COMMISSION REGULATION (EC) No 2073/2005 of 15 Novermber 2005 on microbiological criteria for foodstuffs (OJ L338, 22.12.2005, p.1)

歐盟執委會 2005 年 11 月 15 日第 2073/2005 號規章關於食品微生物標準

Amended by Commission Regulation (EC) No 1441/2007 of 5 December 2007 (L332 p.12) (M1) (第 1 次修訂)
Amended by Commission Regulation (EU) No 365/2010 of 28 April 2010 (L107 p.9) (M2) (第 2 次修訂)
Amended by Commission Regulation (EU) No 1086/2011 of 27 October 2011 (L281 p.7) (M3) (第 3 次修訂)
Amended by Council Regulation (EU) No 209/2013 of 11 March 2013 (L68 p.19) (M4) (第 4 次修訂)
Amended by Commission Regulation (EU) No 1019/2013 of 23 October 2013 (L282 p.46) (M5) (第 5 次修訂)
Amended by Commission Regulation (EU) No 217/2014 of 7 March 2014 (L69 p.93) (M6) (第 6 次修訂)
Amended by Commission Regulation (EU) 2015/2285 of 8 December 2015 (L323 p.2) (M7) (第 7 次修訂)
Amended by Commission Regulation (EU) 2017/1495 of 23 August 2017 (L218 p.1) (M8) (第 8 次修訂)
Amended by Commission Regulation (EU) 2019/229 of 7 February 2019 (L37 p.106) (M9) (第 9 次修訂)
Amended by Commission Regulation (EU) 2020/205 of 14 February 2020 (L43 p.63) (M10) (第 10 次修訂)

Corrected by Corrigendum, OJ L 278, 10.10.2006, p.32 (2073/2005) (C1) (第 1 次勘誤)
Corrected by Corrigendum, OJ L 283, 14.10.2006, p.62 (2073/2005) (C2) (第 2 次勘誤)
Corrected by Corrigendum, OJ L 068, 13.3.2015, p.90 (1086/2011) (C3) (第 3 次勘誤)
Corrected by Corrigendum, OJ L 195, 20.7.2016, p.82 (1441/2007) (C4) (第 4 次勘誤)
Corrected by Corrigendum, OJ L 195, 20.7.2016, p.83 (1019/2013) (C5) (第 5 次勘誤)

(Based on the consolidation of 8 March, 2020) (本譯文係參照歐盟 Eur-Lex 網站之該規章 2020 年 3 月 8 日合訂版編譯)

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原(修正)條文	中譯文(條號請參照原條文)
THE COMMISSION OF THE EUROPEAN COMMUNITIES,	歐盟執委會，
Having regard to the Treaty establishing the European Community,	鑑於建立歐洲共同體的條約(下稱歐盟)，
Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[1], and in particular Articles 4(4) and 12 thereof,	鑑於歐洲議會和理事會2004年4月29日第852/2004號規章關於食品衛生規定，尤其是其中第4(4)條和第12條，
Whereas:	茲以：
(1) A high level of protection of public health is one of the fundamental objectives of food law, as laid down in 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[2]. Microbiological hazards in foodstuffs form a major source of food-borne diseases in humans.	對於公眾健康高標準的保護是食品法的基本目標之一，如同規定於歐洲議會和理事會2002年1月28日第178/2002號規章[2]中。食品中的微生物危害形成人類食源性疾病之主要來源。
(2) Foodstuffs should not contain micro-organisms or their toxins or metabolites in quantities that present an unacceptable risk for human health.	食品不應存有對人類健康造成不可接受風險數量的微生物或其毒素或代謝物。

1 OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3./ Regulation (EC) No 852/2004 關於食品衛生規定
2 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)./ Regulation (EC) No 178/2002 關於食品法總則和要求以建立歐洲食品安全局及訂定食品安全事務的程序

