>
<p>and</p>	<p>和</p>
<p>(c) Directive 2004/41/EC.</p>	<p>2004/41/EC指令。</p>
<p>However, it shall apply no earlier than 1 January 2006.</p>	<p>但是，其適用日期應不早於2006年1月1日。</p>
<p>This Regulation shall be binding in its entirety and directly applicable in all Member States.</p>	<p>本規章應具有整體約束性且直接適用於所有會員國。</p>
<p style="text-align: center;">ANNEX I</p>	<p style="text-align: center;">附錄 I</p>

DEFINITIONS	定義
For the purpose of this Regulation:	就本規章目的而言：
1. MEAT	肉
1.1. 'Meat' means edible parts of the animals referred to in points 1.2 to 1.8, including blood.	「肉」意指第1.2至1.8點所述動物之可食部位，包括血。
1.2. 'Domestic ungulates' means domestic bovine (including <i>Bubalus</i> and Bison species), porcine, ovine and caprine animals, and domestic solipeds.	「家養有蹄類」意指家庭養牛(包括水牛和野牛)、豬、綿羊和山羊，以及家養單蹄類動物。
1.3. 'Poultry' means farmed birds, including birds that are not considered as domestic but which are farmed as domestic animals, with the exception of ratites.	「家禽」意指平胸鳥除外的農場養殖鳥類，包括不被視作家養但作為家畜養殖的鳥類。
1.4. 'Lagomorphs' means rabbits, hares and rodents.	「兔形目」意指兔子、野兔和齧齒動物。
1.5. 'Wild game' means: — wild ungulates and lagomorphs, as well as other land mammals that are hunted for human consumption and are considered to be wild game under the applicable law in the Member State concerned, including mammals living in enclosed territory under conditions of freedom similar to those of wild game; and — wild birds that are hunted for human consumption.	「野味」意指： (略) (略)
1.6. 'Farmed game' means farmed ratites and farmed land mammals other than those referred to in point 1.2.	「養殖野味」意指除第1.2點述及外之養殖平胸鳥和養殖陸生哺乳類。
1.7. 'Small wild game' means wild game birds and lagomorphs living freely in the wild.	「小型野味」意指在野外自由生活之野生鳥和兔形目動物。
1.8. 'Large wild game' means wild land mammals living freely in the wild that do not fall within the definition of small wild game.	「大型野味」(略)
1.9. 'Carcase' means the body of an animal after slaughter and dressing.	「胴體」意指經屠宰和修整處理 <small>(譯注指拔毛去臟、切掉頭足等處理)</small> 後的動物軀體。
1.10. 'Fresh meat' means meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere.	「鮮肉」意指除了冷藏、冷凍或快速冷凍以外，未經任何保存過程之肉類，包括真空或調氣包裝肉類。
1.11. 'Offal' means fresh meat other than that of the carcase, including viscera and blood.	「下水」意指除胴體之外的鮮肉，包括內臟和血。
1.12. 'Viscera' means the organs of the thoracic, abdominal and pelvic cavities, as well as the trachea and oesophagus and, in birds, the crop.	「內臟」意指胸、腹及骨盆腔的器官，以及氣管和食道，在鳥則為嗉囊。
1.13. 'Minced meat' means boned meat that has been minced into fragments and contains less than 1 % salt.	「碎肉」意指已剁碎且含低於1%鹽的帶骨肉。
1.14. 'Mechanically separated meat' or 'MSM' means the product obtained by removing meat from flesh-bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure.	「機械分離肉」或「MSM」意指從剔骨後帶肉的骨頭上或從家禽胴體上，以導致肌肉纖維結構損失或改變的機械方式移除肉所獲得的產品。
1.15. 'Meat preparations' means fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre	「肉製品」意指已成碎片並添加食材、調味料或添加劑的鮮肉，或者經過不足以改變肉品內部肌纖維結

structure of the meat and thus to eliminate the characteristics of fresh meat.	構的加工並因此消除鮮肉特徵的鮮肉。
1.16. 'Slaughterhouse' means an establishment used for slaughtering and dressing animals, the meat of which is intended for human consumption.	「屠宰場」意指用於屠宰和修整處理動物的廠場，其肉是要供人食用。
1.17. 'Cutting plant' means an establishment used for boning and/or cutting up meat.	「分切工廠」意指用於剔骨和/或分切肉的廠場。
1.18. 'Game-handling establishment' means any establishment in which game and game meat obtained after hunting are prepared for placing on the market.	「野味處理廠」意指將獵捕所得野味和其肉製備供上市的任何廠場。
2. LIVE BIVALVE MOLLUSCS	活雙枚貝類
2.1. 'Bivalve molluscs' means filter-feeding lamellibranch molluscs.	「雙枚貝類」意指濾食性具瓣鰓的軟體動物。
2.2. 'Marine biotoxins' means poisonous substances accumulated by bivalve molluscs, in particular as a result of feeding on plankton containing toxins.	「海洋生物毒素」意指雙枚貝類體內累積的毒性物質，尤其是攝食含毒素浮游生物所造成的。
2.3. 'Conditioning' means the storage of live bivalve molluscs coming from class A production areas, purification centres or dispatch centres in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime, to preserve or to improve organoleptic qualities and to ensure that they are in a good state of vitality before wrapping or packaging.	「調節」意指將源自A級生產區、淨化中心或集散中心的活雙枚貝類，貯存在水槽或裝有潔淨海水之任何設備中或者在天然場址中，進行去沙、汙或泥，以保持或提升官能品質，並確保其在包裹或包裝前是在良好的活力狀態。
2.4. 'Gatherer' means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market.	「採集者」意指以任何方式從捕撈區採集活雙枚貝類以供處理及上市的任何自然人或法人。
2.5. 'Production area' means any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken.	「生產區」意指任何海域、河口或瀉湖區，包含天然雙枚貝類床或用於養殖雙枚貝類場址，並從中獲取活雙枚貝類。
2.6. 'Relaying area' means any sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs.	「中繼區」意指任何以浮標、柱子或其他固定方式清楚界定並標明且專用於活雙枚類自然淨化之海域、河口或瀉湖區。
2.7. 'Dispatch centre' means any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption.	「集散中心」意指任何岸上或離岸廠場，用於對供人食用活雙枚貝類的接收、調節、清洗、清潔、分級、打包及包裝等作業。
2.8. 'Purification centre' means an establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption.	「淨化中心」意指配有乾淨海水槽的廠場，讓活雙枚貝類放在裡面必要時間以減少污染使可供人食用。
2.9. 'Relaying' means the transfer of live bivalve molluscs to sea, lagoon or estuarine areas for the time necessary to reduce contamination to make them fit for human consumption. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening.	「中繼」指將活雙枚貝類轉移至海域、瀉湖或河口區一段必要時間，以減少污染使可供人食用。此不包括將雙枚貝類轉移到更適合進一步生長或育肥地區之特定作業。

3. FISHERY PRODUCTS	水產品
3.1. 'Fishery products' means all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals.	「水產品」意指不論野生或養殖的所有海水或淡水動物(活雙枚貝類、活棘皮動物、活被囊動物和活海洋腹足動物，以及全部哺乳動物、爬蟲類和蛙類等除外)並包括此類動物的所有可食用形式、部位和產品。
3.2. 'Factory vessel' means any vessel on board which fishery products undergo one or more of the following operations followed by wrapping or packaging and, if necessary, chilling or freezing: filleting, slicing, skinning, shelling, shucking, mincing or processing.	「加工船」意指水產品在船上經過切排、切片、去皮、去殼、去鱗、剝碎或加工等一個或多個作業後，再包裹或包裝，必要時並進行冷藏或凍結的任何漁船。
3.3. 'Freezer vessel' means any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging.	「凍結船」意指適當時在船上進行諸如放血、去頭、清除內臟和去鰭等製備工作，及必要時接續包裹或包裝後，將水產品冷凍的任何漁船。
3.4. 'Mechanically separated fishery product' means any product obtained by removing flesh from fishery products using mechanical means resulting in the loss or modification of the flesh structure.	「機械分離水產品」意指從水產品上，以導致魚肉結構損失或改變的機械方式移除魚肉所獲得的任何產品。
3.5. 'Fresh fishery products' means unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling.	「生鮮水產品」意指沒有再經過除冷藏外之任何保藏處理，不論是全魚或已處理的未經加工水產品，包括真空或調氣包裝的產品。
3.6. 'Prepared fishery products' means unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting, and chopping.	「經處理之水產品」意指經過諸如去內臟、去頭、切片、切排和切塊等有改變其解剖原貌作業的未經加工水產品。
4. MILK	乳
4.1. 'Raw milk' means milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40°C or undergone any treatment that has an equivalent effect.	「生乳」(略，未經超過40°C或等效處理的乳)
4.2. 'Milk production holding' means an establishment where one or more farmed animals are kept to produce milk with a view to placing it on the market as food.	「乳生產控股公司」(略)
5. EGGS	蛋
5.1. 'Eggs' means eggs in shell — other than broken, incubated or cooked eggs — that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products.	「蛋」(略)
5.2. 'Liquid egg' means unprocessed egg contents after removal of the shell.	「液態蛋」(略)
5.3. 'Cracked eggs' means eggs with damaged shell and intact membranes.	「裂殼蛋」(略)
5.4. 'Packing centre' means an establishment where eggs are graded by quality and weight.	「包裝中心」(略)
6. FROGS' LEGS AND SNAILS	蛙腿和蝸牛
6.1. 'Frogs' legs' means the posterior part of the body divided by a transverse cut behind the front limbs, eviscerated and skinned, of the species <i>Rana</i> (family Ranidae).	「蛙腿」(略)
6.2. 'Snails' means terrestrial gastropods of the species <i>Helix pomatia</i> Linné, <i>Helix</i>	「蝸牛」(略)

<i>aspersa</i> Muller, <i>Helix lucorum</i> and species of the family Achatinidae.	
7. PROCESSED PRODUCTS	加工產品
7.1. 'Meat products' means processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat.	「肉製品」(略)
7.2. 'Dairy products' means processed products resulting from the processing of raw milk or from the further processing of such processed products.	「乳製品」(略)
7.3. 'Egg products' means processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products.	「蛋製品」(略)
7.4. 'Processed fishery products' means processed products resulting from the processing of fishery products or from the further processing of such processed products.	「加工水產品」意指由水產品加工或此類加工產品進一步加工產生的加工產品。
7.5. 'Rendered animal fat' means fat derived from rendering meat, including bones, and intended for human consumption.	「精煉動物脂肪」(略)
7.6. 'Greaves' means the protein-containing residue of rendering, after partial separation of fat and water.	「脂渣」(略)
7.7. 'Gelatine' means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals.	「明膠」(略，膠原蛋白水解產品)
7.8. 'Collagen' means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of this Regulation.	「膠原蛋白」(略)
7.9. 'Treated stomachs, bladders and intestines' means stomachs, bladders and intestines that have been submitted to a treatment such as salting, heating or drying after they have been obtained and after cleaning.	「處理過的胃、膀胱和腸」(略)
8. OTHER DEFINITIONS	其他定義
8.1. 'Products of animal origin' means:	「動物源性產品」意指：
— food of animal origin, including honey and blood;	動物源性食品，包括蜂蜜和血；
— live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption;	欲供人食用的活雙枚貝類、活棘皮動物、活被囊動物和活海洋腹足動物；
and	和
— other animals destined to be prepared with a view to being supplied live to the final consumer.	其他準備以活體供給最終消費者食用之動物。
8.2. 'Wholesale market' means a food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operators.	「批發市場」意指一個包括數個共享共同設施和區域的獨立部門並銷售食材給FBOs的食品企業。
ANNEX II	附錄 II
REQUIREMENTS CONCERNING SEVERAL PRODUCTS OF ANIMAL ORIGIN	關於數個動物源性產品的要求
SECTION I: IDENTIFICATION MARKING	第 I 節：識別標記
When required in accordance with Article 5 or 6, and subject to the provisions of Annex III, food business operators must ensure that products of animal origin have an identification mark applied in compliance with the following provisions.	依第5或第6條要求，及在符合附錄 III 條文的情形下，FBOs 必須確保動物源性產品具有符合以下規定的識別標記。
A. APPLICATION OF THE IDENTIFICATION MARK	A. 識別標記的應用

<p>▼ M6 (按：M6 在本節之修正，旨在釐清歐盟境內與境外生產產品識別標記之混淆)</p> <p>1. The identification mark must be applied before the product leaves the establishment of production. ◀M6</p>	<p>識別標記必須在產品離開生產廠場前標示。</p>
<p>▼ M3 (按：除非 FBO 可清楚說明和基於管控因素，動物源性產品不應帶有一個以上的識別標記)</p> <p>2. However, when a product's packaging and/or wrapping is removed or it is further processed in another establishment, a new mark must be applied to the product. In such case, the new mark must indicate the approval number of the establishment where these operations take place. ◀M3</p>	<p>然而，當產品的內外包裝被移除或在另一個廠場再加工時，必須在產品上使用新的標記。在此情況下，新標記須標明進行這些作業的廠場之核准號碼。</p>
<p>▼ M6</p> <p>3. An identification mark is not necessary on packs of eggs when a packing centre code is applied in accordance with Part A of Annex XIV to Council Regulation (EC) No 1234/2007²⁴. ◀M6</p> <p>4. Food business operators must, in accordance with Article 18 of Regulation (EC) No 178/2002, have in place systems and procedures to identify food business operators from whom they have received and to whom they have delivered products of animal origin.</p>	<p>當已依理事會第 1234/2007 號規章附錄 XIV 第 A 部分貼附包裝中心代碼時，蛋包裝上不需要識別標記。</p> <p>依第 178/2002 號規章第 18 條規定，FBOs 必須建立可鑑別他們動物源性產品之來源與去向的系統與程序。</p>
<p>B. FORM OF THE IDENTIFICATION MARK</p>	<p>B. 識別標記的形式</p>
<p>5. The mark must be legible and indelible, and the characters easily decipherable. It must be clearly displayed for the competent authorities.</p> <p>6. The mark must indicate the name of the country in which the establishment is located, which may be written out in full or shown as a two-letter code in accordance with the relevant ISO standard.</p>	<p>標記必須清晰並不可磨滅，以及文字容易辨認。它必須可對權責機關清楚展示。</p> <p>標記必須指出廠場所在國家的名稱，可以書寫全名或依 ISO 相關標準之雙字母代碼顯示國名。</p>
<p>▼ M22</p> <p>In the case of Member States²⁵, however, these codes are BE, BG, CZ, DK, DE, EE, GR, ES, FR, HR, IE, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, SI, SK, FI, RO, SE and UK(NI). ◀M22</p>	<p>以歐盟會員國為例，國名代碼為(略)。</p>
<p>▼ M2</p> <p>◀M2</p>	
<p>7. The mark must indicate the approval number of the establishment. If an establishment manufactures both food to which this Regulation applies and food to which it does not, the food business operator may apply the same identification mark to both types of food.</p>	<p>標記必須載明廠場的核准號。如果一個廠場同時產製適用和不適用本規章要求之食品，FBO 可以使用相同的識別標記於此兩類食品上。</p>
<p>▼ M6 ▼ M13</p> <p>8. When applied in an establishment located within the Community, the mark must be oval in shape and include the abbreviation CE, EC, EF, EG, EK, EO, EY, ES, EÜ, EK, EB, EZ or WE. ◀M13</p> <p>Those abbreviations must not be included in marks applied on products imported into the Community from establishments located outside the Community. ◀M6</p>	<p>(略，歐盟廠場之標記須為橢圓形且有縮寫)</p> <p>這些縮寫不包括自歐盟以外廠場進口至歐盟內之產品。</p>
<p>C. METHOD OF MARKING</p>	<p>C. 標記方法</p>
<p>9. The mark may, depending on the presentation of different products of animal</p>	<p>視不同動物源性產品之外觀，標記</p>

²⁴ OJ L 299, 16.11.2007, p. 1.

²⁵ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex, references to Member States include the United Kingdom in respect of Northern Ireland.

<p>origin, be applied directly to the product, the wrapping or the packaging, or be printed on a label affixed to the product, the wrapping or the packaging. The mark may also be an irremovable tag made of a resistant material.</p>	<p>可直接標示於產品、內包材或外包材，或印製於貼附產品或內外包裝上的標籤。標記也可是耐磨材質製成之不易移除附掛。</p>
<p>10. In the case of packaging containing cut meat or offal, the mark must be applied to a label fixed to the packaging, or printed on the packaging, in such a way that it is destroyed when the packaging is opened. This is not necessary, however, if the process of opening destroys the packaging. When wrapping provides the same protection as packaging, the label may be affixed to the wrapping.</p>	<p>(略，分切肉或下水產品要在打開包裝時會被毀壞標記的要求)</p>
<p>11. For products of animal origin that are placed in transport containers or large packages and are intended for further handling, processing, wrapping or packaging in another establishment, the mark may be applied to the external surface of the container or packaging.</p>	<p>以運輸容器或大包裝盛裝動物源性產品，並欲供另一廠場進一步處理、加工、包裹或包裝時，標記可標示於容器或包裝的外表面。</p>
<p>12. In the case of liquid, granulate and powdered products of animal origin carried in bulk, and fishery products carried in bulk, an identification mark is not necessary if accompanying documentation contains the information specified in points 6, 7 and, where appropriate, 8.</p>	<p>對於以散裝載運的液體、粒狀或粉狀動物源性產品，及散裝載運的水產品，若隨附包含第6、7點和適當情況下第8點中指定資訊的文件者，則不需要有識別標記。</p>
<p>13. When products of animal origin are placed in a package destined for direct supply to the final consumer, it is sufficient to apply the mark to the exterior of that package only.</p>	<p>當動物源性產品是直接以包裝型態供應給最終消費者，僅將標記標示於包裝外部即足夠。</p>
<p>14. When the mark is applied directly to products of animal origin, the colours used must be authorised in accordance with Community rules on the use of colouring substances in foodstuffs.</p>	<p>當標記直接標示在動物源性產品上時，所使用色料須符合歐盟法規授權使用於食品中著色物質之規定。</p>
<p>SECTION II: OBJECTIVES OF HACCP-BASED PROCEDURES</p>	<p>第II節：基於HACCP程序的目標</p>
<p>1. Food business operators operating slaughterhouses must ensure that the procedures that they have put in place in accordance with the general requirements of Article 5 of Regulation (EC) No 852/2004 meet the requirements that the hazard analysis shows to be necessary and the specific requirements listed in point 2.</p>	<p>(略，屠宰場FBOs必須確認實施程序之要求)</p>
<p>2. The procedures must guarantee that each animal or, where appropriate, each lot of animals accepted onto the slaughterhouse premises:</p>	<p>(略，進入屠宰場之動物須可被識別、可追溯、無受移動管制、清潔、業者可自行判定是健康的及送屠宰場時令人滿意的動物福利)</p>
<p>(a) is properly identified;</p>	
<p>(b) is accompanied by the relevant information from the holding of provenance referred to in Section III;</p>	
<p>(c) does not come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health, except when the competent authority so permits;</p>	
<p>(d) is clean;</p>	
<p>(e) is healthy, as far as the food business operator can judge;</p>	
<p>and</p>	
<p>(f) is in a satisfactory state as regards welfare on arrival at the slaughterhouse.</p>	
<p>3. In the event of failure to comply with any of the requirements listed under point 2, the food business operator must notify the official veterinarian and take appropriate measures.</p>	<p>(略，若業者無法達到前點要求的措施)</p>
<p>SECTION III: FOOD CHAIN INFORMATION</p>	<p>第III節：食物鏈資訊</p>

<p>Food business operators operating slaughterhouses must, as appropriate, request, receive, check and act upon food chain information as set out in this Section in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse.</p>	<p>除野味外，經營屠宰場FBOs對所有送進或欲送進屠宰場的動物，必須酌情要求、接收、檢查和執行關於本節對食物鏈資訊的要求。</p>
<p>▼M6</p>	
<p>1. Slaughterhouse operators must not accept animals onto the slaughterhouse premises unless they have requested, and been provided with, relevant food chain information contained in the records kept at the holding of provenance in accordance with Regulation (EC) No 852/2004. ◀M6</p>	<p>屠宰場業者不得接受動物進入屠宰場所，除非已要求並取得依第852/2004號規章保存於原產地含有食物鏈相關資訊在內的紀錄。</p>
<p>2. Slaughterhouse operators must be provided with the information no less than 24 hours before the arrival of animals at the slaughterhouse, except in the circumstances mentioned in point 7.</p>	<p>除第7點所提狀況外，屠宰場業者必須在動物抵達屠宰場24小時前獲得相關資訊。</p>
<p>▼M6</p>	
<p>3. The relevant food chain information referred to in point 1 is to cover, in particular: ◀M6</p>	<p>第1點所指的食物鏈相關資訊應包括，特別是：</p>
<p>▼M15</p>	
<p>(a) the status of the holding of provenance or the regional animal health status, and whether the holding is officially recognised to apply controlled housing conditions in relation to <i>Trichinella</i> in accordance with Point A of Chapter I of Annex IV to Commission Regulation (EC) No 2075/2005²⁶; ◀M15</p>	<p>原產地狀態或區域動物健康狀態，及是否依據執委會第2075/2005號規章附錄IV第I章第A點被官方認可適用關於控制旋毛蟲的養養條件；</p>
<p>(b) the animals' health status;</p>	<p>動物健康的狀態；</p>
<p>(c) veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods;</p>	<p>在相關期間內對動物施用停藥期大於0的獸藥產品或其他治療處方，併同其施用日期和停藥期規定。</p>
<p>(d) the occurrence of diseases that may affect the safety of meat;</p>	<p>可能影響肉品安全之疾病的發生；</p>
<p>(e) the results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat, including samples taken in the framework of the monitoring and control of zoonoses and residues;</p>	<p>任何與保護公共衛生相關之分析結果，其採集自動物或為診斷可能影響肉品安全疾病之樣本，包括在監測和控制人畜共通疾病和殘留物框架內所採集之樣本；</p>
<p>(f) relevant reports about previous <i>ante-</i> and <i>post-mortem</i> inspections of animals from the same holding of provenance including, in particular, reports from the official veterinarian;</p>	<p>過往對同一產地動物宰前和宰後檢查的相關報告，特別是包括官方獸醫的報告；</p>
<p>(g) production data, when this might indicate the presence of disease;</p>	<p>生產數據，當它可能預示疾病存在時；</p>
<p>and</p>	<p>和</p>
<p>(h) the name and address of the private veterinarian normally attending the holding of provenance.</p>	<p>依規定參與產地檢查之私人獸醫的姓名和地址。</p>
<p>4. (a) However, it is not necessary for the slaughterhouse operator to be provided with:</p>	<p>然而，屠宰場業者非必須要提供：</p>
<p>(i) the information referred to in point 3(a), (b), (f) and (h), if the operator is already aware of this information (for example, through a standing arrangement or a quality assurance scheme);</p>	<p>第3(a)、(b)、(f)和(h)點中所指的資訊，若業者已知該資訊(例如透過常設安排或品質保證方案)；</p>
<p>or</p>	<p>或是</p>

26 OJ L 338, 22.12.2005, p. 60.

(ii) the information referred to in point 3(a), (b), (f) and (g), if the producer declares that there is no relevant information to report.	第3(a)、(b)、(f)和(g)點中所指的資訊，若業者聲明沒有需要報告的相關資訊。
(b) The information need not be provided as a verbatim extract from the records of the holding of provenance. It may be provided through electronic data exchange or in the form of a standardised declaration signed by the producer.	資訊不需要依產地紀錄中逐字摘錄提供。它可透過電子數據交換或以生產者簽署的標準化聲明形式提供。
5. Food business operators deciding to accept animals onto the slaughterhouse premises after evaluating the relevant food chain information must make it available to the official veterinarian without delay and, except in the circumstances mentioned in point 7, no less than 24 hours before the arrival of the animal or lot. The food business operator must notify the official veterinarian of any information that gives rise to health concerns before <i>ante-mortem</i> inspection of the animal concerned.	FBOs在評估相關食物鏈資訊後決定接受動物進入屠宰場，必須毫無延遲地讓官方獸醫可取得相關資訊，並且除第7點所述情況外，且應在動物或批次到達前24小時以上。FBO在對關注動物進行屠前檢查前，必須將任何引起健康問題的資訊通知官方獸醫。
6. If any animal arrives at the slaughterhouse without food chain information, the operator must immediately notify the official veterinarian. Slaughter of the animal may not take place until the official veterinarian so permits.	若任何抵達屠宰場的動物未有食物鏈資訊，業者必須立即通知官方獸醫。在官方獸醫核准前，不得屠宰動物。
▼M8	
7. If the competent authority so permits and provided it does not jeopardise the objectives of this Regulation, food chain information may arrive less than 24 hours before the arrival of the animals of all species to which it relates at the slaughterhouse or accompany these animals to the slaughterhouse.	若主管機關准許且在不損害本條例的目標下，食物鏈資訊可以在所有動物物種到達屠宰場前24小時內或伴隨這些動物到達屠宰場。
However, any item of food chain information, knowledge of which may result in serious disruption of the slaughterhouse activity, is to be made available to the food business operator operating the slaughterhouse in sufficient time before the animals arrive at the slaughterhouse, in order for that food business operator to plan the slaughterhouse activity accordingly.	然而，可能導致屠宰場活動嚴重中斷的任何食物鏈資訊項目，都應在動物到達屠宰場前有足夠的時間提供給屠宰場的FBO，以便FBO因應規劃屠宰場活動。
The food business operator operating the slaughterhouse must evaluate the relevant information and must submit the food chain information received to the official veterinarian. The slaughter or dressing of the animals may not take place until the official veterinarian so permits. ◀M8	屠宰場FBO必須評估相關資訊且必須提交收到的食物鏈資訊給官方獸醫。在官方獸醫核准前，不得屠宰或修整處理動物。
8. Food business operators must check passports accompanying domestic solipeds to ensure that the animal is intended for slaughter for human consumption. If they accept the animal for slaughter, they must give the passport to the official veterinarian.	FBOs必須檢查隨附家畜的護照，以確保動物是被屠宰供人食用的。若接受動物供屠宰，他們必須將護照交給官方獸醫。
▼M12(按：基於在儲存所遇到的問題，若註明動物源性食品初始冷凍日期，將更有利FBOs判斷其是否適合供人食用)	
SECTION IV: REQUIREMENTS APPLICABLE TO FROZEN FOOD OF ANIMAL ORIGIN	
1. For the purposes of this Section, 'date of production' means:	對本節目的而言，「生產日期」是指：
(a) the date of slaughter in the case of carcasses, half carcasses or quarter carcasses;	胴體、半胴體或1/4胴體的屠宰日期；
(b) the date of killing in the case of bodies of wild game;	野味屠體的獵殺日期；
(c) the date of harvesting or catching, in the case of fishery products;	漁產品的收穫或捕撈日期；

(d) the date of processing, cutting, mincing or preparation, as appropriate, for any other food of animal origin.	適當時，任何其他動物源食品的加工、切割、切碎或製備日期。
2. Until the stage at which a food is labelled in accordance with Directive 2000/13/EC or used for further processing, food business operators must ensure that in the case of frozen food of animal origin intended for human consumption, the following information is made available to the food business operator to whom the food is supplied and, upon request, to the competent authority: (按：Directive 2000/13/EC 不適用於食品生產的前期階段，但動物源性食品在交付前，其生產階段的生產和冷凍更詳細要求對最終消費者來說是必要的。)	供人食用動物源性的冷凍食品在依 2000/13/EC 指令標示或用於進一步加工階段之前，FBOs 必須確保下列資訊是可被下游 FBO 或應主管機關要求而取得：
(a) the date of production; and	生產日期；及
(b) the date of freezing, if different from the date of production.	凍結日期，若與生產日期不同時。
Where a food is made from a batch of raw materials with different dates of production and of freezing, the oldest dates of production and/or of freezing, as appropriate, must be made available.	若食品是由不同生產或凍結日期的批次原料製成，適當時，必須提供最早的生產和/或冷凍日期。
3. The appropriate form in which the information must be made available is up to the choice of the supplier of the frozen food, as long as the information requested in paragraph 2 will be clearly and unequivocally available to and retrievable by the business operator to whom the food is supplied. ◀M12	必要資訊之適恰格式是取決於冷凍食品供應者的選擇，只要第 2 段要求的資訊可被清楚及明確地提供給下游 FBO 並可被追溯。
ANNEX III SPECIFIC REQUIREMENTS	附錄 III 具體要求
SECTION I: MEAT OF DOMESTIC UNGULATES	第 I 節：畜養有蹄動物的肉
CHAPTER I: TRANSPORT OF LIVE ANIMALS TO THE SLAUGHTERHOUSE	第 I 章：將活動物運送到屠宰場
Food business operators transporting live animals to slaughterhouses must ensure compliance with the following requirements.	(略，運送業者應注意的動物福利及有病或受汙染動物的要求)
1. During collection and transport, animals must be handled carefully without causing unnecessary distress.	
2. Animals showing symptoms of disease or originating in herds known to be contaminated with agents of public health importance may only be transported to the slaughterhouse when the competent authority so permits.	
CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES	第 II 章：對屠宰場的要求
Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which domestic ungulates are slaughtered meet the following requirements.	(略，業者應確認屠宰場的設施條件)
1. (a) Slaughterhouses must have adequate and hygienic lairage facilities or, climate permitting, waiting pens that are easy to clean and disinfect. These facilities must be equipped for watering the animals and, if necessary, feeding them. The drainage of the wastewater must not compromise food safety.	(略，屠宰場的畜欄、等候室及廢水處理要求)
(b) They must also have separate lockable facilities or, climate permitting, pens for sick or suspect animals with separate draining and sited in such a way as to avoid contamination of other animals, unless the competent authority considers that such facilities are unnecessary.	(略，患病動物的處理)
(c) The size of the lairage facilities must ensure that the welfare of the animals is respected. Their layout must facilitate ante-mortem inspections, including the identification of the animals or groups of animals.	(略，畜欄的動物福利及動物識別要求)
2. To avoid contaminating meat, they must:	(略，避免汙染肉品的要求)
(a) have a sufficient number of rooms, appropriate to the operations being carried out;	(略，有足夠數量房舍)
(b) have a separate room for the emptying and cleaning of stomachs and intestines, unless the competent authority authorises the separation in time of these operations within a specific slaughterhouse on a case-by-case basis;	(略，動物清腸胃的獨立房舍要求)

(c) ensure separation in space or time of the following operations:	(略，空間或時間區隔的作業要求)
(i) stunning and bleeding;	(略，擊暈及放血)
(ii) in the case of porcine animals, scalding, depilation, scraping and singeing;	(略，豬隻燙、脫、刮和燒毛)
(iii) evisceration and further dressing;	(略，去臟及修整)
(iv) handling clean guts and tripe;	(略，腸及牛肚處理)
(v) preparation and cleaning of other offal, particularly the handling of skinned heads if it does not take place at the slaughter line;	(略，其他下水的處理)
(vi) packaging offal;	(略，包裝下水)
and	
(vii) dispatching meat;	(略，分銷肉品)
(d) have installations that prevent contact between the meat and the floors, walls and fixtures;	(略，避免肉品與地牆等直接接觸設施)
and	
(e) have slaughter lines (where operated) that are designed to allow constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.	(略，屠宰動線關於避免交叉污染的要求)
3. They must have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.	(略，以82°C以上熱水來消毒工具)
4. The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.	(略，洗手設備要求)
5. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.	(略，留置及不適食用肉品之上鎖貯存要求)
6. There must be a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock. However, slaughterhouses need not have these places and facilities if the competent authority so permits and official authorised places and facilities exist nearby.	(略，牲畜運輸工具管理要求)
7. They must have lockable facilities reserved for the slaughter of sick and suspect animals. This is not essential if this slaughter takes place in other establishments authorised by the competent authority for this purpose, or at the end of the normal slaughter period.	(略，患病動物的隔離管制要求)
8. If manure or digestive tract content is stored in the slaughterhouse, there must be a special area or place for that purpose.	(略，糞便或腸內物之貯存要求)
9. They must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.	(略，獸醫服務專用房間或設備)
CHAPTER III: REQUIREMENTS FOR CUTTING PLANTS	第三章：對分切工廠的要求
Food business operators must ensure that cutting plants handling meat of domestic ungulates:	(略，FBOs應確認處理畜養有蹄類肉之分切工廠的要求)
1. are constructed so as to avoid contamination of meat, in particular by:	(略，作業結構要求)
(a) allowing constant progress of the operations;	
or	
(b) ensuring separation between the different production batches;	
2. have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;	(略，儲存空間的要求)
3. have cutting rooms equipped to ensure compliance with the requirements laid down in Chapter V;	(略，切割室的要求)
4. have equipment for washing hands with taps designed to prevent the spread of contamination, for use by staff engaged in handling exposed meat; and	(略，洗手設備的要求)

5. have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.	(略，82°C熱水來消毒工具的要求)
CHAPTER IV: SLAUGHTER HYGIENE	第IV章：屠宰衛生
Food business operators operating slaughterhouses in which domestic ungulates are slaughtered must ensure compliance with the following requirements.	(略)
1. After arrival in the slaughterhouse, the slaughter of the animals must not be unduly delayed. However, where required for welfare reasons, animals must be given a resting period before slaughter.	(略，不得無故延遲屠宰)
2. (a) Meat from animals other than those referred to in subparagraphs (b) and (c) must not be used for human consumption if they die otherwise than by being slaughtered in the slaughterhouse.	(略，非因屠宰死亡動物不可供人食用)
(b) Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of:	(略，活體才能進屠宰場)
(i) animals that have undergone emergency slaughter outside the slaughterhouse in accordance with Chapter VI;	(略，緊急屠宰除外)
▼ M23	
(ii) animals slaughtered at the holding of provenance in accordance with Chapter VIa of this Section or in accordance with point 3 of Section III; ◀ M23	(略，原產地屠宰除外)
(iii) wild game, in compliance with Section IV, Chapter II.	(略，野味除外)
(c) Meat from animals that undergo slaughter following an accident in a slaughterhouse may be used for human consumption if, on inspection, no serious lesions other than those due to the accident are found.	(略，在屠宰場事故後被屠宰的動物肉，經檢查後可供人食用)
3. The animals or, where appropriate, each batch of animals sent for slaughter must be identified so that their origin can be traced.	(略，每批送去屠宰動物要可被識別及追溯)
4. Animals must be clean.	(略)
5. Slaughterhouse operators must follow the instructions of the veterinarian appointed by the competent authority in accordance with Regulation (EC) No 854/2004 to ensure that ante-mortem inspection of every animal to be slaughtered is carried out under suitable conditions.	(略，遵循獸醫指示進行屠前檢查)
6. Animals brought into the slaughter hall must be slaughtered without undue delay.	(略，動物進入屠宰室須立即屠宰)
7. Stunning, bleeding, skinning, evisceration and other dressing must be carried out without undue delay and in a manner that avoids contaminating the meat. In particular:	(略，擊暈、放血、剝皮、去臟及其他修整須即時執行，避免汙染)
(a) the trachea and oesophagus must remain intact during bleeding, except in the case of slaughter according to a religious custom;	(略，除非宗教要求，放血期間應保持氣管及食道完整)
(b) during the removal of hides and fleece:	(略，去除皮革和毛皮過程要求)
(i) contact between the outside of the skin and the carcase must be prevented;	(略，避免皮的外部與胴體接觸)
and	
(ii) operators and equipment coming into contact with the outer surface of hides and fleece must not touch the meat;	(略，接觸皮革及毛皮人員及設備不得接觸肉品)
(c) measures must be taken to prevent the spillage of digestive tract content during and after evisceration and to ensure that evisceration is completed as soon as possible after stunning;	(略，擊昏後盡速完成去內臟避免內容物溢出)
and	
(d) removal of the udder must not result in contamination of the carcase with milk or colostrum.	(略，移除乳房不得導致乳或初乳汙染胴體)
▼ M3	
8. Carcases and other parts of the body intended for human consumption must be completely skinned, except in the case of porcine animals, the heads of ovine and	(略，胴體去皮之要求，部分動物

caprine animals and calves, the muzzle and lips of bovine animals and the feet of bovine, ovine and caprine animals. Heads, including muzzle and lips, and feet must be handled in such a way as to avoid contamination. ◀M3	頭、鼻口、唇、腳除外)
9. When not skinned, porcine animals must have their bristles removed immediately. The risk of contamination of the meat with scalding water must be minimised. Only approved additives may be used for this operation. Porcine animals must be thoroughly rinsed afterwards with potable water.	(略，不去皮的豬要立即去鬃毛並以滾水降低汙染風險)
10. The carcasses must not contain visible faecal contamination. Any visible contamination must be removed without delay by trimming or alternative means having an equivalent effect.	(略，胴體上不得有可視之糞便)
11. Carcasses and offal must not come into contact with floors, walls or work stands.	(略，胴體等不得與地牆等接觸)
12. Slaughterhouse operators must follow the instructions of the competent authority to ensure that post-mortem inspection of all slaughtered animals is carried out under suitable conditions in accordance with Regulation (EC) No 854/2004.	(略，業者必須依指示確認執行屠後檢查)
13. Until post-mortem inspection is completed, parts of a slaughtered animal subject to such inspection must:	(略，屠後檢查前的胴體要求)
(a) remain identifiable as belonging to a given carcass;	(略，維持可識別性)
and	
(b) come into contact with no other carcass, offal or viscera, including those that have already undergone post-mortem inspection.	(略，不可與其他胴體等接觸)
However, provided that it shows no pathological lesion, the penis may be discarded immediately.	(略，未顯病徵則陰莖可立即丟棄)
14. Both kidneys must be removed from their fatty covering. In the case of bovine and porcine animals, and solipeds, the peri-renal capsule must also be removed.	(略，腎要移除脂肪囊，豬牛單蹄動物亦須移除腎囊)
15. If the blood or other offal of several animals is collected in the same container before completion of post-mortem inspection, the entire contents must be declared unfit for human consumption if the carcass of one or more of the animals concerned has been declared unfit for human consumption.	(略，屠後檢查認定某胴體不適食用，則在檢查前混裝同一容器的血及臟器也全不適食用)
16. After post-mortem inspection:	(略，屠後檢查後的要求)
▼M3	
(a) the tonsils of bovine animals, porcine animals and solipeds must be removed hygienically; ◀M3 (按：扁桃腺體是所有進入動物口腔有害物質的過濾器，出於衛生安全理由，加入對豬扁桃體強制性切除的漏植規定)	(略，豬牛單蹄動物移除扁桃腺體)
(b) parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;	(略，不適食用部分盡速自廠房清潔區移除)
(c) meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption;	(略，不適食用的肉及副產品不可與適食用的肉接觸)
and	
(d) viscera or parts of viscera remaining in the carcass, except for the kidneys, must be removed entirely and as soon as possible, unless the competent authority authorises otherwise.	(略，除腎外，應盡快完全移除胴體中的內臟)
17. After completion of slaughter and post-mortem inspection, the meat must be stored in accordance with the requirements laid down in Chapter VII.	(略，依第七章規定儲存完成屠後檢查肉品)
▼M17 ▼M23	
18. Unless intended for use as animal by-product in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council ²⁷ :	(略，除非用作動物副產品的臟器處理要求)
(a) stomachs must be scalded or cleaned; however, when intended for rennet production, the stomachs:	(略)
(i) are only required to be emptied in the case of young bovine animals,	
(ii) are not required to be emptied, scalded or cleaned in the case of young ovine and caprine animals;	

²⁷ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

(b) intestines must be emptied and cleaned;	(略)
(c) heads and feet must be skinned or scalded and depilated; however, when authorised by the competent authority, visibly clean heads, not containing specified risk materials in accordance with Article 8 of Regulation (EC) No 999/2001 of the European Parliament and of the Council ²⁸ (2), and visibly clean feet, intended for processing into food, may be transported to and skinned or scalded and depilated in an approved establishment. ◀M17◀M23	(略)
19. Where establishments are approved for the slaughter of different animal species or for the handling of carcasses of farmed game and wild game, precautions must be taken to prevent cross-contamination by separation either in time or in space of operations carried out on the different species. Separate facilities for the reception and storage of unskinned carcasses of farmed game slaughtered at the farm and for wild game must be available.	(略，當廠場獲准屠宰或處理不同物種或野味時，以時空區隔等預防措施來避免交叉污染的要求)
20. If the slaughterhouse does not have lockable facilities reserved for the slaughter of sick or suspect animals, the facilities used to slaughter such animals must be cleaned, washed and disinfected under official supervision before the slaughter of other animals is resumed.	(略，若廠場未設病畜上鎖設施，則須在官方監督下完成清潔、清洗和消毒後方能屠宰其他動物)
CHAPTER V: HYGIENE DURING CUTTING AND BONING	第V章：分切和去骨期間的衛生
Food business operators must ensure that cutting and boning of meat of domestic ungulates takes place in accordance with the following requirements.	(略)
1. Carcasses of domestic ungulates may be cut into half-carcasses or quarters, and half carcasses into no more than three wholesale cuts, in slaughterhouses. Further cutting and boning must be carried out in a cutting plant.	(略，屠宰場可將胴體切成4等份或半胴體不超過3切塊，進一步分切及去骨則須在分切工廠進行)
2. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:	(略，避免污染的要求)
(a) meat intended for cutting is brought into the workrooms progressively as needed;	(略，逐步將肉運至分切室分切)
(b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the meat is maintained at not more than 3°C for offal and 7°C for other meat, by means of an ambient temperature of not more than 12°C or an alternative system having an equivalent effect;	(略，環境溫度12°C以下，內臟3°C以下，肉7°C以下)
and	
(c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.	(略，分切不同物種，要有時空區隔等預防措施避免交叉污染)
3. However, meat may be boned and cut before it reaches the temperature referred to in point 2(b) in accordance with Chapter VII, point 3.	(略，肉可依第七章第3點在達到7°C前進行分切和去骨)
4. Meat may also be boned and cut prior to reaching the temperature referred to in point 2(b) when the cutting room is on the same site as the slaughter premises. In this case, the meat must be transferred to the cutting room either directly from the slaughter premises or after a waiting period in a chilling or refrigerating room. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 2(b).	(略，分切室與屠宰場在同一地點時的胴體溫度要求)
▼M20	
5. Carcasses, half carcasses, quarters, or half carcasses cut into no more than three wholesale cuts may be boned and cut prior to reaching the temperature referred to in point 2(b) when they have been transported under the derogation set out in point 3(b) of Chapter VII of Section I. In this case, throughout cutting or boning, the meat must be subjected to air temperatures that ensure a continuous decrease of the temperature of the meat. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 2(b) if it is not already below this temperature. ◀M20	(略，第I節第七章第3(b)點運輸條件下，對胴體分切去骨之例外溫度要求，包裝時則要達到3或7°C以下要求)
CHAPTER VI: EMERGENCY SLAUGHTER OUTSIDE THE SLAUGHTERHOUSE	第VI章：屠宰場外的緊急屠宰

²⁸ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

Food business operators must ensure that meat from domestic ungulates that have undergone emergency slaughter outside the slaughterhouse may be used for human consumption only if it complies with all the following requirements.	(略)
1. An otherwise healthy animal must have suffered an accident that prevented its transport to the slaughterhouse for welfare reasons.	(略，基於動物福利理由因事故無法運抵屠宰場)
▼ M23	
2. The official veterinarian must carry out an ante-mortem inspection of the animal.	(略，官方獸醫應完成屠前檢查)
3. The slaughtered and bled animal must be transported to the slaughterhouse hygienically and without undue delay. Removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the official veterinarian. Any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to that animal. ◀M23	(略，屠宰及放血等程序要求)
4. If more than two hours elapse between slaughter and arrival at the slaughterhouse, the animal must be refrigerated. Where climatic conditions so permit, active chilling is not necessary.	(略，屠宰後抵達屠宰場時間要在2小時內，否則要冷藏)
5. A declaration by the food business operator who reared the animal, stating the identity of the animal and indicating any veterinary products or other treatments administered to the animal, dates of administration and withdrawal periods, must accompany the slaughtered animal to the slaughterhouse.	(略，飼養業者聲明動物用藥及追溯之責任要求)
▼ M23	
6. The official certificate set out in Chapter 5 of Annex IV to Commission Implementing Regulation (EU) 2020/2235 ²⁹ shall accompany the slaughtered animal to the slaughterhouse or be sent in advance in any format. ◀M23	(略，要隨附官方證明文件之要求)
7. The slaughtered animal must be fit for human consumption following post-mortem inspection carried out in the slaughterhouse in accordance with Regulation (EC) No 854/2004, including any additional tests required in the case of emergency slaughter.	(略，屠後檢查及測試)
8. Food business operators must follow any instructions that the official veterinarian may give after post-mortem inspection concerning the use of the meat.	(略，業者應遵循屠後檢查之官方獸醫指示)
▼ M15	
◀M15	
▼ M23	
CHAPTER VIa: SLAUGHTER AT THE HOLDING OF PROVENANCE OF DOMESTIC BOVINE, OTHERS THAN BISONS, AND PORCINE ANIMALS AND DOMESTIC SOLIPEDES OTHER THAN EMERGENCY SLAUGHTER	第VIa章：非緊急屠宰之畜養牛隻(野牛除外)、豬隻和單蹄動物的產地屠宰
Up to three domestic bovine, others than bisons, or up to six domestic porcine animals or up to three domestic solipeds may be slaughtered at the same occasion at the holding of provenance, when authorised by the competent authority in accordance with the following requirements:	(略，產地屠宰的隻數限制及要求)
(a) the animals cannot be transported to the slaughterhouse, to avoid any risk for the handler and to prevent any injuries to the animals during transport;	(略)
(b) there is an agreement between the slaughterhouse and the owner of the animal intended for slaughter; the owner must inform the competent authority in writing of such an agreement;	
(c) the slaughterhouse or the owner of the animals intended for slaughter must inform the official veterinarian at least three days in advance of the date and time of intended slaughter of the animals;	
(d) the official veterinarian who carries out the ante-mortem inspection of the animal intended for slaughter must be present at the time of slaughter;	
(e) the mobile unit to be used for the bleeding and transport of the slaughtered animals to the slaughterhouse must allow their hygienic handling and bleeding, and the proper disposal of their blood and must be part of a slaughterhouse approved by the competent authority in accordance with Article 4(2); however the competent authority may allow bleeding outside the mobile unit if the blood is not intended for human consumption and the slaughter does not take place in	

²⁹ Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

<p>restricted zones as defined in Article 4(41) of Regulation (EU) 2016/429 of the European Parliament and of the Council³⁰ (2) or establishments in which animal health restrictions are applied in accordance with Regulation (EU) 2016/429 and any acts adopted on its basis;</p> <p>(f) the slaughtered and bled animals must be transported directly to the slaughterhouse hygienically and without undue delay; removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the official veterinarian; any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to each individual animal;</p> <p>(g) if more than two hours elapse between the time of slaughter of the first animal and the time of arrival at the slaughterhouse of the slaughtered animals, the slaughtered animals must be refrigerated; where climatic conditions so permit, active chilling is not necessary;</p> <p>(h) the owner of the animal must inform the slaughterhouse in advance of the intended time of arrival of the slaughtered animals, which must be handled without undue delay after arrival at the slaughterhouse;</p> <p>(i) in addition to the food chain information to be submitted in accordance with Section III of Annex II to this Regulation, the official certificate set out in Chapter 3 of Annex IV to Implementing Regulation (EU) 2020/2235 must accompany the slaughtered animals to the slaughterhouse or be sent in advance in any format. ◀M23</p>	
<p>CHAPTER VII: STORAGE AND TRANSPORT</p>	<p>第七章：貯存和運輸</p>
<p>Food business operators must ensure that the storage and transport of meat of domestic ungulates takes place in accordance with the following requirements.</p>	<p>(略)</p>
<p>1. (a) Unless other specific provisions provide otherwise, post-mortem inspection must be followed immediately by chilling in the slaughterhouse to ensure a temperature throughout the meat of not more than 3 °C for offal and 7 °C for other meat along a chilling curve that ensures a continuous decrease of the temperature. However, meat may be cut and boned during chilling in accordance with Chapter V, point 4.</p>	<p>(略，肉品溫度要求-內臟3°C以下，肉7°C以下要求)</p>
<p>(b) During the chilling operations, there must be adequate ventilation to prevent condensation on the surface of the meat.</p>	<p>(略，肉表面不可有冷凝水)</p>
<p>2. Meat must attain the temperature specified in point 1 and remain at that temperature during storage.</p>	<p>(略，在儲存期間的溫度要求)</p>
<p>▼M20</p>	
<p>3. Meat must attain the temperature specified in point 1 before transport, and remain at that temperature during transport.</p>	<p>(略，運輸前及期間的溫度要求)</p>
<p>However, following points (a) and (b) shall apply.</p>	<p>(略)</p>
<p>(a) Transport of meat for the production of specific products may take place before the temperature specified in point 1 is attained if the competent authority so authorises, provided that:</p>	<p>(略，高於前述溫度時須主管機關同意的要求)</p>
<p>(i) such transport takes place in accordance with the requirements that the competent authorities of origin and destination specify in respect of transport from one given establishment to another;</p>	<p>(略)</p>
<p>(ii) the meat leaves the slaughterhouse, or a cutting room on the same site as the slaughter premises, immediately and transport takes no more than 2 hours;</p>	<p>(略)</p>
<p>and,</p>	
<p>(iii) such transport is justified for technological reasons.</p>	<p>(略)</p>
<p>(b) Transport of carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts of ovine and caprine animals, bovine animals and porcine animals may commence before the temperature specified in point 1 is attained, provided that all of the following conditions are fulfilled:</p>	<p>(略，達到上述溫度前的運輸，應滿足下列所有條件)</p>
<p>(i) the temperature is monitored and recorded within the framework of procedures based on the HACCP principles;</p>	<p>(略，在HACCP框架下監測和紀錄溫度)</p>
<p>(ii) food business operators dispatching and transporting the carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts have received documented authorisation from the competent authority at the</p>	<p>(略，經啟運地主管機關書面同意)</p>