(3) Regulation (EC) No 178/2002 lays down general food safety requirements, according to which food must not be placed on the market if it is unsafe. Food business operators have an obligation to withdraw unsafe food from the market. In order to contribute to the protection of public health and to prevent differing interpretations, it is appropriate to establish harmonised safety criteria on the acceptability of food, in particular as regards the presence of certain pathogenic micro-organisms.	制定一般食品安全要求的第178/2002號規章，規定不安全的食品不准上市。食品經營者(下稱FBOs)有義務自市場回收不安全食品。為了有助於保護公眾健康和防止解釋歧異，建立可接受性食品的一致安全標準是適當的，特別是關於某些致病微生物的存在。
(4) Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures.	微生物標準還為食品可接受性及其製造、處理和分銷過程提供了指導。微生物標準的運用應是實施基於HACCP程序和其他衛生管制措施不可或缺的一部分。
(5) The safety of foodstuffs is mainly ensured by a preventive approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles. Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. It is therefore appropriate to set microbiological criteria defining the acceptability of the processes, and also food safety microbiological criteria setting a limit above which a foodstuff should be considered unacceptably contaminated with the micro-organisms for which the criteria are set.	食品安全主要是以預防措施進行保證，例如實施良好衛生規範(下稱GHP)和應用基於危害分析重要管制點(下稱HACCP)原則的程序。微生物標準能用於確效和查證HACCP程序和其他衛生管控措施。因此，設定微生物標準來界定過程的可接受性是適當的，也應對食品安全微生物標準設定一個限量值，超過該值的食品則視為被所設定標準的微生物不可接受地污染了。
(6) According to Article 4 of Regulation (EC) No 852/2004, food business operators are to comply with microbiological criteria. This should include testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective actions, in accordance with food law and the instructions given by the competent authority. It is therefore appropriate to lay down implementing measures concerning the analytical methods, including, where necessary, the measurement uncertainty, the sampling plan, the microbiological limits, the number of analytical units that should comply with these limits. Furthermore, it is appropriate to lay down implementing measures concerning the foodstuff to which the criterion applies, the points of the food chain where the criterion applies, as well as the actions to be taken when the criterion is not met. The measures to be taken by the food business operators in order to ensure compliance with criteria defining the acceptability of a process may include, among other things, controls of raw materials, hygiene, temperature and shelf-life of the product.	依據第852/2004號規章第4條，FBOs應遵守微生物標準。這應該包括依據設定值進行的測試，該設定值標準是要符合食品法和主管機關指引的取樣、執行分析和實施矯正措施。因此，宜制定有關分析方法的實施措施，必要時包括測量不確定度、取樣計畫、微生物限量值、應符合這些限值的分析單位數量。此外，宜針對標準適用食品、標準適用食物鏈環節，以及對不符合標準時所採取行動，制定實施措施。FBOs為確保符合標準所界定可接受性的生產過程所採取的措施，可以包括對產品之原料、衛生、溫度和保存期限的控制。
(7) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[3] requires the Member States to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency. Those controls should take place at appropriate stages of the production, processing and distribution of food to ensure that the criteria laid down in this Regulation are complied with by food business operators.	歐洲議會和理事會2004年4月29日第882/2004號規章[3]要求會員國要確保在風險基礎上以適當頻率定期執行官方管制。這些管制應在食品生產、加工和分銷的適當階段進行，以確保FBOs遵守本規章所制訂的標準。
(8) The Communication from the Commission on the Community Strategy for setting microbiological criteria for foodstuffs[4] describes the strategy to lay down and revise the criteria in Community legislation, as well as the principles for the development and application of the criteria. This strategy should be applied when microbiological criteria are laid down.	來自執委會對於設定食品微生物標準的歐盟策略的通訊，描述了制定和修訂歐盟立法標準的策略，以及標準制定程序和應用的原則。當制定微生物標準時應適用此策略。
(9) The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) issued an opinion on 23 September 1999 on the evaluation of microbiological criteria for food products of animal origin for human consumption. It highlighted the relevance of basing microbiological criteria on formal risk assessment and internationally approved principles. The opinion recommends that microbiological criteria should be relevant and effective in relation to consumer health protection. The SCVPH proposed, while awaiting formal risk assessments, certain revised criteria as interim measures.	有關公共衛生獸醫措施科學委員會(SCVPH)於1999年9月23日發表關於評估供人類食用動物源性食品的微生物標準之意見。它強調在正式風險評估和國際認可原則上建立微生物標準的相關性。該意見建議微生物標準應與消費者健康保護相關並且有效。在等待正式風險評估時期，SCVPH提議以某些已修訂標準作為臨時措施。
(10) The SCVPH issued at the same time a separate opinion on *Listeria monocytogenes*. That opinion recommended that it be an objective to keep the concentration of *Listeria monocytogenes* in food below 100 cfu/g. The Scientific Committee on Food (SCF) agreed with these recommendations in its opinion of 22 June 2000.	SCVPH同時發表關於*單核細胞增生李斯特菌*(下稱*Listeria*)的個別意見。該意見建議將食品中*Listeria*濃度保持在100 cfu/g以下作為目標。食品科學委員會(SCF)在2000年6月22日的意見中同意這些建議。