³⁰ Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

place of departure to make use of this derogation;																	
(iii) the vehicle transporting the carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts are fitted with an instrument that monitors and records air temperatures to which the carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts are subjected in such a way that competent authorities are enabled to verify compliance with the time and temperature conditions set out in point (viii);	(略，運輸車輛配有設備監測及紀錄溫度並可供主管機關檢核符合性)																
(iv) the vehicle transporting the carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts collects meat from only one slaughterhouse per transport;	(略，運輸車輛每次僅從1個屠宰場收集肉品)																
(v) carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts subject to this derogation must have a core temperature of 15 degrees at the start of the transport if they are to be transported in the same compartment as carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts which meets the temperature requirement at Point 1 (i.e. 7 degrees);	(略，與相同部位7度的胴體等同時運輸者，其中心溫度在啟運時須達15度)																
(vi) a declaration by the food business operator accompanies the consignment; that declaration must state the duration of chilling before loading, the time at which loading of the carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts were started, the surface temperature at that time, the maximum transportation air temperature to which carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts may be subjected, the maximum transport time permitted, the date of authorisation and the name of the competent authority providing the derogation;	(略，業者隨附聲明須有裝載前冷藏持續時間、開始裝載時間、該時間的產品表面溫度、允許的環境最高溫度和運輸時間、主管機關名稱和核准日期)																
(vii) the food business operator of destination must notify the competent authorities before he receives for the first time carcasses, half carcasses, quarters, or half carcasses cut into three wholesale cuts, not attaining the temperature specified in point 1 before transport;	(略，目的地業者須在收貨前通告主管機關)																
(viii) such meat is transported in accordance with the following parameters:	(略，依下列參數進行運輸)																
— for a maximum transport time ³¹ of 6 hours:	(略，6小時內的運輸條件)																
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▲ M20																	
▼ M23																	

31 Maximum time allowed from the start of loading of meat into the vehicle until the completion of the final delivery. Loading of the meat into the vehicle may be postponed beyond the maximum time allowed for chilling of the meat to its specified surface temperature. If this happens, then the maximum transport time allowed must be shortened by the same length of time by which the loading was postponed. The competent authority of the Member State of destination may limit the number of delivery points. / 從裝載開始到最終交付產品的最長時間。若裝貨時間過長須縮短運輸時間。目的地主管機關可以限制交貨量。

32 Maximum surface temperature allowed at loading and thereafter measures at the thickest part of the carcass, half carcasses, quarters, or half carcasses cut into three wholesale cuts. / 在最厚處測量表面溫度

33 Maximum time allowed from the moment of killing until the reaching of the maximum surface temperature allowed at loading. / 從屠宰到裝載時間從裝載開始到整個運輸過程的環境溫度

34 The maximum air temperature to which the meat is allowed to be subjected from the moment loading begins, and throughout the whole duration of the transport. / 從裝載開始到整個運輸過程的環境溫度

35 Slaughterhouse maximum daily mean carcass aerobic colony count using a rolling window of 10 weeks, allowed for carcasses of the relevant species, as assessed by the operator to the satisfaction of the competent authority, according to the sampling and testing procedures laid out in points 2.1.1, 2.1.2 of Chapter 2, and point 3.2 of Chapter 3, of Annex I to Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1). / 屠宰場日平均最大菌數(10週滾動式計數)

36 The maximum core temperature of the meat allowed at the time of loading, and thereafter. / 裝載前及之後的最大中心溫度

<p>4. Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing.</p>	<p>(略，供冷凍的肉須立即予以冷凍)</p>
<p>However, food business operators carrying out a retail activity may freeze meat in view of its redistribution for the purpose of food donations in accordance with the following conditions:</p> <p>(i) in the case of meat for which a 'use by' date is applied in accordance with Article 24 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council³⁷, before the expiry of that date;</p> <p>(ii) without undue delay to a temperature of -18°C or lower;</p> <p>(iii) ensuring that the date of freezing is documented and provided either on the label or by other means;</p> <p>(iv) excluding meat that has been frozen before (defrosted meat); and,</p> <p>(v) in accordance with any condition laid down by the competent authorities for freezing and further use as food. ◀M23</p>	<p>(略，以捐贈為目的的冷凍條件，在使用期限前、盡快冷至-18°C或以下、提供凍結日期、不可再冷凍解凍肉和依主管機關規定條件)</p> <p>(按：2018年9月27日，EFSA通過了針對某些小型零售場所和食品捐贈的危害分析方法的第2份科學意見，建議在零售層面進行冷凍，作為確保將食品安全地重新分配給有需要的人的額外工具。促進安全的食物捐贈做法，既可以防止食物浪費，又有助於糧食安全，這符合委員會從農場到餐桌的戰略中規定的目標及其建立公平、健康和環保食品系統的歐洲綠色協議總體目標。食品冷凍是確保食品銀行和其他慈善機構安全重新分配食品的重要手段。)</p>
<p>5. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.</p>	<p>(略，有無包裝的肉須分別儲存和運輸，除非在不同時間儲運或包材和儲運方式不會成為肉品污染源)</p>
<p>SECTION II: MEAT FROM POULTRY AND LAGOMORPHS</p>	<p>第II節：禽兔肉</p>
<p>CHAPTER I: TRANSPORT OF LIVE ANIMALS TO THE SLAUGHTERHOUSE</p>	<p>第I章：將活動物運送到屠宰場</p>
<p>Food business operators transporting live animals to slaughterhouses must ensure compliance with the following requirements.</p>	<p>(略，運送業者應注意的動物福利及有病或受汙染動物的要求)</p>
<p>1. During collection and transport, animals must be handled carefully without causing unnecessary distress.</p>	
<p>2. Animals showing symptoms of disease or originating in flocks known to be contaminated with agents of public-health importance may only be transported to the slaughterhouse when permitted by the competent authority.</p>	
<p>3. Crates for delivering animals to the slaughterhouse and modules, where used, must be made of non-corrodible material and be easy to clean and disinfect. Immediately after emptying and, if necessary, before re-use, all equipment used for collecting and delivering live animals must be cleaned, washed and disinfected.</p>	
<p>CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES</p>	<p>第II章：對屠宰場的要求</p>
<p>Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which poultry or lagomorphs are slaughtered meet the following requirements.</p>	<p>(略，業者應確認屠宰場的設施條件)</p>
<p>1. They must have a room or covered space for the reception of the animals and for their inspection before slaughter.</p>	<p>(略，要有房間作為接收及屠宰前檢查的要求)</p>
<p>2. To avoid contaminating meat, they must:</p>	<p>(略，避免汙染肉品的要求)</p>
<p>(a) have a sufficient number of rooms, appropriate to the operations being carried out;</p>	<p>(略，有足夠數量房舍)</p>
<p>(b) have a separate room for evisceration and further dressing, including the addition of seasonings to whole poultry carcasses, unless the competent authority authorises separation in time of these operations within a specific slaughterhouse on a case-by-case basis;</p>	<p>(略，動物清腸胃的獨立房舍要求)</p>
<p>(c) ensure separation in space or time of the following operations:</p>	<p>(略，空間或時間區隔的作業要求)</p>
<p>(i) stunning and bleeding;</p>	<p>(略，擊暈及放血)</p>
<p>(ii) plucking or skinning, and any scalding;</p>	<p>(略，拔毛、去皮和燒毛)</p>
<p>and</p>	
<p>(iii) dispatching meat;</p>	<p>(略，分銷肉品)</p>

³⁷ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 609/2004 (OJ L 304, 22.11.2011, p. 18).

(d) have installations that prevent contact between the meat and the floors, walls and fixtures;	(略，避免肉品與地牆等接觸的設施)
and	
(e) have slaughter lines (where operated) that are designed to allow a constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.	(略，屠宰動線關於避免交叉污染的要求)
3. They must have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.	(略，以82°C以上熱水來消毒工具)
4. The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.	(略，洗手設備要求)
5. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.	(略，留置及不適食用肉品之上鎖貯存要求)
6. There must be a separate place with appropriate facilities for the cleaning, washing and disinfection of:	(略，要有獨立區域供清潔、清洗和消毒運輸工具及設備)
(a) transport equipment such as crates;	
and	
(b) means of transport.	
These places and facilities are not compulsory for (b) if officially authorised places and facilities exist nearby.	
7. They must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.	(略，獸醫服務專用房間或設備)
CHAPTER III: REQUIREMENTS FOR CUTTING PLANTS	第三章：對分切工廠的要求
1. Food business operators must ensure that cutting plants handling meat from poultry or lagomorphs:	(略，FBOs應確認處理禽兔肉分切工廠的要求)
(a) are constructed so as to avoid contamination of meat, in particular by:	(略，作業結構要求)
(i) allowing constant progress of the operations;	
or	
(ii) ensuring separation between the different production batches;	
(b) have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;	(略，儲存空間的要求)
(c) have cutting rooms equipped to ensure compliance with the requirements laid down in Chapter V;	(略，切割室的要求)
(d) have equipment for washing hands used by staff handling exposed meat with taps designed to prevent the spread of contamination;	(略，洗手設備的要求)
and	
(e) have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.	(略，82°C熱水來消毒工具的要求)
2. If the following operations are undertaken in a cutting plant:	(略，分切廠對取禽內臟作業要求)
(a) the evisceration of geese and ducks reared for the production of 'foie gras', which have been stunned, bled and plucked on the fattening farm;	
or	
(b) the evisceration of delayed eviscerated poultry,	
food business operators must ensure that separate rooms are available for that purpose.	

CHAPTER IV: SLAUGHTER HYGIENE	第四章：屠宰衛生
Food business operators operating slaughterhouses in which poultry or lagomorphs are slaughtered must ensure compliance with the following requirements.	(略)
1. (a) Meat from animals other than those referred to in (b) must not be used for human consumption if they die otherwise than by being slaughtered in the slaughterhouse.	(略，非因屠宰死亡動物不可供人食用)
(b) Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of:	(略，活體才能進屠宰場)
(i) delayed eviscerated poultry, geese and ducks reared for the production of 'foie gras' and birds that are not considered as domestic but which are farmed as domestic animals, if slaughtered at the farm in accordance with Chapter VI;	(略，為取鵝肝等內臟者除外)
(ii) farmed game slaughtered at the place of production in accordance with Section III;	(略，原產地屠宰除外)
and	
(iii) small wild game in accordance with Section IV, Chapter III.	(略，小型野味除外)
2. Slaughterhouse operators must follow the instructions of the competent authority to ensure that ante-mortem inspection is carried out under suitable conditions.	(略，屠前檢查規定)
3. Where establishments are approved for the slaughter of different animal species or for the handling of farmed ratites and small wild game, precautions must be taken to prevent cross contamination by separation either in time or in space of the operations carried out on the different species. Separate facilities for the reception and storage of carcasses of farmed ratites slaughtered at the farm and for small wild game must be available.	(略，不同物種之交叉污染預防措施)
4. Animals brought into the slaughter room must be slaughtered without undue delay.	(略，動物進入屠宰室須立即屠宰)
5. Stunning, bleeding, skinning or plucking, evisceration and other dressing must be carried out without undue delay in such a way that contamination of the meat is avoided. In particular, measures must be taken to prevent the spillage of digestive tract contents during evisceration.	(略，擊暈、放血、剝皮、去臟及其他修整須即時執行，避免消化道內容物溢出及汙染)
6. Slaughterhouse operators must follow the instructions of the competent authority to ensure that the post-mortem inspection is carried out under suitable conditions, and in particular that slaughtered animals can be inspected properly.	(略，屠後檢查規定)
7. After post-mortem inspection:	(略，屠後檢查後之作業要求)
(a) parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;	
(b) meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption;	
and	
(c) viscera or parts of viscera remaining in the carcase, except for the kidneys, must be removed entirely, if possible, and as soon as possible, unless otherwise authorised by the competent authority.	
8. After inspection and evisceration, slaughtered animals must be cleaned and chilled to not more than 4°C as soon as possible, unless the meat is cut while warm.	(略，屠後檢查後盡快清洗及冷卻至4°C以下)
9. When carcasses are subjected to an immersion chilling process, account must be taken of the following.	(略，浸入式冷卻胴體之要求)
(a) Every precaution must be taken to avoid contamination of carcasses, taking into account parameters such as carcase weight, water temperature, volume and direction of water flow and chilling time.	
(b) Equipment must be entirely emptied, cleaned and disinfected whenever this is necessary and at least once a day.	
10. Sick or suspect animals, and animals slaughtered in application of disease eradication or control programmes, must not be slaughtered in the establishment except when permitted by the competent authority. In that event, slaughter must be performed under official supervision and steps taken to prevent contamination; the	(略，患病動物屠宰規定)

premises must be cleaned and disinfected before being used again.	
CHAPTER V: HYGIENE DURING AND AFTER CUTTING AND BONING	第 V 章：分切和去骨期間與之後的衛生
Food business operators must ensure that cutting and boning of meat of poultry and lagomorphs takes place in accordance with the following requirements.	(略，FBOs應確保事項)
1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:	(略，避免或減少污染)
(a) meat intended for cutting is brought into the workrooms progressively as needed;	(略，有序地將肉運進工作區分切)
(b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the temperature of the meat is maintained at not more than 4°C by means of an ambient temperature of 12°C or an alternative system having an equivalent effect;	(略，環境溫度在12°C以下以維持肉品溫度在4°C以下)
and	
(c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.	(略，處理不同物種交叉污染的預防措施)
2. However, meat may be boned and cut prior to reaching the temperature referred to in point 1(b) when the cutting room is on the same site as the slaughter premises, provided that it is transferred to the cutting room either:	(略，切割室與屠宰設施在同一地點之要求)
(a) directly from the slaughter premises;	
or	
(b) after a waiting period in a chilling or refrigerating room.	
▼ M9	
3. As soon as the meat is cut and, where appropriate, packaged, it must be chilled to a temperature of not more than 4°C.	(略，肉經切割包裝後，應盡快冷卻至4°C以下)
4. Meat must attain a temperature of not more than 4°C before transport, and be maintained at that temperature during transport. However, if the competent authority so authorises, livers for the production of <i>foie gras</i> may be transported at a temperature of more than 4°C, provided that:	(略，肉應在運輸前達4°C以下並於運輸過程維持在該溫度下，鵝肝在下列特殊情形下可例外)
(a) such transport takes place in accordance with the requirements that the competent authority specifies in respect of transport from one given establishment to another; and	(略，依主管機關要求進行者)
(b) the meat leaves the slaughterhouse, or a cutting room immediately and transport takes no more than two hours. ◀M9	(略，運輸時間不超過2hrs者)
▼ M23	
5. Meat intended for freezing must be frozen without undue delay. However, food business operators carrying out a retail activity may freeze meat in view of its redistribution for the purpose of food donations in accordance with the following conditions:	(略，用於冷凍的肉應立即冷凍，不得無故延遲；但用於食品捐贈目的者，可有例外情形，解凍肉除外)
(i) in the case of meat 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;	
(ii) without undue delay to a temperature of -18°C or lower;	
(iii) ensuring that the date of freezing is documented and provided either on the label or by other means;	
(iv) excluding meat that has been frozen before (defrosted meat); and,	
(v) in accordance with any condition laid down by the competent authorities for freezing and further use as food. ◀M23	
▼ M9	
6. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat. ◀M9	(略，未包裝肉須與包裝肉分開貯存及運輸，避免污染)

CHAPTER VI: SLAUGHTER ON THE FARM	第VI章：農場屠宰
Food business operators may slaughter poultry referred to in Chapter IV, point 1(b)(i), on the farm only with the authorisation of the competent authority and in compliance with the following requirements.	(略，家禽農場的屠宰要求)
1. The farm must undergo regular veterinary inspection.	(略，農場經定期獸醫檢查)
2. The food business operator must inform the competent authority in advance of the date and time of slaughter.	(略，FBO事先通知主管機關屠宰日期及時間)
3. The holding must have facilities for concentrating the birds to allow an ante- mortem inspection of the group to be made.	(略，具集中禽鳥設施進行屠前檢查)
4. The holding must have premises suitable for the hygienic slaughter and further handling of the birds.	(略，具衛生之屠宰及處理場所)
5. Animal welfare requirements must be complied with.	(略，動物福利)
▼M23	
7. In addition to the food chain information to be submitted in accordance with Section III of Annex II to this Regulation, the official certificate set out in Chapter 3 of Annex IV to Implementing Regulation (EU) 2020/2235 must accompany the slaughtered animal to the slaughterhouse or cutting plant, or be sent in advance in any format. ◀M23	(略，食物鏈資訊及隨附之官方證明)
8. In the case of poultry reared for the production of 'foie gras', the uneviscerated birds must be transported immediately and, if necessary, refrigerated to a slaughterhouse or cutting plant. They must be eviscerated within 24 hours of slaughter under the supervision of the competent authority.	(略，為生產鵝肝醬之家禽運輸要求並應在屠後24hrs內取出內臟)
9. Delayed eviscerated poultry obtained at the farm of production may be kept for up to 15 days at a temperature of not more than 4 °C. It must then be eviscerated in a slaughterhouse or in a cutting plant located in the same Member State as the farm of production.	(略，農場可在4°C以下保存延遲去內臟家禽15天，並應在國內屠宰場或分切廠取出內臟)
▼M1	
CHAPTER VII: WATER RETENTION AGENTS	第VII章：保水劑
Food business operators shall ensure that poultrymeat that has been treated specifically to promote water retention is not placed on the market as fresh meat but as meat preparations or used for the production of processed products. ◀M1	FBOs應確保經特殊保水處理禽肉不投放到溫體肉市場，而是供作肉製品或加工產品生產之使用。
SECTION III: MEAT OF FARMED GAME	第III節：養殖野味的肉
▼M23	
1. The provisions of Section I apply to the production and placing on the market of meat from even-toed farmed game mammals, unless the competent authority considers them inappropriate. ◀M23	(略)
2. The provisions of Section II apply to the production and placing on the market of meat from ratites. However, those of Section I apply where the competent authority considers them appropriate. Appropriate facilities must be provided, adapted to the size of the animals.	
3. Notwithstanding points 1 and 2, food business operators may slaughter farmed ratites and farmed ungulates referred to in point 1 at the place of origin with the authorisation of the competent authority if:	
(a) the animals cannot be transported, to avoid any risk for the handler or to protect the welfare of the animals;	
(b) the herd undergoes regular veterinary inspection;	
(c) the owner of the animals submits a request;	
(d) the competent authority is informed in advance of the date and time of slaughter of the animals;	

(e) the holding has procedures for concentrating the animals to allow an ante-mortem inspection of the group to be made;	
(f) the holding has facilities suitable for the slaughter, bleeding and, where ratites are to be plucked, plucking of the animals;	
(g) animal welfare requirements are complied with;	
(h) slaughtered and bled animals are transported to the slaughterhouse hygienically and without undue delay. If transport takes more than two hours, the animals are, if necessary, refrigerated. Evisceration may take place on the spot, under the supervision of the veterinarian;	
(i) a declaration by the food business operator who reared the animals, stating their identity and indicating any veterinary products or other treatments administered, dates of administration and withdrawal periods, accompanies the slaughtered animals to the slaughterhouse;	
and	
▼ M23	
(j) the official certificate set out in Chapter 3 of Annex IV to Commission Implementing Regulation (EU) 2020/2235, issued and signed by the official veterinarian, attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the date and time of slaughter, accompanies the slaughtered animal to the slaughterhouse or was sent in advance in any format. ◀ M23	
▼ M10	
3a. By way of derogation from point 3(j), the competent authority may authorise that the attestation of the correct slaughter and bleeding and of the date and time of slaughter be included only in the declaration by the food business operator referred to in point 3(i), provided that:	
(a) the holding is situated in a Member State or region, as defined in Article 2(2)(p) of Directive 64/432/EEC which is not under health restrictions in accordance with Union law or national legislation;	
(b) the food business operator has demonstrated the appropriate level of competence to slaughter animals without causing the animals any avoidable pain, distress or suffering in accordance with Article 7(2) of Regulation (EC) No 1099/2009 and without prejudice to Article 12 of that Regulation. ◀ M10	
4. Food business operators may also slaughter bison on the farm in accordance with point 3 in exceptional circumstances.	
SECTION IV: WILD GAME MEAT	第IV節：野生獵物的肉
▼ M23	
For the purpose of this Section, 'collection centre' means an establishment used to store the bodies and viscera of wild game before their transport to a game handling establishment. ◀ M23	(略，本節的「收集中心」是指獵物送至處理廠前的貯存場所)
CHAPTER I: TRAINING OF HUNTERS IN HEALTH AND HYGIENE	第I章：對獵人在健康和衛生的培訓
1. Persons who hunt wild game with a view to placing it on the market for human consumption must have sufficient knowledge of the pathology of wild game, and of the production and handling of wild game and wild game meat after hunting, to undertake an initial examination of wild game on the spot.	(略，獵人應具備對獵物的病理學及野味處理等知識，以在獵捕後進行現場檢查)
2. It is however enough if at least one person of a hunting team has the knowledge referred to in point 1. References in this Section to a 'trained person' are references to that person.	(略，狩獵隊只要至少1人具備前點知識即可)
3. The trained person could also be the gamekeeper or the game manager if he or she is part of the hunting team or located in the immediate vicinity of where hunting is taking place. In the latter case, the hunter must present the wild game to the gamekeeper or game manager and inform them of any abnormal behaviour observed before killing.	(略，未受訓獵人應將獵物呈現給已受訓者並報告觀察到獵物被獵殺前的任何異常行為)
4. Training must be provided to the satisfaction of the competent authority to enable hunters to become trained persons. It should cover at least the following subjects:	(略，培訓涵蓋主題要求)