3 OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1./ Regulation (EC) No 882/2004 關於執行官方管制以確保查證符合飼料和食品法、動物健康和動物福利規定
4 SANCO/1252/2001 Discussion paper on strategy for setting microbiological criteria for foodstuffs in Community legislation, p. 34./ 在歐盟立法中關於制訂食品微生物標準的策略的討論文件

(11) The SCVPH adopted an opinion on *Vibrio vulnificus* and *Vibrio parahaemolyticus* on 19 and 20 September 2001. It concluded that currently available scientific data do not support setting specific criteria for pathogenic *V. vulnificus* and *parahaemolyticus* in seafood. However, it recommended that codes of practice should be established to ensure that good hygiene practice has been applied.	SCVPH於2001年9月19日及20日採納關於*創傷弧菌*和*腸炎弧菌*的意見。結論是目前可得的科學數據並不支持設定海鮮中的致病性*創傷弧菌*和*腸炎弧菌*之特定標準。但是，建議應建立實務規範以確保施行GHP。
(12) The SCVPH issued an opinion on Norwalk-like viruses (NLVs, noroviruses) on 30-31 January 2002. In that opinion it concluded that the conventional faecal indicators are unreliable for demonstrating the presence or absence of NLVs and that the reliance on faecal bacterial indicator removal for determining shellfish purification times is unsafe practice. It also recommended using *E. coli* rather than faecal coliforms to indicate faecal contamination in shellfish harvesting areas, when applying bacterial indicators.	SCVPH於2002年1月30日至31日發表關於諾沃克樣病毒（NLVs，諾輪病毒）的意見。該意見之結論認為，傳統的糞便指標菌無法作為NLVs存在或不存在的可靠證明，並且依賴對移除糞便細菌指標作為決定貝類淨化次數是不安全的做法。當適用細菌性指標時，它還建議使用*大腸桿菌*而不是糞便大腸桿菌群，來表示貝類收穫區域之糞便污染程度。
(13) On 27 February 2002 the SCF adopted an opinion on specifications for gelatine in terms of consumer health. It concluded that the microbiological criteria set in Chapter 4 of Annex II to 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 90/425/EEC[5] in terms of consumer health were excessive, and considered it sufficient to apply a mandatory microbiological criterion for salmonella only.	SCF於2002年2月27日採納關於消費者健康方面明膠規格的意見。結論是1992年12月17日理事會92/118/EEC指令[5]之附件II第4章中所設定的微生物標準，就消費者健康而言是過高的，並認為僅對沙門氏菌適用強制性微生物標準就足夠了。
(14) The SCVPH issued an opinion on verotoxigenic *E. coli* (VTEC) in foodstuffs on 21 and 22 January 2003. In its opinion it concluded that applying an end-product microbiological standard for VTEC O157 is unlikely to deliver meaningful reductions in the associated risk for the consumers. However, microbiological guidelines aimed at reducing the faecal contamination along the food chain can contribute to a reduction in public health risks, including VTEC. The SCVPH identified the following food categories where VTEC represents a hazard to public health: raw or undercooked beef and possibly meat from other ruminants, minced meat and fermented beef and products thereof, raw milk and raw milk products, fresh produce, in particular sprouted seeds, and unpasteurised fruit and vegetable juices.	SCVPH於2003年1月21日至22日發表關於食品中致毒性*大腸桿菌*(VTEC)的意見。該意見之結論認為，對最終產品應用VTEC O157的微生物標準不似可達到有意義的降低對消費者的相關風險。然而，旨在減少食物鏈中糞便污染的微生物指引可有助於降低涵括VTEC的公眾健康風險。SCVPH界定以下VTEC對公眾健康構成危害的食品類別：生牛肉或未煮熟的牛肉、可能來自其他反芻動物的肉、絞肉和發酵牛肉及其相關製品、生乳和生乳製品、新鮮農產品，特別是芽菜以及未經巴斯德殺菌的果蔬汁。