(a) the normal anatomy, physiology and behaviour of wild game;	(略，解剖學、生理學、行為學)
(b) abnormal behaviour and pathological changes in wild game due to diseases, environmental contamination or other factors which may affect human health after consumption;	(略，因疾病等造成的異常行為及病理變化)
(c) the hygiene rules and proper techniques for the handling, transportation, evisceration, etc. of wild game animals after killing;	(略，衛生規定及處理獵物技術)
and	
(d) legislation and administrative provisions on the animal and public health and hygiene conditions governing the placing on the market of wild game.	(略，相關法律及行政規定)
5. The competent authority should encourage hunters' organisations to provide such training.	(略，鼓勵獵人組織辦理培訓課程)
CHAPTER II: HANDLING OF LARGE WILD GAME	第二章：大型野生獵物的處理
1. After killing, large wild game must have their stomachs and intestines removed as soon as possible and, if necessary, be bled.	(略，盡快移除消化器官及放血)
2. The trained person must carry out an examination of the body, and of any viscera removed, to identify any characteristics that may indicate that the meat presents a health risk. The examination must take place as soon as possible after killing.	(略，獵殺後盡快完成相關檢查)
3. Meat of large wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 2. The viscera must accompany the body as specified in point 4. The viscera must be identifiable as belonging to a given animal.	(略，完成前點檢查獵物盡快運到野味處理廠，內臟要隨附胴體並可被識別)
▼ M10	
4. (a) If no abnormal characteristics are found during the examination referred to in point 2, no abnormal behaviour was observed before killing, and there is no suspicion of environmental contamination, the trained person must attach to the animal body a numbered declaration stating this. This declaration must also indicate the date, time and place of killing.	(略，受訓獵人要對檢查過的正常獵物簽發帶編號的聲明，包括獵殺日期、時間和地點)
The declaration need not be attached to the animal body and may cover more than one animal body, provided that each animal body is appropriately identified and the declaration bears an indication of the identification number of each animal body covered by it, with the corresponding date, time and place of killing. All animal bodies covered by a single declaration may only be sent to a single game-handling establishment.	(略，上述聲明可涵蓋多隻獵物，但要能清楚逐一識別，且只能送至同一個野味處理廠)
The head and the viscera need not accompany the body to the game-handling establishment, except in the case of species susceptible to trichinosis (porcine animals, solipeds and others), whose heads (except for tusks) and diaphragm must accompany the body.	(略，除易感旋毛蟲的豬/奇蹄物種之頭-象牙除外及橫膈膜外，餘物種的頭及內臟無須附隨至處理廠)
However, the competent authority may authorise that heads of animals susceptible to <i>Trichinella</i> infestation be sent to a technical plant for the production of game trophies, which has been approved in accordance with Article 18 of Regulation (EC) No 1774/2002. The technical plant shall be indicated in the declaration of the trained person. A copy of that declaration shall be sent to the technical plant. Where the results of the <i>Trichinella</i> examination of the carcase are positive, the competent authority shall carry out an official check to verify the proper handling of the head in the technical plant.	(略，易感旋毛蟲物種的頭可被授權送到技術工廠製作為戰利品之規定)
However, hunters must comply with any additional requirements imposed in the Member State where hunting takes place, in particular to permit the monitoring of certain residues and substances in accordance with Directive 96/23/EC. ◀M10	(略，獵人應遵守狩獵地所在國的額外要求)
(b) In other circumstances, the head (except for tusks, antlers and horns) and all the viscera except for the stomach and intestines must accompany the body. The trained person who carried out the examination must inform the competent authority of the abnormal characteristics, abnormal behaviour or suspicion of environmental contamination that prevented him or her from making a declaration in accordance with (a);	(略，不包括象牙、鹿角和犀牛角之頭和不包括胃腸的內臟應附隨胴體及相關規定)
▼ M23	
(c) If no trained person is available to carry out the examination referred to in point 2 in a particular case, the head, except for tusks, antlers and horns, and all the	(略，若無受訓獵人對獵物檢查之

viscera, except for the stomach and the intestines, must accompany the body which must be transported to a game handling- establishment as soon as possible after killing. ◀ M23	特殊情形下，要盡快將獵物送到處理廠)
5. Chilling must begin within a reasonable period of time after killing and achieve a temperature throughout the meat of not more than 7°C. Where climatic conditions so permit, active chilling is not necessary.	(略，在獵殺後合理時間內，要將肉溫降至7°C以下)
6. During transport to the game-handling establishment, heaping must be avoided.	(略，運送過程避免堆疊)
7. Large wild game delivered to a game-handling establishment must be presented to the competent authority for inspection.	(略，報請主管機關查驗)
▼ M16	
8. In addition, unskinned large wild game:	(略，去皮野味之要求)
(a) may be skinned and placed on the market only if:	
(i) before skinning, it is stored and handled separately from other food and it is not frozen;	(略，去皮前與其他食物有所區隔且不冷凍)
(ii) after skinning, it undergoes a final inspection in a game-handling establishment in accordance with Regulation (EC) No 854/2004; ◀ M16	(略，去皮後在處理廠進行最終檢查)
▼ M23	
(b) may be sent to a game handling establishment in another Member State only if, during transport to that game-handling establishment, it is accompanied by an official certificate set out in Chapter 2 of Annex II to Implementing Regulation (EU) 2020/2235 issued and signed by an official veterinarian, attesting that the requirements set out in point 4 of this Chapter as regards the availability of a declaration, when relevant, and the accompaniment of relevant parts of the body, have been complied with. ◀ M23	(略，運送至跨國處理廠的隨附官方證明書要求)
▼ M16	
In case the game handling establishment, close to the hunting area, is in another Member State, transport to this game handling establishment need not be accompanied by the certificate but by the declaration of the trained person referred to in point 2 to comply with Article 3(1) of Directive 89/662/EEC, taking into account the animal health status of the Member State of origin. ◀ M16	(略，狩獵場緊鄰跨國處理廠，有受訓獵人的聲明即可)
9. The rules laid down in Section I, Chapter V, apply to the cutting and boning of large wild game.	(略)
▼ M23	
10. The bodies and viscera of large wild game may be transported to and stored in a collection centre before being sent to a game handling establishment provided that:	(略，先運至收集中心存放之要求規定)
(a) the collection centre is either:	
(1) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) when only receiving bodies as first collection centre, or	
(2) approved by the competent authority as a food business in accordance with Article 4(2) when receiving bodies from other collection centres;	
(b) if the animals are eviscerated, their heaping is prohibited during transport to and storage in the collection centre;	
(c) killed animals are transported to the collection centre hygienically and without delay;	
(d) the temperature conditions laid down in point 5 are complied with;	
(e) storage time is kept to the minimum possible;	
(f) no other handling takes place on the bodies and viscera of the large wild game; however the examination by a trained person and the removal of viscera may take place under the conditions laid down in points 2, 3 and 4. ◀ M23	
CHAPTER III: HANDLING OF SMALL WILD GAME	第三章：小型野生獵物的處理
1. The trained person must carry out an examination to identify any characteristics that may indicate that the meat presents a health risk. The examination must take place as soon as possible after killing.	(略)
2. If abnormal characteristics are found during the examination, abnormal behaviour was observed before killing, or environmental contamination is suspected, the	(略)

trained person must inform the competent authority.	
▼M23	
3. Meat of small wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 1 or, if no trained person is available to carry out that examination in a particular case, as soon as possible after killing. ◀M23	(略)
4. Chilling must begin within a reasonable period of time of killing and achieve a temperature throughout the meat of not more than 4°C. Where climatic conditions so permit, active chilling is not necessary.	(略，在獵殺後合理時間內，要將肉溫降至4°C以下)
5. Evisceration must be carried out, or completed, without undue delay upon arrival at the game -handling establishment, unless the competent authority permits otherwise.	(略)
6. Small wild game delivered to a game-handling establishment must be presented to the competent authority for inspection.	(略)
7. The rules laid down in Section II, Chapter V, apply to the cutting and boning of small wild game.	(略)
▼M23	
8. The bodies, including viscera, of small wild game may be transported to and stored in a collection centre before being sent to a game handling establishment provided that:	(略)
(a) the collection centre is either:	
(1) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) when only receiving bodies as first collection centre, or	
(2) approved by the competent authority as a food business in accordance with Article 4(2) when receiving bodies from other collection centres;	
(b) if the animals are eviscerated, their heaping is prohibited during transport to and storage in the collection centre;	
(c) killed animals are transported to the collection centre hygienically and without delay;	
(d) the temperature conditions laid down in point 4 are complied with;	
(e) storage time is kept to the minimum possible;	
(f) no other handling takes place on the bodies, including viscera, of the small wild game; however the examination by a trained person and the removal of viscera may take place under the conditions laid down in points 1 and 2. ◀M23	
SECTION V: MINCED MEAT, MEAT PREPARATIONS AND MECHANICALLY SEPARATED MEAT (MSM)	第V節：絞肉、肉製品和機械分離肉(MSM)
CHAPTER I: REQUIREMENTS FOR PRODUCTION ESTABLISHMENTS	第I章：生產廠場的要求
Food business operators operating establishments producing minced meat, meat preparations or MSM must ensure that they:	(略)
1. are constructed so as to avoid contamination of meat and products, in particular by:	(略，生產結構不會污染肉品)
(a) allowing constant progress of the operations;	
or	
(b) ensuring separation between the different production batches;	
2. have rooms for the separate storage of packaged and exposed meat and products, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat or products;	(略，存放空間不會造成交叉污染的要求)
3. have rooms equipped to ensure compliance with the temperature requirements laid down in Chapter III;	(略，配有溫控設備的廠房)
4. have equipment for washing hands used by staff handling exposed meat and products with taps designed to prevent the spread of contamination;	(略，洗手設施要求)
and	

5. have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.	(略，用82°C以上熱水消毒設施)
CHAPTER II: REQUIREMENTS FOR RAW MATERIAL	第二章：原料的要求
Food business operators producing minced meat, meat preparations or MSM must ensure that the raw materials used satisfy the following requirements.	(略)
1. The raw material used to prepare minced meat must meet the following requirements.	(略，絞肉原料的要求)
(a) It must comply with the requirements for fresh meat;	(略，符合鮮肉要求)
(b) It must derive from skeletal muscle, including adherent fatty tissues;	(略，骨骼肌含附著的脂肪組織)
(c) It must not derive from:	(略，不可以是以下來源：)
(i) scrap cuttings and scrap trimmings (other than whole muscle cuttings);	(略，切下的和修整下的肉碎)
(ii) MSM;	(略)
(iii) meat containing bone fragments or skin;	(略，帶碎骨或皮的肉)
or	
(iv) meat of the head with the exception of the masseters, the non-muscular part of the <i>linea alba</i> , the region of the carpus and the tarsus, bone scrapings and the muscles of the diaphragm (unless the serosa has been removed).	(略，除了特定部位的頭部的肉)
2. The following raw material may be used to prepare meat preparations:	(略，肉製品原料的要求)
(a) fresh meat;	(略，符合鮮肉要求)
(b) meat meeting the requirements of point 1;	(略，符合前點要求的肉)
and	
(c) if the meat preparation is clearly not intended to be consumed without first undergoing heat treatment:	(略，不供作未經熱處理食用的要求)
(i) meat derived from the mincing or fragmentation of meat meeting the requirements of point 1 other than point 1(c)(i);	
and	
(ii) MSM meeting the requirements of Chapter III, point 3(d).	
3. The raw material used to produce MSM must meet the following requirements.	(略，MSM原料的要求)
(a) It must comply with the requirements for fresh meat;	
(b) The following material must not be used to produce MSM:	
(i) for poultry, the feet, neckskin and head;	
and	
(ii) for other animals, the bones of the head, feet, tails, femur, tibia, fibula, humerus, radius and ulna.	
CHAPTER III: HYGIENE DURING AND AFTER PRODUCTION	第三章：製造期間和之後的衛生
Food business operators producing minced meat, meat preparations or MSM must ensure compliance with the following requirements.	(略)
1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that the meat used is:	(略)
(a) at a temperature of not more than 4°C for poultry, 3°C for offal and 7°C for other meat;	(略，禽4°C、內臟3°C、其他肉7°C以下)

and	
(b) brought into the preparation room progressively as needed.	
2. The following requirements apply to the production of minced meat and meat preparations.	(略，絞肉和肉製品生產要求)
(a) Unless the competent authority authorises boning immediately before mincing, frozen or deep-frozen meat used for the preparation of minced meat or meat preparations must be boned before freezing. It may be stored only for a limited period.	(略，在冷凍前去骨且只能貯存一定期間)
(b) When prepared from chilled meat, minced meat must be prepared:	(略)
(i) in the case of poultry, within no more than three days of their slaughter;	(略，禽肉宰後3天內)
(ii) in the case of animal other than poultry, within no more than six days of their slaughter;	(略，禽以外動物的肉宰後6天內)
or	
(iii) within no more than 15 days from the slaughter of the animals in the case of boned, vacuum-packed beef and veal.	(略，牛和小牛肉宰後15天內)
(c) Immediately after production, minced meat and meat preparations must be wrapped or packaged and be:	(略，生產後要立即包裝並降溫)
(i) chilled to an internal temperature of not more than 2°C for minced meat and 4°C for meat preparations;	(略，冷藏至內部溫度絞肉2°C和肉製品4°C以下)
or	
(ii) frozen to an internal temperature of not more than -18 °C.	(略，冷凍至內部溫度-18°C以下)
These temperature conditions must be maintained during storage and transport.	(略，儲存和運輸溫度要求同上)
3. The following requirements apply to the production and use of MSM produced using techniques that do not alter the structure of the bones used in the production of MSM and the calcium content of which is not significantly higher than that of minced meat.	(略，不帶骨的MSM生產要求)
(a) Raw material for deboning from an on-site slaughterhouse must be no more than seven days old; otherwise, raw material for deboning must be no more than five days old. However, poultry carcasses must be no more than three days old.	
(b) Mechanical separation must take place immediately after deboning.	
(c) If not used immediately after being obtained, MSM must be wrapped or packaged and then chilled to a temperature of not more than 2 °C or frozen to an internal temperature of not more than -18 °C. These temperature requirements must be maintained during storage and transport.	
(d) If the food business operator has carried out analyses demonstrating that MSM complies with the microbiological criteria for minced meat adopted in accordance with Regulation (EC) No 852/2004 it may be used in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment and in meat products.	
(e) MSM not shown to comply with the criteria referred to in (d) may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.	
4. The following requirements apply to the production and use of MSM produced using techniques other than those mentioned in point 3.	(略，前點以外的MSM生產要求)
(a) Raw material for deboning from an on-site slaughterhouse must be no more than seven days old; otherwise, raw material for deboning must be no more than five days old. However, poultry carcasses must be no more than three days old.	
(b) If mechanical separation does not take place immediately after deboning the flesh-bearing bones must be stored and transported at a temperature of not more than 2 °C or, if frozen, at a temperature of not more than -18 °C.	
(c) Flesh-bearing bones obtained from frozen carcasses must not be refrozen.	
(d) If not used within one hour of being obtained, MSM must be chilled immediately to a temperature of not more than 2 °C.	

(e) If, after chilling, MSM is not processed within 24 hours, it must be frozen within 12 hours of production and reach an internal temperature of not more than –18 °C within six hours.	
(f) Frozen MSM must be wrapped or packaged before storage or transport, must not be stored for more than three months and must be maintained at a temperature of not more than –18 °C during storage and transport.	
(g) MSM may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.	
5. Minced meat, meat preparations and MSM must not be re-frozen after thawing.	(略，解凍後不可再冷凍)
CHAPTER IV: LABELLING	第四章：標示
1. In addition to the requirements of Directive 2000/13/EC ³⁸ , food business operators must ensure compliance with the requirement of point 2 if, and to the extent that, national rules in the Member State in the territory of which the product is placed on the market so require.	(略)
2. Packages intended for supply to the final consumer containing minced meat from poultry or solipeds or meat preparations containing MSM must bear a notice indicating that such products should be cooked before consumption.	(略，供最終消費者食用的絞肉或含MSM肉製品，要標明食用前煮熟)
SECTION VI: MEAT PRODUCTS	第六節：肉類產品
1. Food business operators must ensure that the following items are not used in the preparation of meat products:	(略，不得用作肉類產品的部分)
(a) genital organs of either female or male animals, except testicles;	(略，除睪丸外的生殖器官)
(b) urinary organs, except the kidneys and the bladder;	(略，除腎和膀胱外的泌尿器官)
(c) the cartilage of the larynx, the trachea and the extra-lobular bronchi;	(略，喉軟骨、氣管和支氣管)
(d) eyes and eyelids;	(略，眼和眼瞼)
(e) the external auditory meatus;	(略，外耳道)
(f) horn tissue;	(略，角組織)
and	
(g) in poultry, the head — except the comb and the ears, the wattles and caruncles — the oesophagus, the crop, the intestines and the genital organs.	(略，禽類除冠及肉垂等的頭、食道、嗉囊、腸和生殖器官)
2. All meat, including minced meat and meat preparations, used to produce meat product must meet the requirements for fresh meat. However, minced meat and meat preparations used to produce meat products need not satisfy other specific requirements of Section V.	(略，要符合鮮肉要求，但無須滿足第V節特定要求)
SECTION VII: LIVE BIVALVE MOLLUSCS	第七節：活雙枚貝類
▼ M19	
1. This Section applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, live tunicates and live marine gastropods. The provisions on the classification of production areas set out in Chapter II, Part A, of that Section do not apply to marine gastropods and to echinoderms which are not filter feeders. ◀M19(按：生產區域應根據糞便污染程度進行分類，濾食性動物，例如雙殼貝類，會積聚對公眾健康構成風險的微生物；海洋腹足類和棘皮動物通常不是濾食動物，與糞便污染相關的微生物積聚的風險被認為是微乎其微的，且沒有流行病學報告產區分類規定與公共衛生風險相關，故將之排除於生產區分類規定之外。)	本節適用於活雙枚貝類(LBM)。除淨化條款外，亦適用於活的棘皮、被囊類及海洋腹足類動物。在第II章A部分中關於生產區域分類的規定，不適用於海洋腹足類和非濾食性之棘皮動物。
▼ M23	
1a. For the purpose of this Section, 'intermediary operator' means a food business operator, including traders, other than the first supplier, with or without premises, who carries out its activities between production areas, relaying areas or any	就本節而言，「中介商」是指除第1供應者外之FBO，包括貿易商，不

38 Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

establishments. ◀ M23	論有無場所，其活動於生產區、中繼區或任何廠場間。
2. Chapters I to VIII apply to animals harvested from production areas that the competent authority has classified in accordance with Regulation (EC) No 854/2004. Chapter IX applies to pectinidae harvested outside those areas.	第 I 至 VIII 章適用於依 854/2004 規章分類的生產區所採集的動物。第 IX 章適用於那些區域外採集的扇貝
3. Chapters V, VI, VIII and IX, and point 3 of Chapter VII, apply to retail.	第 V、VI、VIII 和 IX 章，及第七章第 3 點適用於零售。
4. The requirements of this Section supplement those laid down in Regulation (EC) No 852/2004:	本節對 852/2004 規章要求進行下列補充：
(a) In the case of operations that take place before live bivalve molluscs arrive at a dispatch or purification centre, they supplement the requirements of Annex I to that Regulation.	補充其附錄 I 對 LBM 抵達集散或淨化中心前的作業要求。
(b) In the case of other operations, they supplement the requirements of Annex II to that Regulation.	補充其附錄 II 的其他作業要求。
CHAPTER I: GENERAL REQUIREMENTS FOR THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS	第 I 章：LBM 上市之一般要求
1. Live bivalve molluscs may not be placed on the market for retail sale otherwise than via a dispatch centre, where an identification mark must be applied in accordance with Chapter VII.	LBM 不可上市零售，除非已於集散中心依第七章規定進行識別標記。
2. Food business operators may accept batches of live bivalve molluscs only if the documentary requirements set out in points 3 to 7 have been complied with.	FBOs 只有在符合第 3~7 點文件要求下，可分批接收 LBM。
▼ M23	
3. Whenever a food business operator moves a batch of live bivalve molluscs between production areas, relaying areas or any establishments, a registration document must accompany the batch. ◀ M23	當 FBO 於產區、中繼區或任何廠場間移動 LBM 時，應隨批附有登記文件。
4. The registration document must be in at least one official language of the Member State in which the receiving establishment is located and contain at least the information specified below.	登記文件應至少是接收廠場所在會員國之 1 種官方語言並至少包含下列資訊。
(a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:	自產區運出之 LBM，登記文件應包括：
(i) the gatherer's identity and address;	集貨者身分和地址；
(ii) the date of harvesting;	採集日期；
(iii) the location of the production area described in as precise detail as is practicable or by a code number;	盡可能詳細描述產區位置或代碼；
(iv) the health status of the production area;	產區衛生狀況；
(v) the shellfish species and quantity;	貝類種類及數量；
and	
(vi) the destination of the batch.	該批的目的地。
(b) In the case of a batch of live bivalve molluscs sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:	自中繼區運出之 LBM，登記文件除 (a) 點外還應包括：
(i) the location of the relaying area;	中繼區位置；
and	
(ii) the duration of relaying.	中繼期間。
(c) In the case of a batch of live bivalve molluscs sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:	自淨化中心運出之 LBM，登記文件除 (a) 點外還應包括：

(i) the address of the purification centre;	淨化中心地址；
(ii) the duration of purification;	淨化期間；
and	
(iii) the dates on which the batch entered and left the purification centre.	該批進出淨化中心的日期。
▼ M23	
(d) Where a batch of live bivalve molluscs is sent by an intermediary operator, a new registration document, filled-in by the intermediary operator, must accompany the batch. The registration document must contain at least the information referred to in points (a), (b) and (c) and the following information:	當由中介商運送LBM時，他須隨批附上1張新填寫的登記文件。此登記文件除(a)、(b)和(c)點外還應包括：
(i) the name and address of the intermediary operator;	中介商姓名和地址；
(ii) in the case of conditioning or in the case of re-immersion for storing purpose, the date of starting, the date of end and the place of the conditioning or the re-immersion;	因儲存目的而調節或再浸置時，起始和結束日期及地點；
(iii) if a conditioning in a natural site was carried out, the intermediary operator must confirm that the natural site where the conditioning took place was classified at the time of conditioning as an class A production area open for harvest;	若在天然場址進行調節，中介商應確認該址在該時間被歸類為開放採集的A級產區；
(iv) if a re-immersion in natural site was carried out, the intermediary operator must confirm that the natural site where the re-immersion took place was classified at the time of re-immersion with the same classification of the production area where the live bivalve molluscs were harvested.	若在天然場址進行再浸置，中介商應確認該址在該時間與LBM被採集產區為同等級。
(v) if a re-immersion was carried out in an establishment, the intermediary operator must confirm that the establishment was approved at the time of the re-immersion. The re-immersion shall not cause additional contamination to the live bivalve molluscs.	若在工廠進行再浸置，中介商應確認該廠在該時被核准。再浸置作業不應對LBM造成其他污染。
(vi) in the case of grouping, the species, the date when the grouping started, the date of the end of the grouping, the status of the area where the live bivalve molluscs were harvested, and the batch of the grouping, that always consists of the same species, captured on the same date, and in the same production area. ◀M23	若有分群情形，永遠依同種、同日採集及同產區進行物種、分群始末日期、產區狀態和分群批次進行。
5. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date-stamp the document on receipt of the batch or record the date of receipt in another manner.	運送的FBOs必須以易讀且不可塗改方式完成登記文件相關節次。接收的FBOs必須在接收批次的文件上蓋印接收日期或以其他方式記錄之。
6. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the competent authority may specify).	FBOs必須保存每批登記文件影本，自發送或接收日期起至少12個月(或依CA指定之更長期間)。
7. However, if:	但若是：
(a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs;	採集LBM的員工，同時也在集散中心、淨化中心、中繼區或接收加工廠作業；
and	和
(b) a single competent authority supervises all the establishments concerned,	單一CA監管所有相關廠場，
registration documents are not necessary if that competent authority so permits.	若CA允許，登記文件是非必要的。
▼ M23	
8. Intermediary operators must be:	中介商必須是：
(a) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) if they do not have premises or if they have premises where they only handle, wash and store at ambient temperature live bivalve molluscs, without grouping nor conditioning, or	若自己無場所或沒有分群也沒調節只有在室溫下處理、清洗和儲存LBM的場所，經CA登記為第4(2)(a)條所指的初級生產業者，或
(b) approved by the competent authority as a food business operator in accordance with Article 4(2) if, in addition to carrying out the activities referred to in point (a), they have a cold store or they group or split batches of live bivalve molluscs or they carry out conditioning or reimmersion.	除(a)所述活動外，若其擁有冷庫或會對LMB分群或分批或進行調節或再浸置，經CA依第4(2)條核准為

	FBO。
<p>9. Intermediary operators may receive live bivalve molluscs from production areas classified as A, B or C, from relaying areas or from other intermediary operators. Intermediary operators can send live bivalve molluscs:</p> <p>(a) from class A production areas to dispatch centres or another intermediary operator;</p> <p>(b) from class B production areas only to purification centres, processing establishments or to another intermediary operator;</p> <p>(c) from class C production areas to processing establishments or to another intermediary operator with premises. ◀M23</p>	<p>中介商得自A、B或C級產區、自中繼區或自其他中介商處接收LBM。中介商能運送LBM：</p> <p>自A級產區至集散中心或其他中介商；</p> <p>自B級產區只能至淨化中心、加工廠或其他中介商；</p> <p>自C級產區至加工廠或備有場所的中介商。</p>
CHAPTER II: HYGIENE REQUIREMENTS FOR THE PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS	第II章：LBM的生產及採集的衛生要求
A. REQUIREMENTS FOR PRODUCTION AREAS	A. 對生產區的要求
1. Gatherers may only harvest live bivalve molluscs from production areas with fixed locations and boundaries that the competent authority has classified — where appropriate, in cooperation with food business operators — as being of class A, B or C in accordance with Regulation (EC) No 854/2004.	採集者只能自固定位址和範圍的產區採收LBM，該等產區經CA依據854/2004規章分為A、B或C級，適當時，與FBOs合作。
2. Food business operators may place live bivalve molluscs collected from class A production areas on the market for direct human consumption only if they meet the requirements of Chapter V.	FBOs收集自A級產區的LBM，只有在符合第V章要求時才能上市直接供人食用。
3. Food business operators may place live bivalve molluscs collected from class B production areas on the market for human consumption only after treatment in a purification centre or after relaying.	FBOs收集自B級產區的LBM，只有在淨化中心處理後或中繼後才能上市供人食用。
4. Food business operators may place live bivalve molluscs collected from class C production areas on the market for human consumption only after relaying over a long period in accordance with Part C of this Chapter.	FBOs收集自C級產區的LBM，只有在依據本章C節經過長期間中繼後才能上市供人食用。
5. After purification or relaying, live bivalve molluscs from class B or C production areas must meet all of the requirements of Chapter V. However, live bivalve molluscs from such areas that have not been submitted for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic micro-organisms (where appropriate, after removal of sand, mud or slime in the same or another establishment). The permitted treatment methods are:	在淨化或中繼後，源自B或C級產區的LBM必須符合第V章所有要求規定。但是，此等未經淨化或中繼的LBM可以被送至加工廠，在工廠應經過去除病原性微生物消除處理（適當時，在同廠或另一廠先移除砂、土或黏液後）。許可的處理方法是：
(a) sterilisation in hermetically sealed containers;	在密封容器中滅菌；
and	和
(b) heat treatments involving:	下述的熱處理：
(i) immersion in boiling water for the period required to raise the internal temperature of the mollusc flesh to not less than 90 °C and maintenance of this minimum temperature for a period of not less than 90 seconds;	浸置熱水中至貝肉內部溫度達至少90 °C並維持此溫度至少90秒；
(ii) cooking for three to five minutes in an enclosed space where the temperature is between 120 and 160 °C and the pressure is between 2 and 5 kg/cm ² , followed by shelling and freezing of the flesh to a core temperature of – 20 °C;	在溫度為120~160 °C及壓力為2~5 kg/cm ² 的封閉空間內煮3~5分鐘，接續去殼並冷凍貝類至中心溫度–20 °C；
and	和
(iii) steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the	在滿足(i)所提及關於貝肉烹煮時

<p>mollusc flesh mentioned under (i). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.</p>	<p>間和內部溫度要求的封閉空間內加壓蒸煮。必須使用經驗證的方法。必須有基於HACCP原則的程序來驗證熱分布的一致性。</p>
<p>6. Food business operators must not produce live bivalve molluscs in, or harvest them from, areas that the competent authority has not classified, or which are unsuitable for health reasons. Food business operators must take account of any relevant information concerning areas' suitability for production and harvesting, including information obtained from own-checks and the competent authority. They must use this information, particularly information on environmental and weather conditions, to determine the appropriate treatment to apply to harvested batches.</p>	<p>FBOs不可自CA未分類或因衛生原因不適合的區域生產或採收LBM。FBOs必須考慮任何關於地區適合生產及採集的相關資訊，包括來自自我檢查及CA的資訊。他們應使用這資訊，特別是環境和氣候方面，來決定適用於採集批次的適當處理。</p>
<p>B. REQUIREMENTS FOR HARVESTING AND HANDLING FOLLOWING HARVESTING</p>	<p>B. 採集和採集後處理的要求</p>
<p>Food business operators harvesting live bivalve molluscs, or handling them immediately after harvesting, must ensure compliance with the following requirements.</p>	<p>採集或採集後即刻處理LBM之FBOs，須確認符合下列要求。</p>
<p>1. Harvesting techniques and further handling must not cause additional contamination or excessive damage to the shells or tissues of the live bivalve molluscs or result in changes significantly affecting their suitability for treatment by purification, processing or relaying. Food business operators must in particular:</p>	<p>採集技術和接續處理不可對LBM的殼或組織造成其他污染或過度損傷，或導致顯著影響其對純化、加工或中繼處理適用性的改變。FBOs特別須：</p>
<p>(a) adequately protect live bivalve molluscs from crushing, abrasion or vibration;</p>	<p>充分保護LBM免受壓碎、磨損或振動；</p>
<p>(b) not expose live bivalve molluscs to extreme temperatures;</p>	<p>不曝露LBM於極端溫度；</p>
<p>(c) not re-immerses live bivalve molluscs in water that could cause additional contamination;</p>	<p>不再浸置LBM於可能造成其他污染的水中；</p>
<p>and</p>	<p>及</p>
<p>(d) if carrying out conditioning in natural sites, use only areas that the competent authority has classified as being of class A.</p>	<p>若在天然場址進行調節，僅使用CA劃分為A級之場域。</p>
<p>2. Means of transport must permit adequate drainage, be equipped to ensure the best survival conditions possible and provide efficient protection against contamination.</p>	<p>運輸工具須允許可完全排水，裝置備有確保可能的最佳存活條件及提供有效防止污染之保護。</p>
<p>C. REQUIREMENTS FOR RELAYING LIVE BIVALVE MOLLUSCS</p>	<p>C. 對LBM的中繼要求</p>
<p>Food business operators relaying live bivalve molluscs must ensure compliance with the following requirements.</p>	<p>中繼LBM的FBOs須確認符合下列要求。</p>
<p>1. Food business operators may use only those areas that the competent authority has approved for relaying live bivalve molluscs. Buoys, poles or other fixed means must clearly identify the boundaries of the sites. There must be a minimum distance between relaying areas, and also between relaying areas and production areas, so as to minimise any risk of the spread of contamination.</p>	<p>FBOs只能使用CA核准用作LBM中繼的那些區域。浮標、柱桿或其他固定方式必須清楚界定場址的邊界。在中繼區之間以及中繼區與生產區之間須有最小距離，以最小化任何污染擴散的風險。</p>
<p>2. Conditions for relaying must ensure optimal conditions for purification. In particular, food business operators must:</p>	<p>中繼的調節須確認淨化的最適條件。特別是，FBOs須：</p>
<p>(a) use techniques for handling live bivalve molluscs intended for relaying that permit the resumption of filter-feeding activity after immersion in natural waters;</p>	<p>使用欲中繼LBM的處理技術，以使其在浸置於天然水域後恢復濾食活動；</p>

(b) not relay live bivalve molluscs at a density that prevents purification;	不在有礙淨化的密度下中繼LBM；
(c) immerse live bivalve molluscs in seawater at the relaying area for an appropriate period, fixed depending on the water temperature, which period must be of at least two months' duration unless the competent authority agrees to a shorter period on the basis of the food business operator's risk analysis;	在中繼區海水中浸置LBM一段至少2個月的適當期間並視海水溫度調整，除非基於FBO的危害分析，CA同意較短的期間。
and	及
(d) ensure sufficient separation of sites within a relaying area to prevent mixing of batches; the 'all in, all out' system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed.	確認在中繼區內有足夠的獨立位址可以避免批次間的混合；須使用「全進全出」系統，在前一批完全移出前，不可有新的一批進入。
3. Food business operators managing relaying areas must keep permanent records of the source of live bivalve molluscs, relaying periods, relaying areas used and the subsequent destination of the batch after relaying, for inspection by the competent authority.	管理中繼區的FBOs須永久保存關於LBM來源、中繼期間、使用中繼區域及中繼後批次流向的紀錄，以供CA的檢查。
CHAPTER III: STRUCTURAL REQUIREMENTS FOR DISPATCH AND PURIFICATION CENTRES	第三章：集散和淨化中心的結構要求
1. The location of premises on land must not be subject to flooding by ordinary high tides or run-off from surrounding areas.	陸上設施位置須不受日常漲潮或周遭地區徑流淹沒。
2. Tanks and water storage containers must meet the following requirements:	槽箱及儲水容器須符合下列要求：
(a) Internal surfaces must be smooth, durable, impermeable and easy to clean.	內表面須光滑、耐用、防水且易清潔。
(b) They must be constructed so as to allow complete draining of water.	其構造須能夠完全排水。
(c) Any water intake must be situated in a position that avoids contamination of the water supply.	任何進水口須設於避免污染水供應之位置。
3. In addition, in purification centres, purification tanks must be suitable for the volume and type of products to be purified.	此外，在淨化中心，淨化槽須適合待淨化產品之體積和類型。
CHAPTER IV: HYGIENE REQUIREMENTS FOR PURIFICATION AND DISPATCH CENTRES	第四章：淨化和集散中心的衛生要求
A. REQUIREMENTS FOR PURIFICATION CENTRES	對淨化中心的要求
Food business operators purifying live bivalve molluscs must ensure compliance with the following requirements.	淨化LBM的FBOs須確認符合下列要求。
▼ M23 (按：為節約用水，沒必要強制性清洗乾淨的LBM，所以修正第1點。)	
1. Before purification commences, live bivalve molluscs must be free of mud and accumulated debris and washed if necessary , using clean water. ◀ M23	在淨化開始前，LBM須無泥和積碎屑，必要時以清水清洗。
2. Operation of the purification system must allow live bivalve molluscs rapidly to resume and to maintain filter-feeding activity, to eliminate sewage contamination, not to become re-contaminated and to be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.	淨化系統的操作須允許LBM快速地恢復及維持濾食活動、滌除廢水污染、不可受再次污染和能在淨化後保持良好存活狀態，以供上市前包裝、儲存及運輸。
3. The quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre. The live bivalve molluscs must be continuously purified for a period sufficient to achieve compliance with allow the health standards of Chapter V and microbiological criteria adopted in accordance with Regulation (EC) No 852/2004.	待淨化LBM的數量須不超過淨化中心容量。LBM須被持續淨化一段足夠期間，以達到符合第V章的衛生標準及依第852/2004號規章採行的微生物基準。

<p>4. Should a purification tank contain several batches of live bivalve molluscs, they must be of the same species and the length of the treatment must be based on the time required by the batch needing the longest period of purification.</p>	<p>一淨化槽若含有數批LBM，其須屬於同種及處理時間須是需淨化最長的那批時間。</p>
<p>5. Containers used to hold live bivalve molluscs in purification systems must have a construction that allows clean seawater to flow through. The depth of layers of live bivalve molluscs must not impede the opening of shells during purification.</p>	<p>用於淨化系統中盛裝LBM的容器須具允許清潔海水貫流的結構。每層LBM的深度須不妨礙淨化期間殼的開闔。</p>
<p>6. No crustaceans, fish or other marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.</p>	<p>不可在LBM正淨化之淨化槽中放養甲殼類、魚類或其他海洋物種。</p>
<p>7. Every package containing purified live bivalve molluscs sent to a dispatch centre must be provided with a label certifying that all molluscs have been purified.</p>	<p>送去集散中心之每個含已淨化LBM的包裝，須提供1個標籤來證明所有貝類已完成淨化。</p>
<p>B. REQUIREMENTS FOR DISPATCH CENTRES</p>	<p>對集散中心的要求</p>
<p>Food business operators operating dispatch centres must ensure compliance with the following requirements.</p>	<p>經營集散中心的FBOs須確認符合下列要求。</p>
<p>1. Handling of live bivalve molluscs, particularly conditioning, calibration, wrapping and packing, must not cause contamination of the product or affect the viability of the molluscs.</p>	<p>LBM的處理，特別是調節、校準、內包和包裝，須不可造成產品污染或影響貝類活力。</p>
<p>2. Before dispatch, the shells of live bivalve molluscs must be washed thoroughly with clean water.</p>	<p>在發貨前，LBM的殼須以清水徹底清洗過。</p>
<p>3. Live bivalve molluscs must come from:</p>	<p>LBM須來自：</p>
<p>(a) a class A production area;</p>	<p>A級生產區；</p>
<p>(b) a relaying area;</p>	<p>中繼區；</p>
<p>(c) a purification centre;</p>	<p>淨化中心；</p>
<p>or</p>	<p>或</p>
<p>(d) another dispatch centre.</p>	<p>其他集散中心。</p>
<p>4. The requirements laid down in points 1 and 2 also apply to dispatch centres situated on board vessels. Molluscs handled in such centres must come from a class A production area or a relaying area.</p>	<p>第1點和第2點的要求亦適用位於船上的集散中心。在此類中心處理的貝類須來自A級產區或中繼區。</p>
<p>CHAPTER V: HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS</p>	<p>第V章：LBM的衛生標準</p>
<p>In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.</p>	<p>除確保符合第852/2004號規章規範的微生物基準外，FBOs須確認上市供人食用的LBM符合本章規定的標準：</p>
<p>1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.</p>	<p>其須具有鮮度和活力的官能特徵，包括殼上無髒污、對敲擊有充分反應和足量的瓣膜內液體。</p>
<p>2. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:</p>	<p>其須不含超過下列限值總量(以整類或任何可分離食用部位來量測)的海洋生物毒素：</p>
<p>(a) for paralytic shellfish poison (PSP), ► M23 800 micrograms of saxitoxin equivalents diHCl per kilogram; ◀ M23</p>	<p>麻痺性貝類毒(PSP)，每公斤800 μg的石房蛤毒素2HCL當量；</p>
<p>(b) for amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram;</p>	<p>失憶性貝毒(ASP)，每公斤20mg的</p>

	軟骨藻酸；
(c) ► M23 for okadaic acid and dinophysistoxins together 160 micrograms of okadaic acid equivalents per kilogram; ◀ M23 (EFSA 對貝類中的 Pectenotoxins (PTX) 之意見結論，沒有關於與 PTX 毒素相關的人類不良影響的報告，而 PTX 總是伴隨著岡田酸，故刪除此點對 PTX 的引用。)	岡田酸和甲藻毒素總和，每公斤 160 μg 的岡田酸當量；
(d) ► M14 for yessotoxins, 3,75 milligrams of yessotoxin equivalent per kilogram; ◀ M14	扇貝毒素，每公斤 3.75mg 的扇貝毒素當量；
and	和
(e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.	氮雜螺酸，每公斤 160 μg 的氮雜螺酸當量。
CHAPTER VI: WRAPPING AND PACKAGING OF LIVE BIVALVE MOLLUSCS	第 VI 章：LBM 的內外包裝
1. Oysters must be wrapped or packaged with the concave shell downwards.	牡蠣須以凹殼向下方式包裝。
▼ M9	
2. All packages of live bivalve molluscs leaving dispatch centres or destined for another dispatch centre, must be closed. Packages of live bivalve molluscs, intended for direct retail sale, must remain closed until they are presented for sale to the final consumer. ◀ M9	所有離開集散中心或運往另一個集散中心的 LBM 包裹，須是密閉的。欲直接供應零售的 LBM 包裝，須保持密閉直到售至最終消費者。
CHAPTER VII: IDENTIFICATION MARKING AND LABELLING	第 VII 章：識別標記和標示
1. The label, including the identification mark, must be waterproof.	標籤，含識別標記，須是防水的。
2. In addition to the general requirements for identification marks contained in Annex II, Section I, the following information must be present on the label:	除在附錄 II 第 I 節對識別標記的一般要求外，標籤還須呈現下列資訊：
(a) the species of bivalve mollusc (common name and scientific name);	雙枚貝類的種類(俗名和學名)；
and	和
(b) the date of packaging, comprising at least the day and the month.	包裝日期，至少包含月份和日期。
By way of derogation from Directive 2000/13/EC, the date of minimum durability may be replaced by the entry 'these animals must be alive when sold'.	對 2000/13/EC 指令要求的豁免，最短保存日期可以「當出售時，這些動物必須是活的」來取代。
3. The retailer must keep the label attached to the packaging of live bivalve molluscs that are not in individual consumer-size packages for at least 60 days after splitting up the contents.	對於非供個人消費大小包裝的 LBM，零售商須在分售後，將貼附在包裝上的標籤保存至少 60 天。
CHAPTER VIII: OTHER REQUIREMENTS	第 VIII 章：其他要求
1. Food business operators storing and transporting live bivalve molluscs must ensure that they are kept at a temperature that does not adversely affect food safety or their viability.	貯存和運輸 LBM 的 FBOs 須確認將 LBM 保存在不會對食品安全或存活力有不利影響的溫度。
2. Live bivalve molluscs must not be re-immersed in, or sprayed with, water after they have been packaged for retail sale and left the dispatch centre.	LBM 在被包裝供零售及離開集散中心後，不可再浸入或噴灑水。
▼ M23	
CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE, MARINE GASTROPODS AND HOLOTHUROIDEA WHICH ARE NOT FILTER FEEDERS HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS	第 IX 章：自分類產區外採收之非濾食性的扇貝、海洋腹足類及海參總綱類之特殊要求

<p>Food business operators harvesting pectinidae, marine gastropods and holothuroidea which are not filter feeders, outside classified production areas or handling such pectinidae, and/or such marine gastropods and/or holothuroidea must comply with the following requirements:</p>	<p>FBOs採收或處理分類產區外之非濾食性的扇貝、海洋腹足類及/或海參總綱類須符合下列規定：</p>
<p>1. Pectinidae, marine gastropods and holothuroidea which are not filter feeders, must not be placed on the market unless they are harvested and handled in accordance with Part B of Chapter II and meet the standards laid down in Chapter V, as demonstrated by a system of own-checks by the food business operators operating a fish auction, a dispatch centre or a processing establishment;</p>	<p>非濾食性之扇貝、海洋腹足類及海參總綱類，除非依第II章第B部分採收及處理並符合第V章標準，及由經營魚拍賣市場、集散中心或加工廠業者自主檢查系統予以證明，FBOs不可將之上市。</p>
<p>2. In addition to point 1, where data from official monitoring programmes enable the competent authority to classify fishing grounds — where appropriate, in cooperation with food business operators — the provisions of Part A of Chapter II apply by analogy to pectinidae;</p>	<p>除第1點，官方監測計畫之數據能使CA對漁場進行分類，如適當時與FBOs合作，第II章第A部份規定類推適用於扇貝；</p>
<p>3. Pectinidae, marine gastropods and holothuroidea which are not filter feeders, must not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae and/or such marine gastropods, and/or holothuroidea food business operators operating such establishments must inform the competent authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV;</p>	<p>除非經由魚拍賣市場、集散中心或加工廠，非濾食性的扇貝、海洋腹足類及海參總綱類不可上市供人食用。當FBOs經營處理扇貝及/或海洋腹足類及/或海參總綱類之廠場時，集散中心亦同，須通知CA並符合第三章及第四章相關規定。</p>
<p>4. Food business operators handling pectinidae, marine gastropods and holothuroidea which are not filter feeders, must comply with the following requirements:</p>	<p>FBOs處理非濾食性的扇貝、海洋腹足類及海參總綱類須符合下列要求：</p>
<p>(a) with the documentary requirements of points 3 to 7 of Chapter I, where applicable. In this case, the registration document must clearly indicate the location of the area, indicating the system used to describe the coordinates, where the live pectinidae and/or live marine gastropods and/or live holothuroidea were harvested; or</p>	<p>如適用時，符合第I章第3點至第7點之文件要求。於此案例，登記文件須清楚載明採收活扇貝及/或活海洋腹足類及/或海參總綱類的區域位置，要標明有描述座標的系統；或</p>
<p>(b) with the requirements of point 2 of Chapter VI concerning the closing of all packages of live pectinidae, live marine gastropods and live holothuroidea dispatched for retail sale and Chapter VII concerning identification marking and labelling.</p>	<p>符合第VI章第2點有關運送供零售之活扇貝、活海洋腹足類及活海參總綱類之所有包裝的密閉性，以及第VII章關於識別標記及標示</p>
<p>CHAPTER X: MODEL OF REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS</p>	<p>第X章:活的雙枚貝類、棘皮、被囊類及海洋腹足類動物之登記文件樣張</p>

REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS											
Part I – Supplier	<table border="1"> <tr> <td>I.1 IMSOC Reference number</td> <td>I.2 Internal reference number</td> </tr> <tr> <td>I.3 Supplier Name Address Registration or Approval No Country ISO Country code Activity</td> <td>I.4 Receiving food business operator Name Address Registration or Approval No Country ISO Country code Activity</td> </tr> <tr> <td colspan="2">I.5 Description of goods Aquaculture <input type="checkbox"/> Natural Banks <input type="checkbox"/> • CN code or FAO 3-Alpha code species quantity package batch date of harvesting date of starting of conditioning date of end of conditioning place of conditioning date of starting of re-immersion date of end of re-immersion place of re-immersion date of starting of grouping date of end of grouping production area health status including, if applicable, harvested in accordance with Article 62(2) of Implementing Regulation (EU) 2019/627</td> </tr> <tr> <td>I.6 From relaying area Yes <input type="checkbox"/> No <input type="checkbox"/> Relaying area Duration of relaying Date of starting Date of end</td> <td>I.7 From purification/dispatch centre Auction hall Yes <input type="checkbox"/> No <input type="checkbox"/> Purification/dispatch centre/auction hall approval number Date of entry Date of exit Duration of purification</td> </tr> <tr> <td colspan="2">I.8 From Intermediary operator Yes <input type="checkbox"/> No <input type="checkbox"/> Name Address Registration or Approval No Country ISO Country code Activity Date of arrival Date of exit</td> </tr> </table>	I.1 IMSOC Reference number	I.2 Internal reference number	I.3 Supplier Name Address Registration or Approval No Country ISO Country code Activity	I.4 Receiving food business operator Name Address Registration or Approval No Country ISO Country code Activity	I.5 Description of goods Aquaculture <input type="checkbox"/> Natural Banks <input type="checkbox"/> • CN code or FAO 3-Alpha code species quantity package batch date of harvesting date of starting of conditioning date of end of conditioning place of conditioning date of starting of re-immersion date of end of re-immersion place of re-immersion date of starting of grouping date of end of grouping production area health status including, if applicable, harvested in accordance with Article 62(2) of Implementing Regulation (EU) 2019/627		I.6 From relaying area Yes <input type="checkbox"/> No <input type="checkbox"/> Relaying area Duration of relaying Date of starting Date of end	I.7 From purification/dispatch centre Auction hall Yes <input type="checkbox"/> No <input type="checkbox"/> Purification/dispatch centre/auction hall approval number Date of entry Date of exit Duration of purification	I.8 From Intermediary operator Yes <input type="checkbox"/> No <input type="checkbox"/> Name Address Registration or Approval No Country ISO Country code Activity Date of arrival Date of exit	
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I.8 From Intermediary operator Yes <input type="checkbox"/> No <input type="checkbox"/> Name Address Registration or Approval No Country ISO Country code Activity Date of arrival Date of exit											
I.9 Declaration of the supplier I, the undersigned food business operator responsible for dispatching the consignment declare that, to the best of my knowledge and belief, the information provided in Part I of this document is true and complete.											
Date _____ Name of signatory _____ Signature _____											
Part II – Receiving operator	<table border="1"> <tr> <td>II.1 Internal reference number (receiving)</td> </tr> <tr> <td>II.2 Declaration of the receiving food business operator I, the undersigned food business operator responsible for receiving the consignment declare that the consignment has arrived on [DATE] in my premises.</td> </tr> <tr> <td>Name of signatory _____ Signature _____</td> </tr> </table>	II.1 Internal reference number (receiving)	II.2 Declaration of the receiving food business operator I, the undersigned food business operator responsible for receiving the consignment declare that the consignment has arrived on [DATE] in my premises.	Name of signatory _____ Signature _____							
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II.2 Declaration of the receiving food business operator I, the undersigned food business operator responsible for receiving the consignment declare that the consignment has arrived on [DATE] in my premises.											
Name of signatory _____ Signature _____											
Explanatory notes											
Box	Description										
Part I – Supplier											
This part of the document shall be filled by the food business operator dispatching a batch of live bivalve molluscs.											
I.1	IMSOC reference number This is the unique alpha-numeric code assigned by the IMSOC.										
I.2	Internal reference number This box may be used by the dispatching food business operator to indicate an internal reference number.										
I.3	Supplier Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of origin. In the case of production areas, please indicate the area as authorised by the competent authorities (CAs). In the case of live pectinidae, marine gastropods or holothuroidea, indicate the location of the harvesting area. Where applicable, indicate the registration or approval number of the establishment. Indicate the activity (gatherer, purification centre, dispatch centre, auction hall or intermediary activities). Where the batch of live bivalve molluscs is sent from a purification centre/dispatch centre, or, in case of pectinidae, marine gastropods and Holothuroidea which are not filter feeders harvested outside classified production areas, from a fish auction, indicate the approval number and the address of the purification centre/dispatch centre or fish auction.										
I.4	Receiving food business operator Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of destination. In the case of production or relaying areas please indicate the area as authorised by the CAs. Where applicable, indicate the registration or approval number of the establishment Indicate the activity (gatherer, purification centre, dispatch centre, processing establishment or intermediary activities).										
I.5	Description of goods Indicate as required, the Combined Nomenclature code or FAO 3-Alpha code, species, quantity, type of packaging (bags, bulk, etc.), batch, date of harvesting, date of starting and end of conditioning (when applicable), place of conditioning (indicate the classification of the production area and its location or the approval number of the establishment, when applicable), date of starting and end of re-immersion (when applicable), place of re-immersion (indicate the classification of the production area and its location or the approval number of the establishment when applicable), date of starting and end of grouping (when applicable), production area and its health status (classification of the production area when applicable). When LBMs have been harvested in accordance with Article 62(2) of the Implementing Regulation 2019/627 then this should be explicitly stated. When grouping of live bivalve molluscs is performed, the batch must refer to bivalves of the same species, harvested on the same day and coming from the same production area. Delete as appropriate.										
I.6	From relaying area										

(略，第 I 部分供應商資訊、第 II 部分接收業者資訊、最後是各欄位註解)

	Where the batch of live bivalve molluscs is sent from a relaying area, indicate the relaying area, as authorised by the CAs, and the duration of the relaying (date of starting and end).
1.7	From purification centre/dispatch centre or fish auction Where the batch of live bivalve molluscs is sent from a purification centre/dispatch centre, or, in case of pectinidae, marine gastropods and holothuroidea which are not filter feeders harvested outside classified production areas, from an auction hall, indicate the approval number and the address of the purification centre/dispatch centre or auction hall. If sent from a purification centre the duration of the purification and the dates on which the batch entered and left the purification centre. Delete as appropriate.
1.8	From intermediary operator Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the intermediary operator. Where applicable, indicate the registration or approval number and the activity.
1.9	Declaration of the supplier Include the date, name of the signatory and the signature.
Part II – Receiving food business operator This part of the document shall be filled by the food business operator receiving a batch of live bivalve molluscs.	
II.1	Internal reference number (receiving) This box may be used by the food business operator receiving the batch to indicate an internal reference number.
II.2	Declaration of the receiving food business operator Indicate the date of arrival of the batch of live bivalve molluscs at the premises of the receiving food business operator. In the case of an intermediary operator without premises indicate the date of purchase of the batch. Include the name of the signatory and the signature.

◀M23

SECTION VIII: FISHERY PRODUCTS

第VIII節：水產品

▼M9

1. This Section does not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods if they are still alive when placed on the market. With the exception of Chapters I and II, it applies to such animals when not placed on the market live, in which case they must have been obtained in accordance with Section VII.

本節不適用於上市販售之活的雙枚貝類、棘皮類、被囊類及海洋腹足類動物。除第I章及第II章外，本部分適用依第VII節收穫且非活體上市之此類動物。

It applies to thawed unprocessed fishery products and fresh fishery products to which food additives have been added in accordance with the appropriate Union legislation. ◀M9

本部分適用依歐盟法規使用食品添加物之解凍未加工及生鮮水產品。

▼M6

2. Chapter III, Parts A, C and D, Chapter IV, Part A and Chapter V apply to retail. ◀M6

第III章A、C和D部分、第IV章A部份和第V章適用於零售業。

3. The requirements of this Section supplement those laid down in Regulation (EC) No 852/2004:

本節為第852/2004號規章之補充：

(a) In the case of establishments, including vessels, engaged in primary production and associated operations they supplement the requirements of Annex I to that Regulation.