(15) On 26 and 27 March 2003 the SCVPH adopted an opinion on staphylococcal enterotoxins in milk products, particularly in cheeses. It recommended revising the criteria for coagulase-positive staphylococci in cheeses, in raw milk intended for processing and in powdered milk. In addition, criteria for staphylococcal enterotoxins should be laid down for cheeses and powdered milk.	SCVPH於2003年3月26日至27日採納關於乳製品，尤其是乳酪中葡萄球菌腸毒素的意見。它建議修訂乳酪、加工用原料乳以及奶粉中凝固酶陽性葡萄球菌的標準。此外，應對乳酪和奶粉制定葡萄球菌腸毒素標準。
(16) The SCVPH adopted an opinion on salmonella in foodstuffs on 14 and 15 April 2003. According to the opinion, food categories possibly posing a high risk to public health include raw meat and some products intended to be eaten raw, raw and undercooked products of poultry meat, eggs and products containing raw eggs, unpasteurised milk and some products thereof. Sprouted seeds and unpasteurised fruit juices are also of concern. It recommended that the decision on the need for microbiological criteria should be taken on the basis of its ability to protect the consumers and its feasibility.	SCVPH於2003年4月14日至15日採納關於食品中沙門氏菌的意見。根據該意見，可能對公眾健康構成高風險的食品類別包括生肉和一些欲作為生食的產品、生的和未煮熟的禽肉產品、蛋和含有生蛋的產品、未經巴斯德殺菌的牛乳及其某些相關製品。芽菜和未經巴斯德殺菌的果汁也受到關注。它建議關於微生物標準的必要性應以其保護消費者的能力和其可行性為基礎來決定。
(17) The Scientific Panel on Biological Hazards (BIOHAZ Panel) of the European Food Safety Authority (EFSA) issued an opinion on the microbiological risks in infant formulae and follow-on formulae on 9 September 2004. It concluded that *Salmonella* and *Enterobacter sakazakii* are the micro-organisms of greatest concern in infant formulae, formulae for special medical purposes and follow-on formulae. The presence of these pathogens constitutes a considerable risk if conditions after reconstitution permit multiplication. Enterobacteriaceae, which are more often present, could be used as an indicator for risk. Monitoring and testing of Enterobacteriaceae was recommended in both the manufacturing environment and the finished product by the EFSA. However, besides pathogenic species the family Enterobacteriaceae includes also environmental species, which often appear in the food manufacturing environment without posing any health hazard.	歐洲食品安全局(下稱EFSA)的生物危害科學小組(BIOHAZ小組)於2004年9月9日發表關於嬰兒配方和較大嬰兒配方奶粉中微生物風險的意見。結論為*沙門氏菌*和*阪崎腸桿菌*是嬰兒配方、特殊醫療用途配方和較大嬰兒配方奶粉中最受關注的微生物。若調配後的條件允許繁殖，這些病原菌的存在構成了可見的風險。更常見的腸桿菌科可以作為風險指標菌。EFSA建議同時在製造環境和成品中監測和檢測腸桿菌科。然而，除了致病性菌種，腸桿菌科也包括常出現在食品製造環境中而不會對健康造成任何危害的環境菌種。因此，腸桿菌科屬能用作日常監測，如有存