如為從事初級生產及相關作業的廠場，包括漁船，本節為該規章附錄I之補充。

(b) In the case of other establishments, including vessels, they supplement the requirements of Annex II to that Regulation

如為其他廠場，包括漁船，本節為該規章附錄II之補充。

▼M6

(c) In the case of water supply, they supplement the requirements of Annex II, Chapter VII to that Regulation; clean seawater may be used for the handling and washing of fishery products, the production of ice used to chill fishery products and the rapid cooling of crustaceans and molluscs after their cooking. ◀M6 (按：M6 在本節之修正，是基於海水的使用，在技術上有助於消除水產品滲透壓休克之風險，來保持感官特性的完整性，且只要有基於 HACCP 原則的控管程序，使用清潔海水來處理和清洗水產品並不會對公眾健康構成風險。)

如為水供應，本節為該規章附錄II第七章之補充；潔淨海水可用於清洗及處理水產品，製造用於冷藏水產品與快速冷卻烹煮後之甲殼及軟體動物之冰塊。

▼M5

By way of derogation from point (a), point 7 of Part A of Annex I to Regulation (EC) No 852/2004 may not apply to operators engaged in small-scale coastal fishing within the meaning of Article 26(1) of Council Regulation (EC) No 1198/2006³⁹, and carrying out their activities only for short periods of less than 24 hours. ◀M5

第852/2004號規章附錄IA部分第7點不適用理事會第1198/2006號規章第26(1)條意指作業活動時間只在少於24小時之從事小型沿近海漁

	業業者，可減免(a)點的規定。
4. In relation to fishery products:	關於水產品：
(a) primary production covers the farming, fishing and collection of live fishery products with a view to their being placed on the market;	初級生產涵蓋以上市為目的的活水產品養殖、捕撈和採集。
and	
(b) associated operations cover any of the following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping; they also include:	相關作業涵蓋在漁船上進行以下任一操作：宰殺、放血、去頭、去內臟、去鰭、凍藏和包裝；亦包括：
1. the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land;	於陸上魚養殖場內未重大改變水產品本質之運輸及儲存，包括活的水產品；
and	
2. the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination.	從產地到首個廠場未重大改變水產品本質之運輸，包括活的水產品。
CHAPTER I: REQUIREMENTS FOR VESSELS	第I章：對漁船的要求
Food business operators must ensure that:	FBOs須確保：
▼ M23	
1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, and reefer vessels comply with the structural and equipment requirements laid down in Part I; and ◀ M23	用於從自然環境中捕撈，或捕撈後處理或加工水產品的漁船，和運搬船符合第I部份規定的結構和設備要求；且
2. operations carried out on board vessels take place in accordance with the rules laid down in Part II.	在漁船上的作業依第II部份規定進行。
I. STRUCTURAL AND EQUIPMENT REQUIREMENTS	結構和設備要求
A. Requirements for all vessels	對所有漁船的要求
1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.	漁船的設計和建造必須避免艙底水、污水、煙霧、燃料、油、油脂或其他有害物質污染產品。
2. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.	與水產品接觸之表面必須是平滑且易於清洗之適宜的抗腐蝕材質。表面塗層必須耐用且無毒。
3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.	用於處理水產品的設備和材質必須以易清洗和消毒的抗腐蝕材質製成。
4. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.	當漁船有用於水產品的引水口時，其位置必須設於避免污染供水處。
▼ M23	
5. Vessels must be designed and constructed so as not to cause contamination of the fishery products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. Holds, tanks, or containers used for storing, cooling or freezing unprotected fishery products including those destined for the production of feed, shall not be used for other purposes than the storing, cooling or freezing those products, as well as ice or brine used for such purposes. In the case of reefer vessels, the provisions applicable to	漁船必須以避免艙底水、污水、煙霧、燃料、油、油脂或其他有害物質污染水產品的方式來設計和建造。用於儲存、冷卻或冷凍未受保護的及作為飼料生產的水產品之艙、槽或容器，應不得用於除了儲

<p>unprotected fishery products apply to all the products transported. ◀M23</p>	<p>存、冷卻或冷凍此類產品及冰或鹽水以外的其他用途。對於運搬船，用於未受保護水產品之規定適用於所有運輸的產品。</p>
<p>B. Requirements for vessels designed and equipped to preserve fresh fishery products for more than 24 hours</p>	<p>為保存新鮮水產品超過 24 小時而設計和配備的漁船要求</p>
<p>1. Vessels designed and equipped to preserve fishery products for more than 24 hours must be equipped with holds, tanks or containers for the storage of fishery products at the temperatures laid down in Chapter VII.</p>	<p>為保存新鮮水產品超過24小時而設計和配備的漁船須有裝配艙、槽或容器，用以在第VII章規定的溫度下儲存水產品。</p>
<p>2. Holds must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products. Holds and containers used for the storage of fishery products must ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products.</p>	<p>漁艙與引擎機艙及船員住艙須以可充分避免儲存水產品任何污染的隔板進行區隔。用於儲存水產品的漁艙和容器必須確保在令人滿意的衛生條件下保存，並在必要時確保融水不會滯留與產品接觸。</p>
<p>3. In vessels equipped for chilling fishery products in cooled clean seawater, tanks must incorporate devices for achieving a uniform temperature throughout the tanks. Such devices must achieve a chilling rate that ensures that the mix of fish and clean seawater reaches not more than 3°C six hours after loading and not more than 0°C after 16 hours and allow the monitoring and, where necessary, recording of temperatures.</p>	<p>在配備冷卻清潔海水冷卻水產品的漁船中，水槽須裝設有使整個水槽溫度均一的設備。此設備須具有一定的冷卻速率以確保魚和清潔海水的混合物在裝載後6小時達到3°C以下及16小時後不超過0°C，並允許監測及在必要時記錄溫度。</p>
<p>C. Requirements for freezer vessels</p>	<p>對凍結船的要求</p>
<p>Freezer vessels must:</p>	<p>凍結船必須：</p>
<p>▼ M23</p>	
<p>1. have freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to achieve a core temperature of not more than -18°C;</p>	<p>具有足夠能力在連續過程中盡可能快地冷凍和熱滯期盡可能短的冷凍設備，以達到-18°C以下的中心溫度。</p>
<p>2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18°C. Storage holds must not be used for freezing unless they fulfil the conditions laid down in point 1, and must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest; ◀M23</p>	<p>具有足夠能力使儲存在漁艙中的水產品維持在-18°C以下的製冷設備。除非滿足第1點規定的條件，否則不可將漁艙用於冷凍，且必須在易於讀取的位置裝設溫度記錄器。溫度感應器必須設置在漁艙溫度最高的區域。</p>
<p>3. meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours laid down in part B, point 2.</p>	<p>符合B部份第2點有關為保存新鮮水產品超過24小時而設計和配備的漁船要求。</p>
<p>D. Requirements for factory vessels</p>	<p>對加工船的要求</p>
<p>1. Factory vessels must have at least:</p>	<p>加工船必須至少有：</p>
<p>(a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the</p>	<p>為在船上卸魚而預留的接收區，其設計要可以將每個接續的漁獲物區</p>

elements and from any source of contamination;	隔開。此區域必須易於清潔且在設計上可保護產品避免受陽光或元素及其他污染來源的影響；
(b) a hygienic system for conveying fishery products from the receiving area to the work area;	將水產品從接收區輸送到工作區的衛生系統；
(c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean and disinfect and designed and arranged in such a way as to prevent any contamination of the products;	足夠大的供水產品衛生製備和加工之工作區域，具易於清潔和消毒且有預防產品受到任何污染的設計及佈置；
(d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste-processing unit operates on board, a separate hold must be designated for the storage of such waste;	足夠大的供成品儲存區域，具易於清潔之設計。若船上有廢棄物處理裝置，則必須指定一個獨立艙位來儲存此類廢棄物；
(e) a place for storing packaging materials that is separate from the product preparation and processing areas;	與工作區域分隔的存放包材的地方；
(f) special equipment for disposing waste or fishery products that are unfit for human consumption directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to its sanitation, separate areas must be allocated for that purpose;	將廢棄物或不適合人類食用的水產品直接排入海中的特殊設備，或視情況需要將之放入為此目的而預留的防水槽中。如為衛生目的在船上儲存和處理廢棄物，則必須為此目劃分一個單獨的區域；
(g) a water intake situated in a position that avoids contamination of the water supply;	取水口設於避免污染供水的位置；
and	
(h) hand-washing equipment for use by the staff engaged in handling exposed fishery products with taps designed to prevent the spread of contamination.	供處理裸露水產品員工使用的洗手設備，帶有為防止污染擴散之水龍頭。
2. However, factory vessels on board which crustaceans and molluscs are cooked, chilled and wrapped, need not meet the requirements of point 1 if no other form of handling or processing takes place on board such vessels.	然而，對在船上進行甲殼類與軟體動物的烹煮、冷卻和包裝的加工船，若無進行其他形式的處理或加工者，不需符合第1點的要求。
3. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in part C, points 1 and 2.	會對水產品進行冷凍的加工船須具有符合C部分第1和2點規定的冷凍船要求的設備。
▼ M23	
E. Requirements for reefer vessels	對運搬船的要求
Reefer vessels transporting and/or storing frozen fishery products in bulk must have equipment meeting the requirements for freezer vessels laid down in point 2 of part C concerning their capacity to maintain the temperature. ◀M23	以散裝方式運輸和/或儲存水產品的運搬船必須具有符合C部分第2點規定的冷凍船維持溫度能力要求的設備。
II. HYGIENE REQUIREMENTS	衛生要求
1. When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in good repair and condition. In particular, they must not be contaminated by fuel or bilge water.	當作業時，存放水產品的船體部份或容器須保持清潔並維持在良好的維修狀態。特別是不得被燃料或艙底水污染。
2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source	在水產品卸到船上後，須盡快保護

of heat. ► M6 _____ ◀ M6 (按：刪除必須使用飲用水或潔淨水清洗水產品之要求)	免受污染和陽光或任何其他熱源的影響。
3. Fishery products must be handled and stored so as to prevent bruising. Handlers may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products suffers no damage.	水產品須以避免挫傷方式來處理和儲存。在不造成產品肌肉損傷的情形下，處理者可使用帶刺工具來移動大型魚或可能傷害他們的魚。
4. Fishery products other than those kept alive must undergo chilling as soon as possible after loading. However, when chilling is not possible, fishery products must be landed as soon as possible.	除活魚外的水產品，須在上船後盡快進行冷藏。然而，當無法冷藏時，須盡快將水產品上岸卸魚。
▼ M6	
_____ 5. Ice used to chill fishery products must be made from potable water or clean water.	
▼ M23	
6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the fishery products must be washed immediately. The viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from fishery products intended for human consumption. Livers and roes intended for human consumption must be refrigerated or preserved under ice, at a temperature approaching that of melting ice, or be frozen.	在船上去頭和/或去內臟的情形下，此等作業必須在水產品捕撈後盡快衛生地進行，且必須立即清洗。可能對公共衛生構成威脅的內臟和部位必須盡快去除，並遠離欲供人食用的水產品。欲供人食用的肝臟和魚卵必須在接近融冰溫度下覆冰冷藏或保存，或冷凍。
7. Where freezing in brine of the whole fish intended for canning is practiced, a temperature of not more than -9°C must be achieved for the fishery product. Even if it is subsequently frozen at a temperature of -18°C, the whole fish initially frozen in brine at a temperature of not more than -9°C must be destined for canning. The brine must not be a source of contamination for the fish. ◀ M23 (因發生斷魚最初在-9°C 鹽水中冷凍並運往罐頭工業，但轉而作為新鮮水產品的欺詐消費者行為，因此澄清最初在-9°C 鹽水中冷凍並運往罐頭工廠的全魚產品，即使在-18°C 下進一步冷凍，亦不得用於製罐以外用途。)	對欲供製罐用全魚在鹽水中冷凍的情形下，水產品溫度必須達到不超過-9°C。即使後續在-18°C 溫度下冷凍，該初始浸於鹽水中以不超過-9°C 冷凍的全魚必須僅用於製罐。鹽水不能是魚的污染來源。
CHAPTER II: REQUIREMENTS DURING AND AFTER LANDING	第二章：卸魚期間和卸魚後的要求
1. Food business operators responsible for the unloading and landing of fishery products must:	負責水產品卸載和卸魚的FBOs必須：
(a) ensure that unloading and landing equipment that comes into contact with fishery products is constructed of material that is easy to clean and disinfect and maintained in a good state of repair and cleanliness;	確保與水產品接觸的卸載和卸魚設備是以易清潔和消毒的材質製成並維持在良好的維修和清潔狀態；
and	
(b) avoid contamination of fishery products during unloading and landing, in particular by:	在卸載和卸魚過程中避免水產品的污染，特別是藉由：
(i) carrying out unloading and landing operations rapidly;	迅速地進行卸載和卸魚作業；
(ii) placing fishery products without delay in a protected environment at the temperature specified in Chapter VII;	立即將水產品置於第七章規定溫度之受保護環境中；
and	
(iii) not using equipment and practices that cause unnecessary damage to the edible parts of the fishery products.	不使用會造成水產品可食部位不必要損傷之設備和操作。
2. Food business operators responsible for auction and wholesale markets or parts thereof where fishery products are displayed for sale must ensure compliance with the following requirements.	負責拍賣及批發市場或展售水產品的FBOs必須確保符合下列要求。
(a) (i) There must be lockable facilities for the refrigerated storage of detained fishery products and separate lockable facilities for the storage of fishery	須有可上鎖設施用於冷藏儲存被扣

products declared unfit for human consumption.	留的水產品，並有獨立的可上鎖設施用於儲放被宣告不適合供人食用的水產品。
(ii) If the competent authority so requires, there must be an adequately equipped lockable facility or, where needed, room for the exclusive use of the competent authority.	若CA有此需求，須配有可完全上鎖的設施，或需要時給CA專用的房間。
(b) At the time of display or storage of fishery products:	在展示或儲存水產品時段：
(i) the premises must not be used for other purposes;	該場所不得用做其他用途；
(ii) vehicles emitting exhaust fumes likely to impair the quality of fishery products must not have access to the premises;	會排放可能損害水產品品質廢氣的車輛不得進入該場所；
(iii) persons having access to the premises must not introduce other animals;	進入該場所人員不得引入其他動物；
and	
(iv) the premises must be well lit to facilitate official controls.	該場所須光線良好以利官方管控。
3. When chilling was not possible on board the vessel, fresh fishery products, other than those kept alive, must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice	當船上不可冷藏時，除了活水產品外的生鮮水產品須在上岸卸魚後盡快冷卻並以接近融冰溫度儲存。
4. Food business operators must cooperate with relevant competent authorities so as to permit them to carry out official controls in accordance with Regulation (EC) No 854/2004, in particular as regards any notification procedures for the landing of fishery products that the competent authority of the Member State the flag of which the vessel is flying or the competent authority of the Member State where the fishery products are landed might consider necessary.	FBOs必須與相關CAs合作以允許他們依據第854/2004號規章來執行官方管控，特別是關於船籍會員國CA或卸魚所在的會員國CA認為有必要的任何水產品上岸卸魚通知程序。
CHAPTER III: REQUIREMENTS FOR ESTABLISHMENTS, INCLUDING VESSELS, HANDLING FISHERY PRODUCTS	第三章：對於處理水產品廠場(包括漁船)之要求
Food business operators must ensure compliance with the following requirements, where relevant, in establishments handling fishery products.	FBOs須確保處理水產品的廠場符合下列要求。
A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS	對生鮮水產品的要求
1. Where chilled, unpackaged products are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, they must be stored under ice in appropriate facilities. Re-icing must be carried out as often as necessary. Packaged fresh fishery products must be chilled to a temperature approaching that of melting ice.	若冷藏、未包裝之水產品在送抵陸上廠場後未立即分配、分銷、製備或加工，必須將之存於適當的覆冰設施中。須視需要經常再次覆冰。已包裝的生鮮水產品須以接近融冰溫度進行冷藏。
▼ M6	
2. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly with potable water or, on board vessels, clean water immediately after these operations. ◀ M6	諸如去頭及去內臟等操作必須衛生地進行。從技術和商業觀點，若去內臟是可行時，須在產品捕撈或上岸卸魚後盡快完成。在這些操作後要立即徹底清洗產品。
3. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.	諸如切片及切塊等操作須避免魚片及魚塊被污染或變質。魚片及魚塊不得留置在工作台上超過製備操作所需要的時間。魚片及魚塊須經包裹和必要的包裝，且在製備後要盡

	快冷藏。
▼M23	
4. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water is drained away and does not remain in contact with any fishery products. ◀M23 (按：出於衛生原因，澄清融水不僅不應與水產品保持接觸，而且應排出。)	用來運送或儲存覆冰之已處理未包裝生鮮水產品的容器，須確保融水被排出且不會與任何水產品保持接觸。
5. Whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from aquaculture establishments, until they arrive at the first establishment on land carrying out any activity other than transport or sorting.	漁船上的全魚和去內臟生鮮水產品可以在冰水中運輸和儲存。上岸後也可續在冰水中運送，及從養殖場運輸，直到抵達首個非運輸或分檢作業之陸上廠場。
▼M23	
B. REQUIREMENTS FOR FROZEN PRODUCTS	對冷凍產品的要求
Establishments on land that freeze or store frozen fishery products must have equipment, adapted to the activity carried out , that satisfies the requirements for freezer vessels laid down in Section VIII, Chapter I, part I. C, points 1 and 2. ◀M23	冷凍或儲存冷凍水產品的陸上廠場必須具有適合其活動的設備，該設備要滿足第VIII節第I章第I部分C.1及C.2點對凍結船的要求。
C. REQUIREMENTS FOR MECHANICALLY SEPARATED FISHERY PRODUCTS	對機械分離水產品的要求
Food business operators manufacturing mechanically separated fishery products must ensure compliance with the following requirements.	製造機械分離水產品的FBOs須確保符合下列要求。
1. The raw materials used must satisfy the following requirements.	所使用的原料須滿足下列要求。
(a) Only whole fish and bones after filleting may be used to produce mechanically separated fishery products;	只有全魚和切片後的骨可以用來生產機械分離水產品
(b) All raw materials must be free from guts.	所有原料必須完全不含內臟。
2. The manufacturing process must satisfy the following requirements:	製造過程必須滿足下列要求。
(a) Mechanical separation must take place without undue delay after filleting.	機械分離須在切片後立即進行。
(b) If whole fish are used, they must be gutted and washed beforehand.	若使用全魚，必須事先完成去內臟和清洗。
(c) After production, mechanically separated fishery products must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.	在生產後，機械分離的水產品須盡快冷凍或加入欲進行冷凍的產品中或一穩定的處理製程。
▼M11	
D. REQUIREMENTS CONCERNING PARASITES	關於寄生蟲的要求
1. Food business operators placing on the market the following fishery products derived from finfish or cephalopod molluscs:	上市販售下列源自有鱗魚類或頭足類軟體動物水產品的FBOs：
(a) fishery products intended to be consumed raw; or	欲供作生食的水產品；或
(b) marinated, salted and any other treated fishery products, if the treatment is insufficient to kill the viable parasite;	醃、鹽製和其他任何處理過的水產品，若其處理無法殺死活寄生蟲；
must ensure that the raw material or finished product undergo a freezing treatment in order to kill viable parasites that may be a risk to the health of the consumer.	必須確保原料或成品經過為了殺死可能對消費者健康有害活寄生蟲的冷凍處理。

<p>2. For parasites other than trematodes the freezing treatment must consist of lowering the temperature in all parts of the product to at least:</p>	<p>除吸蟲外的寄生蟲之冷凍處理，必須至少對產品所有部份的溫度降低至：</p>
<p>(a) –20 °C for not less than 24 hours; or</p>	<p>-20°C超過24小時；或</p>
<p>(b) –35 °C for not less than 15 hours.</p>	<p>-35°C超過15小時。</p>
<p>3. Food business operators need not carry out the freezing treatment set out in point 1 for fishery products:</p>	<p>FBOs不需對水產品進行第1點規定的冷凍處理：</p>
<p>(a) that have undergone, or are intended to undergo before consumption a heat treatment that kills the viable parasite. In the case of parasites other than trematodes the product is heated to a core temperature of 60 °C or more for at least one minute;</p>	<p>已經過或欲食用前會經過可殺死活寄生蟲的熱處理。對吸蟲以外之寄生蟲，將產品加熱到中心溫度60°C或更高至少1分鐘；</p>
<p>(b) that have been preserved as frozen fishery products for a sufficiently long period to kill the viable parasites;</p>	<p>已以冷凍水產品保存到足夠長的時間以殺死活寄生蟲；</p>
<p>(c) from wild catches, provided that:</p>	<p>來自野生捕撈，並提供：</p>
<p>(i) there are epidemiological data available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and</p>	<p>有流行病學數據可資證明該漁獲區不會因寄生蟲的存在對健康造成危害；且</p>
<p>(ii) the competent authority so authorises;</p>	<p>得到權責機關的授權；</p>
<p>(d) derived from fish farming, cultured from embryos and have been fed exclusively on a diet that cannot contain viable parasites that present a health hazard, and one of the following requirements is complied with:</p>	<p>源於自胚胎培養之魚類養殖場，並餵食不含對健康有害的活寄生蟲之特定飼料，且符合下列要求之一：</p>
<p>(i) have been exclusively reared in an environment that is free from viable parasites; or</p>	<p>飼養在完全無活寄生蟲的環境；或</p>
<p>(ii) the food business operator verifies through procedures, approved by the competent authority, that the fishery products do not represent a health hazard with regard to the presence of viable parasites.</p>	<p>FBO透過經權責機關核可的程序，來驗證水產品不會因活寄生蟲的存在對健康造成危害。</p>
<p>4.(a) When placing on the market, except when supplied to the final consumer, fishery products referred to in point 1 must be accompanied by a document issued by the food business operator performing the freezing treatment, stating the type of freezing treatment that the products have undergone.</p>	<p>除供應給最終消費者外，第1點所指水產品於上市時必須檢附執行冷凍處理的FBO簽署之文件，敘述產品所經過冷凍處理的類型。</p>
<p>(b) Before placing on the market fishery products referred to in points 3(c) and (d) which have not undergone the freezing treatment or which are not intended to undergo before consumption a treatment that kills viable parasites that present a health hazard, a food business operator must ensure that the fishery products originate from a fishing ground or fish farming which complies with the specific conditions referred to in one of those points. This provision may be met by information in the commercial document or by any other information accompanying the fishery products. ◀M11 (按：依EFSA意見，如果在浮籠或陸上水箱中以不含有活寄生蟲的複合飼料飼養大西洋鮭魚，除非養殖方式改變，否則感染異尖線蟲幼蟲larval anisakids的風險可以忽略。如果遵循基於這些標準的相同飼養程序，大西洋鮭魚以外的養殖魚被認為對消費者健康可能構成威脅的寄生蟲風險可以忽略。故此類養殖魚可免於冷凍而仍可確保高標準的健康保護之要求。)</p>	<p>將第3(c)和(d)點所指未經冷凍處理或在食用前不打算經殺滅對健康有危害的活寄生蟲處理之水產品於上市前，FBO必須確保水產品源自符合上述任一點所指特定條件的魚場或養殖場。此規定可由隨附水產品的商業文件或任何其他資訊來滿足。</p>
<p>▼M6</p>	
<p>CHAPTER IV: REQUIREMENTS FOR CERTAIN PROCESSED FISHERY PRODUCTS</p>	<p>第四章 對特定加工水產品的要求</p>
<p>Food business operators must ensure compliance with the following requirements in establishments handling certain processed fishery products.</p>	<p>FBOs須確保廠場在處理特定加工水產品時，符合下列要求：</p>
<p>A. REQUIREMENTS FOR COOKING OF CRUSTACEANS AND MOLLUSCS</p>	<p>A. 甲殼類及軟體動物之烹煮要求</p>
<p>1. Rapid cooling must follow cooking. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.</p>	<p>烹煮後應快速冷卻。若未使用其他保藏方法，則須持續冷卻至接近融</p>

	冰溫度。
2. Shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands.	須衛生地進行水產品的剝殼或去皮處理，以避免產品污染。當此作業是以手處理時，工人須特別注意手部清洗。
3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature set out laid-down in Chapter VII.	在剝殼或去皮後，已煮熟產品須立即冷凍，或儘速冷卻至第七章規定的溫度。
B. REQUIREMENTS FOR FISH OIL INTENDED FOR HUMAN CONSUMPTION	B. 欲供人食用之魚油要求
1. Raw materials used in the preparation of fish oil for human consumption must:	用於製備供人食用魚油之原料須：
(a) come from establishments, including vessels, registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation;	源自依照第(EC)852/2004號規章或本規章註冊或核可的廠場，包括漁船；
(b) derive from fishery products which are fit for human consumption and which comply with the provisions set out in this Section;	衍生自適合人類食用並符合本節規定的水產品；
(c) be transported and stored in hygienic conditions;	在衛生條件下運輸及貯存；
(d) be chilled as soon as possible and remain at the temperatures set out in Chapter VII.	儘快冷卻並保持在第七章規定之溫度。
By way of derogation from point 1(d), the food business operator may refrain from chilling the fishery products when whole fishery products are used directly in the preparation of fish oil for human consumption, and the raw material is processed within 36 hours after loading, provided that the freshness criteria are met and the total volatile basic nitrogen (TVB-N) value of the unprocessed fishery products do not exceed the limits set out in point 1 of Chapter I of Section II of Annex II to Commission Regulation (EC) No 2074/2005 ⁴⁰ .	在滿足鮮度基準和未加工原料之總揮發性鹽基態氮(TVB-N)值不超過執委會第(EC)2074/2005號規章附錄II第II節第I章第1點規定限值前提下，當原料是在卸魚後36小時內進行加工且全部水產品直接用於製備供人食用之魚油時，FBO可以減免第1(d)點規定，不用冷卻水產品。
2. The production process for fish oil must ensure that all raw material intended for the production of crude fish oil is subject to a treatment including, where relevant, heating, pressing, separation, centrifugation, processing, refining and purification steps before being placed on the market for the final consumer.	在上市供最終消費者前，魚油的生產過程必須確保欲用於生產粗魚油的所有原料是經過，包括加熱、壓榨、分離、離心、加工、精煉和純化等步驟之相關處理。
3. Provided that the raw materials and the production process comply with the requirements applying to fish oil intended for human consumption a food business operator may produce and store both fish oil for human consumption and fish oil and fish meal not intended for human consumption in the same establishment.	在原料和生產過程符合適合供人食用魚油之要求前提下，FBO可以同時在同一廠場生產和儲存供人食用魚油和非供人食用魚油和魚粉。
4. Pending the establishment of specific Community legislation food business operators must ensure compliance with national rules for fish oil being placed on the market for the final consumer. ◀M6	在建立具體的歐盟立法前，FBOs必須確保上市售予最終消費者之魚油符合國家規定。
CHAPTER V: HEALTH STANDARDS FOR FISHERY PRODUCTS	第V章 水產品衛生標準
In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter. ▶M6 The requirements of Parts B and D shall not apply to whole fishery products that are used	除確保符合第(EC)852/2004號規章採行之微生物基準外，FBOs須依產品或物種性質，確保上市供人食用水產品，符合本章規定之標準。B

40 OJ L 338, 22.12.2005, p. 27.

directly for the preparation of fish oil intended for human consumption. ◀M6	和D部分之要求不適用於直接用於製備供人食用魚油的全魚產品。
A. ORGANOLEPTIC PROPERTIES OF FISHERY PRODUCTS	A. 水產品之官能特性
Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.	FBOs必須對水產品進行官能檢查。特別是，此檢查須確保水產品符合任何鮮度基準。
B. HISTAMINE	B. 組織胺
Food business operators must ensure that the limits with regard to histamine are not exceeded.	FBOs必須確保組織胺不超過限量值。
C. TOTAL VOLATILE NITROGEN	C. 總揮發性氮
Unprocessed fishery products must not be placed on the market if chemical tests reveal that the limits with regard to TVB-N or TMA-N have been exceeded.	未加工水產品若其化學檢測顯示TVB-N或TMA-N超過限量值，則不得上市販售。
D. PARASITES	D. 寄生蟲
Food business operators must ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market. They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.	FBOs必須確認水產品在上市前已經過目視檢查是否有可見之寄生蟲。明顯受到寄生蟲污染之水產品不得上市販售供人食用。
E. TOXINS HARMFUL TO HUMAN HEALTH	E. 對人體健康有害之毒素
▼M6	
1. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.	以下有毒魚科之水產品不得上市：四齒魨科、翻車魨科、二齒魨科、尖鼻魨科(譯註:依ITIS官網，與四齒魨科同在魨形目下，為亞科)。
Fresh, prepared, frozen and processed fishery products belonging to the family <i>Gempylidae</i> , in particular <i>Ruvettus pretiosus</i> and <i>Lepidocybium flavobrunneum</i> , may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects. (按：本修正是基於EFSA於2004年8月30日關於蛇鯖科水產品毒性相關的食物鏈污染物的意見)	屬於蛇鯖科之生鮮、備製、冷凍和加工之水產品，特別是(油魚)棘鱗蛇鯖和異鱗蛇鯖，只能以包裝形式上市，且必須提供消費者在備製/烹飪方法及可能存在胃腸不適物質風險之適當的標示資訊。
The scientific name of the fishery products must accompany the common name on the label. ◀M6	水產品學名須與俗名同時在標籤上呈現。
2. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII and comply with the standards laid down in Chapter V, point 2, of that section.	含有像雪卡毒素或肌肉麻痺毒素之生物毒素的水產品不得上市販售。然而，源自雙枚貝類、棘皮類、被囊類和海洋腹足類動物等水產品，若已依第VII節規定生產且符合該節第V章第2點規定的標準，則可以上市販售。

CHAPTER VI: WRAPPING AND PACKAGING OF FISHERY PRODUCTS	第VI章 水產品之內外包裝
1. Receptacles in which fresh fishery products are kept under ice must be water-resistant and ensure that melt-water does not remain in contact with the products.	用來盛裝覆冰生鮮水產品之容器必須是防水的，並確保融水不會持續與產品接觸。
2. Frozen blocks prepared on board vessels must be adequately wrapped before landing.	在船上做好的冷凍魚磚必須在卸魚前充分地包裹。
3. When fishery products are wrapped on board fishing vessels, food business operators must ensure that wrapping material:	當在船上進行水產品包裹時，FBOs 須確保包裝材質：
(a) is not a source of contamination;	不是污染源；
(b) is stored in such a manner that it is not exposed to a risk of contamination;	以不遭受污染風險之方式來儲存；
(c) intended for re-use is easy to clean and, where necessary, to disinfect.	欲重複使用的，要易於清潔，並在必要時進行消毒。
CHAPTER VII: STORAGE OF FISHERY PRODUCTS	第VII章 水產品之儲存
Food business operators storing fishery products must ensure compliance with the following requirements.	儲存水產品的FBOs必須確保符合下列要求：
1. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.	生鮮水產品、解凍未加工水產品和甲殼類及軟體動物之煮熟冷藏產品，必須保持在接近融冰溫度下。
▼ M9	
2. Frozen fishery products must be kept at a temperature of not more than -18 °C in all parts of the product; however, whole fish initially frozen in brine intended for the manufacture of canned food may be kept at a temperature of not more than -9°C. ◀M9	冷凍水產品所有部分必須保持在不高於-18°C的溫度；然而，最初凍於鹽水中用於製造罐頭食品的全魚可以保存在不高於-9°C的溫度。
3. Fishery products kept alive must be kept at a temperature and in a manner that does not adversely affect food safety or their viability.	要維持活的狀態的水產品，必須以不會對食品安全或其活力有不利影響的溫度和方式保存。
CHAPTER VIII: TRANSPORT OF FISHERY PRODUCTS	第VIII章 水產品之運輸
Food business operators transporting fishery products must ensure compliance with the following requirements.	水產品運輸FBOs必須確保符合下列要求：
1. During transport, fishery products must be maintained at the required temperature. In particular:	在運輸期間，水產品必須維持在要求的溫度，特別是：
(a) fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice;	生鮮水產品、解凍未加工水產品和甲殼類及軟體動物之煮熟冷藏產品，必須保持在接近融冰溫度下；
▼ M9	
(b) frozen fishery products, with the exception of whole fish initially frozen in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than -18°C in all parts of the product, possibly with short upward fluctuations of not more than 3°C. ◀M9	除了最初凍於鹽水中用於製造罐頭食品的全魚外，冷凍水產品必須在運輸期間維持產品所有部分在不高於-18°C的均衡溫度，可能的短暫向上波動不超過3°C。
2. Food business operators need not comply with point 1(b) when frozen fishery products are transported from a cold store to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing, if the journey is short and the competent authority so permits.	當冷凍水產品是由冷庫運送至核可廠場，若行程短且權責機關准允，為利進行到達後之製備和/或加工

	目的而進行的解凍，FBOs不需要符合第1(b)點的要求。
3. If fishery products are kept under ice, melt water must not remain in contact with the products.	若水產品以覆冰保存，融水不得持續與產品接觸。
4. Fishery products to be placed on the market live must be transported in such a way as not adversely to affect food safety or their viability.	以活體上市的水產品必須以不會對食品安全或其活力有不利影響的方式運送。
▼ M3	
SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS	第IX節：生乳、初乳、乳製品和初乳製品
For the purpose of this Section,	(略，適用本節目的的名詞定義)
1. 'Colostrum' means the fluid secreted by the mammary glands of milk-producing animals up to three to five days post parturition that is rich in antibodies and minerals, and precedes the production of raw milk.	(略，初乳是指分娩後3-5天富含抗體和礦物質之液體)
2. 'Colostrum-based products' means processed products resulting from the processing of colostrum or from the further processing of such processed products.	(略，初乳製品)
CHAPTER I: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION	第I章：生乳和初乳—初級生產
Food business operators producing or, as appropriate, collecting raw milk and colostrum must ensure compliance with the requirements laid down in this Chapter.	生產或收集生乳和初乳的FBOs必須確保符合本章下列要求：
I. HEALTH REQUIREMENTS FOR RAW MILK AND COLOSTRUM PRODUCTION	生乳和初乳生產之衛生要求
1. Raw milk and colostrum must come from animals:	(略，產乳動物健康要求)
(a) that do not show any symptoms of infectious diseases communicable to humans through milk and colostrum;	(略，無傳染人之病徵)
(b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;	(略，無污染生乳或初乳之疾病，如生殖道感染、痢疾或乳房炎等)
(c) that do not have any udder wound likely to affect the milk and colostrum;	(略，無乳房傷口)
(d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC;	(略，無非法用藥或處理)
(e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.	(略，遵守用藥停藥期規定)
2. (a) In particular, as regards brucellosis, raw milk and colostrum must come from:	(略，針對布氏桿菌症之乳源要求)
(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC ⁴¹ , is free or officially free of brucellosis;	
(ii) sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC ⁴² ; or	
(iii) females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.	
(b) As regards tuberculosis, raw milk and colostrum must come from:	(略，針對結核病之乳源要求)

41 Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 21, 29.7.1964, p. 1977/64). Directive as last amended by Regulation (EC) No 21/2004 (OJ L 5, 9.1.2004, p. 8).

42 Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Commission Decision 2005/932/EC.

(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis; or	
(ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under a control plan that the competent authority has approved.	
(c) If goats are kept together with cows, such goats must be inspected and tested for tuberculosis.	(略，牛羊共養須檢查羊之結核病)
3. However, raw milk from animals that does not meet the requirements of point 2 may be used with the authorisation of the competent authority:	(略，權責機關許可之前點例外情形)
(a) in the case of cows or buffaloes that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the alkaline phosphatase test;	(略，畜體疾病測試非陽性、無病徵，乳品經熱處理後之鹼性磷酸酶測試為陰性)
(b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, either:	(略，畜體疾病測試非陽性或已接種疫苗、無病徵)
(i) for the manufacture of cheese with a maturation period of at least two months; or	(略，用於熟成期至少2個月之乳酪製造)
(ii) after having undergone heat treatment such as to show a negative reaction to the alkaline phosphatase test; and	(略，經熱處理後之鹼性磷酸酶測試為陰性)
(c) in the case of females of other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks referred to in point 2(a)(iii) or 2(b)(ii), if treated to ensure its safety.	(略，若經處理已確認安全者)
4. Raw milk and colostrum from any animal not complying with the appropriate requirements of points 1 to 3, and in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC, must not be used for human consumption.	(略，不符合前3點者，不得供人食用)
5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 must be effective to avoid any adverse effect on other animals' milk and colostrum.	(略，染病動物要有效隔離)
II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS	
A. Requirements for premises and equipment	
對乳和初乳生產控股公司之衛生	
場所和設備之要求	
1. Milking equipment and premises where milk and colostrum are stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk and colostrum.	(略，擠乳設備和場所要能避免乳受到污染之風險)
2. Premises for the storage of milk and colostrum must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.	(略，對儲存場所之要求)
3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.	(略，接觸設備表面易於清潔之要求)
4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of milk and colostrum must be cleaned and disinfected in an appropriate manner before re-use.	(略，使用後之清潔及消毒要求)
B. Hygiene during milking, collection and transport	
擠乳、集乳和運輸之衛生	
1. Milking must be carried out hygienically, ensuring in particular:	(略)

(a) that, before milking starts, the teats, udder and adjacent parts are clean;	
(b) that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption;	
(c) that milk and colostrum from animals showing clinical signs of udder disease are not used for human consumption otherwise than in accordance with the instructions of a veterinarian;	
(d) the identification of animals undergoing medical treatment likely to transfer residues to the milk and colostrum, and that milk and colostrum obtained from such animals before the end of the prescribed withdrawal period are not used for human consumption; and	
(e) that teat dips or sprays are used only after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁴³ ;	
(f) that colostrum is milked separately and not mixed together with raw milk.	
2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination.	(略)
(a) Milk must be cooled immediately to not more than 8°C in the case of daily collection, or not more than 6°C if collection is not daily;	(略，每天收集之乳要立即冷卻至8°C以下，非每日收集的要6°C以下)
(b) Colostrum must be stored separately and immediately cooled to not more than 8°C in the case of daily collection, or not more than 6°C if collection is not daily, or frozen.	(略)
3. During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk and the colostrum must not be more than 10°C.	(略，要冷鏈運輸，且到達目的廠場時不得超過10°C)
4. Food business operators need not comply with the temperature requirements laid down in points 2 and 3 if the milk meets the criteria provided for in Part III and either:	(略，免除前2點溫度要求之情形)
(a) the milk is processed within two hours of milking; or	(略，在擠乳後2小時內進行加工)
(b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.	(略，較高溫度之製造且獲權責機關准許)
C. Staff hygiene	員工衛生
1. Persons performing milking and/or handling raw milk and colostrum must wear suitable clean clothes.	(略，乾淨之服裝)
2. Persons performing milking must maintain a high degree of personal cleanliness. Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk and colostrum to wash their hands and arms.	(略，個人清潔、洗手及臂之設施)
III. CRITERIA FOR RAW MILK AND COLOSTRUM	生乳和初乳之基準
1. (a) The following criteria for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and dairy products.	(略，在具體的品質法規建立前，適用下列基準)
(b) National criteria for colostrum, as regards plate count, somatic cell count or antibiotic residues, apply pending the establishment of specific Community legislation.	(略，在具體的歐盟法規建立前，適用平板計數、體細胞計數或抗生素殘留等國家基準)
2. A representative number of samples of raw milk and colostrum collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4 in case of raw milk and with the existing national criteria referred to in point 1(b) in case of colostrum. The checks may be carried	(略，隨機抽取具代表性樣品檢查，及檢查人員身分要求)

43 OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2006/50/EC (OJ L 142, 30.5.2006, p. 6).

out by, or on behalf of:					
(a) the food business operator producing the milk;	(略，生產業者)				
(b) the food business operator collecting or processing the milk;	(略，集乳或加工業者)				
(c) a group of food business operators; or	(略，一群業者(?))				
(d) in the context of a national or regional control scheme.	(略，列於國家或區域計畫者)				
3. (a) Food business operators must initiate procedures to ensure that raw milk meets the following criteria:	(略，FBOs應確保生乳符合之基準)				
(i) for raw cows' milk:					
<table border="1"> <tr> <td>Plate count at 30°C (per ml)</td> <td>≤ 100 000 (*)</td> </tr> <tr> <td>Somatic cell count (per ml)</td> <td>≤ 400 000 (**)</td> </tr> </table>	Plate count at 30°C (per ml)	≤ 100 000 (*)	Somatic cell count (per ml)	≤ 400 000 (**)	
Plate count at 30°C (per ml)	≤ 100 000 (*)				
Somatic cell count (per ml)	≤ 400 000 (**)				
(*) Rolling geometric average over a two-month period, with at least two samples per month.					
(**) Rolling geometric average over a three-month period, with at least one sample per month, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.	(略，*每個月至少2個樣品之2個月區間的滾動式幾何平均值；**每個月至少1個樣品之3個月區間的滾動式幾何平均值，權責機關指定情形為例外。)				
(ii) for raw milk from other species:					
<table border="1"> <tr> <td>Plate count at 30 °C (per ml)</td> <td>≤ 1 500 000 (*)</td> </tr> </table>	Plate count at 30 °C (per ml)	≤ 1 500 000 (*)			
Plate count at 30 °C (per ml)	≤ 1 500 000 (*)				
(*) Rolling geometric average over a two-month period, with at least two samples per month.					
(b) However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following criterion:	(略，牛以外物種且用作產品加工之生乳要求)				
<table border="1"> <tr> <td>Plate count at 30 °C (per ml)</td> <td>≤ 500 000 (*)</td> </tr> </table>	Plate count at 30 °C (per ml)	≤ 500 000 (*)			
Plate count at 30 °C (per ml)	≤ 500 000 (*)				
(*) Rolling geometric average over a two-month period, with at least two samples per month.					
4. Without prejudice to Directive 96/23/EC, food business operators must initiate procedures to ensure that raw milk is not placed on the market if either:	(略，FBOs應確保不符合抗生素殘留限量標準之生乳不會進入市場)				
(a) it contains antibiotic residues in a quantity that, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90 ⁴⁴ , exceeds the levels authorised under that Regulation; or					
(b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.					
5. When raw milk fails to comply with point 3 or 4, the food business operator must inform the competent authority and take measures to correct the situation.	(略，FBOs對不合規產品之通報義務)				
CHAPTER II: REQUIREMENTS CONCERNING DAIRY AND COLOSTRUM-BASED PRODUCTS	第II章：關於乳製品和初乳製品之要求				
I. TEMPERATURE REQUIREMENTS	溫度要求				
1. Food business operators must ensure that, upon acceptance at a processing establishment,	(略，加工廠接收原料之溫度要求)				
(a) milk is quickly cooled to not more than 6°C;					
(b) colostrum is quickly cooled to not more than 6°C or maintained frozen, and kept at that temperature until processed.					
2. However, food business operators may keep milk and colostrum at a higher temperature if:	(略，可有較高溫度之特定情況)				
(a) processing begins immediately after milking, or within four hours of acceptance at the processing establishment; or					
(b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy or colostrum-based products.					

⁴⁴ 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 origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 1231/2006 (OJ L 225, 17.8.2006, p. 3).

<p>II. REQUIREMENTS FOR HEAT TREATMENT</p>	<p>熱處理之要求</p>
<p>1. When raw milk, colostrum, dairy or colostrum-based products undergo heat treatment, food business operators must ensure that this satisfies the requirements laid down in Chapter XI of Annex II to Regulation (EC) No 852/2004. In particular, they shall ensure, when using the following processes, that they comply with the specifications mentioned:</p>	<p>(略，FBOs應確認之熱處理規定及要求)</p>
<p>(a) Pasteurisation is achieved by a treatment involving:</p>	<p>(略，巴氏殺菌處理條件)</p>
<p>(i) a high temperature for a short time (at least 72 °C for 15 seconds);</p>	
<p>(ii) a low temperature for a long time (at least 63 °C for 30 minutes); or</p>	
<p>(iii) any other combination of time-temperature conditions to obtain an equivalent effect,</p>	
<p>such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment.</p>	<p>(略，處理後之鹼性磷酸酶測試為陰性)</p>
<p>(b) Ultra high temperature (UHT) treatment is achieved by a treatment:</p>	<p>(略，超高溫-UHT處理條件)</p>
<p>(i) involving a continuous flow of heat at a high temperature for a short time (not less than 135 °C in combination with a suitable holding time) such that there are no viable microorganisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature, and</p>	<p>(略，要無菌包裝可室溫保存)</p>
<p>(ii) sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30 °C in closed containers or for seven days at 55 °C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.</p>	<p>(略，保存試驗條件及要求)</p>
<p>2. When considering whether to subject raw milk and colostrum to heat treatment, food business operators must:</p>	<p>(略，FBOs應知道熱處理相關的法規及要求)</p>
<p>(a) have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No 852/2004; and</p>	
<p>(b) comply with any requirements that the competent authority may impose in this regard when approving establishments or carrying out checks in accordance with Regulation (EC) No 854/2004.</p>	
<p>III. CRITERIA FOR RAW COWS' MILK ◀M3</p>	<p>生牛乳之基準</p>
<p>▼ M6</p>	
<p>1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before being heat treated and if its period of acceptance specified in the HACCP-based procedures is exceeded:</p>	<p>(略，乳製品製造業者須確保事項)</p>
<p>(a) raw cows' milk used to prepare dairy products has a plate count at 30 °C of less than 300 000 per ml; and</p>	
<p>(b) heat treated cows' milk used to prepare dairy products has a plate count at 30 °C of less than 100 000 per ml. ◀M6</p>	
<p>▼ M3</p>	
<p>2. When milk fails to meet the criteria laid down in paragraph 1, the food business operator must inform the competent authority and take measures to correct the situation.</p>	<p>(略，FBOs對不合規產品之通報義務)</p>
<p>CHAPTER III: WRAPPING AND PACKAGING</p>	<p>第三章：內外包裝</p>
<p>Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products and colostrum-based products, takes place by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check.</p>	<p>(略，充填-殺菌-密封，以及密封系統之要求)</p>
<p>CHAPTER IV: LABELLING</p>	<p>第四章：標示</p>

1. In addition to the requirements of Directive 2000/13/EC, except in the cases envisaged in Article 13(4) and (5) of that Directive, labelling must clearly show:	(略，標示規定及用字要求)
(a) in the case of raw milk intended for direct human consumption, the words 'raw milk';	
(b) in the case of products made with raw milk, the manufacturing process for which does not include any heat treatment or any physical or chemical treatment, the words 'made with raw milk';	
(c) in case of colostrum, the word 'colostrum';	
(d) in case of products made with colostrum, the words 'made with colostrum'.	
2. The requirements of paragraph 1 apply to products destined for retail trade. The term 'labelling' includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.	(略，標示呈現之型式)
CHAPTER V: IDENTIFICATION MARKING	第V章：識別標記
By way of derogation from the requirements of Annex II, Section I:	免除附錄II第I節要求之情況：
1. rather than indicating the approval number of the establishment, the identification mark may include a reference to where on the wrapping or packaging the approval number of the establishment is indicated;	(略，可以包括核准號碼廠場之所在地)
2. in the case of the reusable bottles, the identification mark may indicate only the initials of the consigning country and the approval number of the establishment. ◀M3	(略，再使用瓶身的識別標記要求)
SECTION X: EGGS AND EGG PRODUCTS	第X節：蛋及蛋製品
CHAPTER I: EGGS	第I章：蛋
1. At the producer's premises, and until sale to the consumer, eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine.	從蛋場到消費者，要保持蛋的清潔、乾燥、無異味，並避免震盪和陽光直曬。
▼ M6	
2. Eggs must be stored and transported until sale to the final consumer at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties, unless the competent authority imposes national temperature requirements for egg storage facilities and for vehicles transporting eggs between such storage facilities. ◀M6	(略，儲存和運輸的條件要求)
3. Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying.	(略，產蛋21天內完成銷售的要求)
CHAPTER II: EGG PRODUCTS	第II章：蛋產品
I. REQUIREMENTS FOR ESTABLISHMENTS	對加工廠之要求
Food business operators must ensure that establishments for the manufacture of egg products are constructed, laid out and equipped so as to ensure separation of the following operations:	(略，廠場結構、設計和設備要確保下列作業的區隔)
1. washing, drying and disinfecting dirty eggs, where carried out;	進行髒蛋清洗、乾燥和消毒場所；
2. breaking eggs, collecting their contents and removing parts of shells and membranes;	打破蛋、收集液體蛋和移除蛋殼及膜；
and	
3. operations other than those referred to in points 1 and 2.	上2點以外的作業。
II. RAW MATERIALS FOR THE MANUFACTURE OF EGG PRODUCTS	用於製造蛋產品的原料
Food business operators must ensure that raw materials used to manufacture egg products comply with the following requirements.	(略)

▼ M6	
1. The shells of eggs used in the manufacture of egg products must be fully developed and contain no breaks. However, cracked eggs may be used for the manufacture of liquid egg or egg products if the establishment of production or a packing centre delivers them directly to an establishment approved for the manufacture of liquid egg or a processing establishment, where they must be broken as soon as possible. ◀M6	(略)
2. Liquid egg obtained in an establishment approved for that purpose may be used as raw material. Liquid egg must be obtained in accordance with the requirements of points 1, 2, 3, 4 and 7 of Part III.	(略)
III. SPECIAL HYGIENE REQUIREMENTS FOR THE MANUFACTURE OF EGG PRODUCTS	蛋產品製造之特殊衛生要求
Food business operators must ensure that all operations are carried out in such a way as to avoid any contamination during production, handling and storage of egg products, in particular by ensuring compliance with the following requirements.	(略)
1. Eggs must not be broken unless they are clean and dry.	(略，除非乾淨及乾燥，不得破蛋)
2. Eggs must be broken in a manner that minimises contamination, in particular by ensuring adequate separation from other operations. Cracked eggs must be processed as soon as possible.	(略，破蛋方式的要求)
3. Eggs other than those of hens, turkeys or guinea fowl must be handled and processed separately. All equipment must be cleaned and disinfected before processing of hens', turkeys' and guinea fowls' eggs is resumed.	(略，母雞、火雞或珍珠雞蛋與其他要區隔處理之要求)
4. Egg contents may not be obtained by the centrifuging or crushing of eggs, nor may centrifuging be used to obtain the remains of egg whites from empty shells for human consumption.	(略，不得用離心或壓碎方式取得液蛋或殘餘蛋清)
▼ M1	
5. After breaking, each particle of the liquid egg must undergo processing as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level. A batch that has been insufficiently processed may immediately undergo processing again in the same establishment if this processing renders it fit for human consumption. Where a batch is found to be unfit for human consumption, it must be denatured to ensure that it is not used for human consumption. ◀M1	(略，液蛋處理之衛生要求)
6. Processing is not required for egg white intended for the manufacture of dried or crystallised albumin destined subsequently to undergo heat treatment.	(略，用作乾燥或結晶白蛋白之蛋清不需要進行加工)
7. If processing is not carried out immediately after breaking, liquid egg must be stored either frozen or at a temperature of not more than 4 °C. The storage period before processing at 4 °C must not exceed 48 hours. However, these requirements do not apply to products to be de-sugared, if de-sugaring process is performed as soon as possible.	(略，液蛋的儲存溫度及時間要求)
8. Products that have not been stabilised so as to be kept at room temperature must be cooled to not more than 4 °C. Products for freezing must be frozen immediately after processing.	(略，非室溫保存產品之溫度要求)
IV. ANALYTICAL SPECIFICATIONS	分析規格
1. The concentration of 3-OH-butyric acid must not exceed 10 mg/kg in the dry matter of the unmodified egg product.	(略，3-OH-丁酸限量值)
2. The lactic acid content of raw material used to manufacture egg products must not exceed 1 g/kg of dry matter. However, for fermented products, this value must be the one recorded before the fermentation process.	(略，乳酸限量值)
3. The quantity of eggshell remains, egg membranes and any other particles in the processed egg product must not exceed 100 mg/kg of egg product.	(略，殘留蛋殼等顆粒限量值)
V. LABELLING AND IDENTIFICATION MARKING	標示和識別標記
1. In addition to the general requirements for identification marking laid down in Annex II, Section I, consignments of egg products, destined not for retail but for use as an ingredient in the manufacture of another product, must have a label	(略，除一般要求外，供作其他產品成分非零售之蛋產品貨物，須有

giving the temperature at which the egg products must be maintained and the period during which conservation may thus be assured.	該蛋產品應維持溫度及保存期間之標籤)
▼ M1	
2. In the case of liquid egg, the label referred to in point 1 must also bear the words: 'non-pasteurised liquid egg — to be treated at place of destination' and indicate the date and hour of breaking. ◀M1	(略，前點所指標籤對液蛋還要加註文字及標明破蛋日期和時間)
SECTION XI: FROGS' LEGS AND SNAILS	第XI節：蛙腿和蝸牛
Food business operators preparing frogs' legs or snails for human consumption must ensure compliance with the following requirements.	(略)
1. Frogs and snails must be killed in an establishment constructed, laid out and equipped for that purpose.	(略，場所之專用要求)
2. Establishment in which frogs' legs are prepared must have a room reserved for the storage and washing of live frogs, and for their slaughter and bleeding. This room must be physically separate from the preparation room.	(略，作業區隔要求)
3. Frogs and snails that die otherwise than by being killed in the establishment must not be prepared for human consumption.	(略，非人工屠宰者禁供人食用)
4. Frogs and snails must be subjected to an organoleptic examination carried out by sampling. If that examination indicates that they might present a hazard, they must not be used for human consumption.	(略，官能檢查要求)
5. Immediately following preparation, frogs' legs must be washed fully with running potable water and immediately chilled to a temperature approaching that of melting ice, frozen or processed.	(略，流動飲用水清洗及溫度要求)
6. After killing, snails' hepato-pancreas must, if it might present a hazard, be removed and not be used for human consumption.	(略，要去除蝸牛的肝胰腺)
▼ M23	
7. The requirements laid down in points 1, 3, 4 and 6, also apply to any other snails of the Family of <i>Helicidae</i> , <i>Hygromiidae</i> or <i>Sphincterochilidae</i> , when intended for human consumption.	(略，特定科屬之適用要求)
8. The requirements laid down in points 1 to 5 also apply to frogs' legs of the genus <i>Pelophylax</i> from the Family of <i>Ranidae</i> , and the genus <i>Fejervarya</i> , <i>Limnonectes</i> and <i>Hoplobatrachus</i> from the Family of <i>Dicroglossidae</i> , when intended for human consumption. ◀M23	
SECTION XII: RENDERED ANIMAL FATS AND GREAVES	第XII節：提煉之動物脂肪和脂渣
CHAPTER I: REQUIREMENTS APPLICABLE TO ESTABLISHMENTS COLLECTING OR PROCESSING RAW MATERIALS	第I章：適用於收集或原料加工廠場之要求
Food business operators must ensure that establishments collecting or processing raw materials for the production of rendered animal fats and greaves comply with the following requirements.	(略)
1. Centres for the collection of raw materials and further transport to processing establishments must be equipped with facilities for the storage of raw materials at a temperature of not more than 7°C.	(略，原料要存於7°C以下之要求)
2. Each processing establishment must have:	(略，脂肪加工廠之設備要求)
(a) refrigeration facilities;	
(b) a dispatch room, unless the establishment dispatches rendered animal fat only in tankers;	
and	
(c) if appropriate, suitable equipment for the preparation of products consisting of rendered animal fats mixed with other foodstuffs and/or seasonings.	
3. However, the refrigeration facilities required under points 1 and 2(a) are not necessary if the arrangements for the supply of raw materials ensure that they are never stored or transported without active refrigeration otherwise than as provided for in Chapter II, point 1(d).	(略，前2點冷藏設備之除外規定)

<p>CHAPTER II: HYGIENE REQUIREMENTS FOR THE PREPARATION OF RENDERED ANIMAL FAT AND GREAVES</p>	<p>第二章：製備提煉動物脂肪和脂渣之衛生要求</p>																																																									
<p>Food business operators preparing rendered animal fats and greaves must ensure compliance with the following requirements.</p>	<p>(略)</p>																																																									
<p>1. Raw materials must:</p>	<p>(略，原料來源要求)</p>																																																									
<p>(a) derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;</p>																																																										
<p>(b) consist of adipose tissues or bones, which are reasonably free from blood and impurities;</p>																																																										
<p>(c) come from establishments registered or approved pursuant to Regulation (EC) No 852/2003 or in accordance with this Regulation;</p>																																																										
<p>and</p>																																																										
<p>(d) be transported, and stored until rendering, in hygienic conditions and at an internal temperature of not more than 7 °C. However, raw materials may be stored and transported without active refrigeration if rendered within 12 hours after the day on which they were obtained.</p>																																																										
<p>2. During rendering the use of solvents is prohibited.</p>	<p>(略，禁止使用溶劑來提煉)</p>																																																									
<p>3. When the fat for refining meets the standards laid down in point 4, rendered animal fat prepared in accordance with points 1 and 2 may be refined in the same establishment or in another establishment with a view to improving its physico-chemical quality.</p>	<p>(略，可在同一廠場進行精煉脂肪之條件)</p>																																																									
<p>4. Rendered animal fat, depending on type, must meet the following standards:</p>	<p>(略，提煉動物脂肪應符合之標準)</p>																																																									
<table border="1"> <thead> <tr> <th rowspan="3"></th> <th colspan="3">Ruminants</th> <th colspan="3">Porcine animals</th> <th colspan="2">Other animal fat</th> </tr> <tr> <th colspan="2">Edible tallow</th> <th rowspan="2">Tallow for refining</th> <th colspan="2">Edible fat</th> <th rowspan="2">Lard and other fat for refining</th> <th rowspan="2">Edible</th> <th rowspan="2">For refining</th> </tr> <tr> <th>Premier jus⁽¹⁾</th> <th>Other</th> <th>Lard⁽²⁾</th> <th>Other</th> </tr> </thead> <tbody> <tr> <td>FFA (m/m % oleic acid) maximum</td> <td>0.75</td> <td>1.25</td> <td>3.0</td> <td>0.75</td> <td>1.25</td> <td>2.0</td> <td>1.25</td> <td>3.0</td> </tr> <tr> <td>Peroxide maximum</td> <td>4 meq/kg</td> <td>4 meq/kg</td> <td>6 meq/kg</td> <td>4 meq/kg</td> <td>4 meq/kg</td> <td>6 meq/kg</td> <td>4 meq/kg</td> <td>10 meq/kg</td> </tr> <tr> <td>Total insoluble impurities</td> <td colspan="3">Maximum 0.15 %</td> <td colspan="3">Maximum 0.5 %</td> <td colspan="2"></td> </tr> <tr> <td>Odour, taste, colour</td> <td colspan="8">Normal</td> </tr> </tbody> </table> <p>(1) Rendered animal fat obtained by low-temperature rendering of fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms. (2) Rendered animal fat obtained from the adipose tissues of porcine animals.</p>		Ruminants			Porcine animals			Other animal fat		Edible tallow		Tallow for refining	Edible fat		Lard and other fat for refining	Edible	For refining	Premier jus ⁽¹⁾	Other	Lard ⁽²⁾	Other	FFA (m/m % oleic acid) maximum	0.75	1.25	3.0	0.75	1.25	2.0	1.25	3.0	Peroxide maximum	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	10 meq/kg	Total insoluble impurities	Maximum 0.15 %			Maximum 0.5 %					Odour, taste, colour	Normal								<p>(略，依反芻動物、豬及其他動物類型區分FFA、過氧化物、總不溶性雜質、氣味/味道/色澤等標準)</p>
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<p>▼ M23</p>																																																										
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<p>SECTION XIII: TREATED STOMACHS, BLADDERS AND INTESTINES</p>	<p>第XIII節：處理過的胃、膀胱和腸</p>																																																									
<p>Food business operators treating stomachs, bladders and intestines must ensure compliance with the following requirements.</p>	<p>(略)</p>																																																									
<p>1. Animal intestines, bladders and stomachs may be placed on the market only if:</p>																																																										
<p>(a) they derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;</p>																																																										
<p>(b) they are salted, heated or dried;</p>																																																										
<p>and</p>																																																										
<p>(c) after the treatment referred to in (b), effective measures are taken to prevent re-contamination.</p>																																																										
<p>2. Treated stomachs, bladders and intestines that cannot be kept at ambient temperature must be stored chilled using facilities intended for that purpose until their dispatch. In particular, products that are not salted or dried must be kept at a temperature of not more than 3 °C.</p>																																																										

SECTION XIV: GELATINE	第XIV節：明膠
1. Food business operators manufacturing gelatine must ensure compliance with the requirements of this section.	(略)
2. For the purpose of this section, 'tanning' means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.	(略，鞣製定義)
CHAPTER I: REQUIREMENTS FOR RAW MATERIALS	
1. For the production of gelatine intended for use in food, the following raw materials may be used:	(略)
▼ M9	
(a) bones, other than specified risk materials as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 of the European Parliament and of the Council ⁴⁵ ; ◀M9	(略，骨頭)
(b) hides and skins of farmed ruminant animals;	(略，畜養反芻動物的皮)
(c) pig skins;	(略，豬皮)
(d) poultry skin;	(略，禽皮)
(e) tendons and sinews;	(略，肌腱)
(f) wild game hides and skins;	(略，野生動物的皮)
and	
(g) fish skin and bones.	(略，魚皮和骨頭)
2. The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed.	(略，禁止使用經鞣製的皮)
3. Raw materials listed in point 1(a) to (e) must derive from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante-mortem and post-mortem inspection or, in the case of hides and skins from wild game, found fit for human consumption.	(略，第1點原料來源要求)
▼ M18	
4. (a) Raw materials that have not undergone any preserving treatment other than chilling, freezing or quick-freezing must come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation,	(略，原料來源廠場之要求)
(b) The following treated raw materials may be used:	(略，可使用經過處理原料之條件)
(i) bones other than specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 coming from establishments under the control of and listed by the competent authority, and that have been subjected to one of the following treatments:	
— crushed to pieces of approximately 15 mm and degreased with hot water at a temperature of minimum 70°C for at least 30 minutes, minimum 80°C for at least 15 minutes, or minimum 90°C for at least 10 minutes, and then separated and subsequently washed and dried for at least 20 minutes in a stream of hot air with an initial temperature of minimum 350°C, or for 15 minutes in a stream of hot air with an initial temperature of more than 700°C,	
— sun-dried for a minimum of 42 days at an average temperature of at least 20°C,	
— acid treatment such that the pH is maintained at less than 6 to the core for at least 1 hour before drying;	
(ii) hides and skins of farmed ruminant animals, pig skins, poultry skins and wild game hides and skins coming from establishments under the control of and	

45 OJ L 147, 31.5.2001, p 1.

<p>listed by the competent authority, and that have been subjected to one of the following treatments:</p> <ul style="list-style-type: none"> — treatment with alkali to establish a pH > 12 to the core followed by salting for at least 7 days, — drying for at least 42 days at a temperature of at least 20°C, — acid treatment such that the pH is maintained at less than 5 to the core for a minimum of 1 hour, — alkali treatment throughout at a pH > 12 for at least 8 hours; 	
<p>(iii) bones other than specified risk material defined in Article 3(1)(g) of Regulation (EC) No 999/2001, hides and skins of farmed ruminant animals, pig skins, poultry skins, fish hides and wild game hides and skins that have undergone any other treatment than those specified in point (i) or (ii) and that come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation.</p>	
<p>For the purposes of the first 2 indents of point (b)(ii), the duration of the treatments may include the time of transportation.</p>	
<p>The treated raw materials referred to in points (b)(i) and (b)(ii) must be derived from:</p> <ul style="list-style-type: none"> — domestic and farmed ruminant animals, pigs and poultry which have been slaughtered in a slaughterhouse and the carcasses of which have been found fit for human consumption following ante- and post-mortem inspection, or — from killed wild game whose carcasses have been found fit for human consumption following post-mortem inspection. ◀M18 	
<p>5. Collection centres and tanneries may also supply raw material for the production of gelatine intended for human consumption if the competent authority specifically authorises them for this purpose and they fulfil the following requirements.</p>	<p>(略，收集中心及製革廠可提供明膠原料之條件要求)</p>
<p>(a) They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.</p>	
<p>(b) The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.</p>	
<p>(c) If raw material not in conformity with this chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this chapter throughout the period of receipt, storage, processing and dispatch.</p>	
<p>CHAPTER II: TRANSPORT AND STORAGE OF RAW MATERIALS</p>	<p>第II章：原料之運輸和儲存</p>
<p>1. In place of the identification mark provided for in Annex II, Section I, a document indicating the establishment of origin and containing the information set out in the Appendix to this Annex must accompany raw materials during transport, when delivered to a collection centre or tannery and when delivered to the gelatine-processing establishment.</p>	<p>(略，附錄II第I節規定之識別標記得以文件替代之情況)</p>
<p>2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.</p>	<p>(略，溫度要求)</p>
<p>▼ M18</p>	
<p>3. After the veterinary checks provided for in Directive 97/78/EC, and without prejudice to the conditions laid down in Article 8(4) of that Directive, raw materials for the production of gelatine for human consumption, for which animal health certification is required, must be transported directly to the establishment at the place of destination.</p>	<p>(略，必須要有動物健康證明之要求及相關疾病傳播之預防措施)</p>
<p>All precautions, including safe disposal of animal by-products, waste, unused or surplus material, shall be taken to avoid risks of spreading diseases to animals. ◀M18</p>	
<p>▼ M5</p>	

CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF GELATINE	第三章：對明膠製造之要求																				
1. The production process for gelatine must ensure that:	(略，BSE的風險控制)																				
(a) all ruminant bone material derived from animals born, reared or slaughtered in countries or regions with a controlled or undetermined BSE risk in accordance with Community legislation is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4 % and pH < 1,5) over a period of at least two days. This treatment is followed either by:																					
— an alkaline treatment of saturated lime solution (pH > 12,5) for a period of at least 20 days with a heat treatment step of 138 °C minimum during at least four seconds, or																					
— an acid treatment (pH < 3,5) during 10 hours minimum with a heat treatment step of 138 °C minimum during at least four seconds, or																					
— a heat-and-pressure process for at least 20 minutes with saturated steam of 133 °C at more than 3 bars, or																					
— any approved equivalent process;																					
(b) other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or more times in succession, followed by purification by means of filtration and heat treatment.																					
2. A food business operator may produce and store both gelatine intended for human consumption and gelatine not intended for human consumption in the same establishment provided that the raw materials and the production process comply with the requirements applying to gelatine intended for human consumption. ◀M5	(略，在同一場所生產和儲存供人 和非供人食用明膠之條件)																				
▼M18																					
CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS	第四章：對成品之要求																				
Food business operators must ensure that gelatine complies with the residue limits set out in the following table.	(略，各殘留物之限量值)																				
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▲M18																					
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CHAPTER V: LABELLING	第五章：標示																				
Wrapping and packaging containing gelatine must bear the words 'gelatine fit for human consumption' and must indicate the date of minimum durability. ◀M5	(略，內外包裝用字及保存期要求)																				
SECTION XV: COLLAGEN	第XV節：膠原蛋白																				
▼M18																					
1. Food business operators manufacturing collagen must ensure compliance with the requirements of this section. Without prejudice to other provisions, products derived from collagen must be made from collagen which complies with the requirements of this section. ◀M18	(略)																				
2. For the purpose of this section, 'tanning' means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.	(略)																				

CHAPTER I: REQUIREMENTS FOR RAW MATERIALS	第 I 章：對原料之要求
▼ M9	
1. For the production of collagen intended for use in food, the following raw materials may be used:	(略)
(a) bones, other than specified risk materials as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;	
(b) hides and skins of farmed ruminant animals;	
(c) pig skins;	
(d) poultry skin;	
(e) tendons and sinews;	
(f) wild game hides and skins; and	
(g) fish skin and bones. ◀ M9	
2. The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed.	(略)
3. Raw materials listed in point 1(a) to (d) must derive from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante-and post-mortem inspection or, in the case of hides and skins from wild game, found fit for human consumption.	(略)
▼ M18	
4. (a) Raw materials that have not undergone any preserving treatment other than chilling, freezing or quick-freezing must come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation.	(略)
(b) The following treated raw materials may be used:	
(i) bones other than specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 coming from establishments under the control of and listed by the competent authority, and that have been subjected to one of the following treatments:	
— crushed to pieces of approximately 15 mm and degreased with hot water at a temperature of minimum 70 °C for at least 30 minutes, minimum 80 °C for at least 15 minutes, or minimum 90 °C for at least 10 minutes, and then separated and subsequently washed and dried for at least 20 minutes in a stream of hot air with an initial temperature of minimum 350 °C, or for 15 minutes in a stream of hot air with an initial temperature of more than 700 °C,	
— sun-dried for a minimum of 42 days at an average temperature of at least 20 °C,	
— acid treatment such that the pH is maintained at less than 6 to the core for at least 1 hour before drying;	
(ii) hides and skins of farmed ruminant animals, pig skins, poultry skins and wild game hides and skins coming from establishments under the control of and listed by the competent authority, and that have been subjected to one of the following treatments:	
— treatment with alkali to establish a pH > 12 to the core followed by salting for at least 7 days,	
— drying for at least 42 days at a temperature of at least 20 °C,	
— acid treatment such that the pH is maintained at less than 5 to the core for a minimum of 1 hour,	
— alkali treatment throughout at a pH > 12 for at least 8 hours;	
(iii) bones other than specified risk material defined in Article 3(1)(g) of Regulation (EC) No 999/2001, hides and skins of farmed ruminant animals, pig skins, poultry skins, fish hides and wild game hides and skins that have undergone any other treatment than those specified in point (i) or (ii) and that come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation.	

For the purposes of the first 2 indents of point (b)(ii), the duration of the treatments may include the time of transportation.	
The treated raw materials referred to in point (b) must be derived from:	
— domestic and farmed ruminant animals, pigs and poultry which have been slaughtered in a slaughterhouse and the carcasses of which have been found fit for human consumption following ante- and post-mortem inspection, or	
— from killed wild game whose carcasses have been found fit for human consumption following post-mortem inspection. ◀M18	
5. Collection centres and tanneries may also supply raw material for the production of collagen intended for human consumption if the competent authority specifically authorises them for this purpose and they fulfil the following requirements.	(略)
(a) They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.	
(b) The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.	
(c) If raw material not in conformity with this chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this chapter throughout the period of receipt, storage, processing and dispatch.	
CHAPTER II: TRANSPORT AND STORAGE OF RAW MATERIALS	第二章：原料之運輸和儲存
1. In place of the identification mark provided for in Annex II, Section I, a document indicating the establishment of origin and containing the information set out in the Appendix to this Annex must accompany raw materials during transport, when delivered to a collection centre or tannery and when delivered to the collagen-processing establishment.	(略)
2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.	(略)
▼M18	
3. After the veterinary checks provided for in Directive 97/78/EC, and without prejudice to the conditions laid down in Article 8(4) of that Directive, raw materials for the production of collagen for human consumption, for which animal health certification is required, must be transported directly to the establishment at the place of destination.	(略)
All precautions, including safe disposal of animal by-products, waste, unused or surplus material, shall be taken to avoid risks of spreading diseases to animals. ◀M18	
CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF COLLAGEN	第三章：對膠原蛋白製造之要求
▼M18	
1. The production process for collagen must ensure that:	(略)
(a) all ruminant bone material derived from animals born, reared or slaughtered in countries or regions with a controlled or undetermined BSE risk as determined in accordance with Article 5 of Regulation (EC) No 999/2001 is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and pH < 1,5) over a period of at least 2 days; this treatment must be followed by pH adjustment using acid or alkali followed by:	
(i) either one or more rinses and at least one of the following processes:	
— filtration,	
— milling,	
— extrusion,	
(ii) or any approved equivalent process;	

(b) raw materials other than that referred to in point (a) must be subjected to a treatment involving washing, pH adjustment using acid or alkali followed by:																					
(i) either one or more rinses and at least one of the following processes:																					
— filtration, — milling, — extrusion,																					
(ii) or any approved equivalent process. ◀M18																					
2. After having been subjected to the process referred to in point 1, collagen may undergo a drying process.	(略)																				
▼M5																					
3. A food business operator may produce and store both collagen intended for human consumption and collagen not intended for human consumption in the same establishment provided that the raw materials and the production process comply with the requirements applying to collagen intended for human consumption. ◀M5	(略)																				
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Food business operators must ensure that collagen complies with the residue limits set out in the following table.	(略)																				
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CHAPTER V: LABELLING	第V章：標示																				
Wrapping and packaging containing collagen must bear the words 'collagen fit for human consumption' and indicate the date of preparation.	(略)																				
▼M18																					
SECTION XVI: HIGHLY REFINED CHONDROITIN SULPHATE, HYALURONIC ACID, OTHER HYDROLYSED CARTILAGE PRODUCTS, CHITOSAN, GLUCOSAMINE, RENNET, ISINGLASS AND AMINO ACIDS	第XVI節：高度精製的硫酸軟骨素、透明質酸、其他水解軟骨產品、殼聚糖、氨基葡萄糖、凝乳酶、魚膠和氨基酸																				
1. Food business operators manufacturing the following highly refined products of animal origin:	(略)																				
(a) chondroitin sulphate, (b) hyaluronic acid, (c) other hydrolysed cartilage products, (d) chitosan, (e) glucosamine, (f) rennet, (g) isinglass, (h) amino acids that are authorised as food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁴⁶ ,																					

⁴⁶ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

must ensure that the treatment of the raw materials used eliminates any animal or public health risk.	
2. The raw materials used for the manufacturing of the highly refined products referred to in point 1 must derive from:	(略)
(a) animals, including feathers thereof, which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante-mortem and post-mortem inspection, or;	
(b) fishery products complying with Section VIII.	
Human hair may not be used as a source for the manufacture of amino acids. ◀M18	
▼ M5	
<i>Appendix to ANNEX III</i>	附錄 III 之附件
MODEL DOCUMENT TO ACCOMPANY RAW MATERIAL DESTINED FOR THE PRODUCTION OF GELATINE OR COLLAGEN INTENDED FOR HUMAN CONSUMPTION	用於生產供人食用之明膠或膠原蛋白的原料隨附文件範本
Number of the commercial document:	
I. Identification of raw material Nature of the raw material: Animal species: Type of packaging: Number of packages: Net weight (kg):	
II. Origin of raw material Type, name, address and approval/registration/special authorisation number of the establishment of origin: Name and address of the consignor ⁴⁷ :	
III. Destination of raw material Type, name, address and approval/registration/special authorisation number of the production establishment of destination: Name and address of the consignee ⁴⁸ :	
IV. Means of transport: Done at, on (Signature of the operator of the establishment of origin or its representatives) ◀M5	

by SW

⁴⁷ Only if different from the establishment of origin.
⁴⁸ Only if different from the establishment of destination.