5 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)./ Directive 92/118/EEC 制定動物健康和公眾健康要求，以管制不受 89/662/EEC 指令附件 A(I)提及關於制定進口歐盟和境內貿易，及 90/425/EEC 指令關於病原體的特定歐盟規定

Therefore, the family Enterobacteriaceae can be used for routine monitoring, and if they are present testing of specific pathogens can be started.	在，則可以開始對特定病原菌進行檢測。 (按：EPSA的BIOHAZ小組於2007年1月24日發表意見，結論是不可能在腸桿菌科和沙門氏菌以及阪崎腸桿菌之間建立相關性，單一工廠內除外。又阪崎腸桿菌後更名為克羅諾桿菌)
(18) International guidelines for microbiological criteria in respect of many foodstuffs have not yet been established. However, the Commission has followed the Codex Alimentarius guideline 'Principles for the establishment and application of microbiological criteria for foods CAC/GL 21 — 1997' and in addition, the advice of the SCVPH and the SCF in laying down microbiological criteria. Existing Codex specifications in respect of dried milk products, foods for infants and children and the histamine criterion for certain fish and fishery products have been taken account. The adoption of Community criteria should benefit trade by providing harmonised microbiological requirements for foodstuffs and replacing national criteria.	許多食品微生物標準之國際準則尚未建立。然而，執委會遵循了食品法典(下稱Codex)「食品微生物標準的建立和應用原則(CAC/GL 21 1997)」指引，並還有SCVPH和SCF在制定微生物標準方面的建議。有考慮到關於乾乳製品、嬰兒和兒童食品的既有Codex規範以及特定魚和漁產品的組織胺標準。歐盟標準的採用應藉由提供一致的食品微生物要求並取代國家標準來促進貿易。
(19) The microbiological criteria set for certain categories of food of animal origin in Directives that were repealed by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC[6] should be revised and certain new criteria set in the light of the scientific advice.	某些動物源性食品類別微生物標準的指令被歐洲議會和理事會於2004年4月21日2004/41/EC指令[6]廢止，應進行修訂並參據科學建議制定某些新標準。
(20) The microbiological criteria laid down in Commission Decision 93/51/EEC of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish[7] are incorporated in this Regulation. It is therefore appropriate to repeal that Decision. Since Commission Decision 2001/471/EC of 8 June 2001 laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultrymeat[8] is repealed with effect from the 1 January 2006, it is appropriate to incorporate microbiological criteria set for carcases in this Regulation.	執委會於1992年12月15日93/51/EEC決定[7]所制訂的微生物標準已納入本規章中。因此，廢止該決定是適當的。自2006年1月1日起廢除執委會於2001年6月8日2001/471/EC[8]決定以來，將屠體微生物標準納入本規章是適當的。
(21) The producer or manufacturer of a food product has to decide whether the product is ready to be consumed as such, without the need to cook or otherwise process it in order to ensure its safety and compliance with the microbiological criteria. According to Article 3 of 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[9], the instructions for use of a foodstuff are compulsory on the labelling when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions. Such instructions should be taken into account by food business operators when deciding appropriate sampling frequencies for the testing against microbiological criteria.	為確保食品安全性並符合微生物標準，生產者或製造商必須決定其產品是否可在無需烹煮或其他方式處理下供人食用。按照歐洲議會和理事會於2000年3月20日2000/13/EC[9]指令第3條規定，當在沒有此類說明的情況下無法正確使用食品時，在標籤上的食品使用說明應是強制性的。FBOs在依據微生物標準決定適當的取樣頻率時，應將此類說明納入考慮。
(22) Sampling of the production and processing environment can be a useful tool to identify and prevent the presence of pathogenic micro-organisms in foodstuffs.	生產和加工環境的取樣可以是鑑別和預防食品中病原微生物存在的有用工具。
(23) Food business operators should decide themselves the necessary sampling and testing frequencies as part of their procedures based on HACCP principles and other hygiene control procedures. However, it may be necessary in certain cases to set harmonised sampling frequencies at Community level, particularly in order to ensure the same level of controls to be performed throughout the Community.	FBOs應自行決定必要的取樣和測試頻率作為基於HACCP原則和其他衛生管控程序所訂自身程序的一部分。然而，在某些案例中可能有必要在歐盟層級設立一致的取樣頻率，特別是為了確保在全歐盟執行相同程度的管制。
(24) Test results are dependent on the analytical method used, and therefore a given reference method should be associated with each microbiological criterion. However, food business operators should have the possibility to use analytical methods other than the reference methods, in particular more rapid methods, as long as the use of these alternative methods provides equivalent results. Moreover, a sampling plan needs to be defined for each criterion in order to ensure harmonised implementation. It is nevertheless necessary to allow the use of other sampling and testing schemes, including	測試結果取決於所使用的分析方法，因此設定的參考方法應與每個微生物標準相關聯。然而，FBOs應有可能使用參考方法以外的分析方法，特別是較快速的方法，只要這些替代方法的使用可提供等效結果。而且為確保執行一致性，必須對每個標準定義取樣計畫。不過還是有必要對其他取樣和測試方案(包括替代指標生物的使用)關於這些方案提

6 OJ L 157, 30.4.2004, p. 33, corrected by OJ L 195, 2.6.2004, p. 12./ Directive 2004/41/EC 廢止對供人食用動物源性某些產品的上市和生產有關食品衛生和健康條件的某些指令並修正理事會 89/662/EEC 和 92/118/EEC 指令和理事會 95/408/EC 決定

7 OJ L 13, 21.1.1993, p. 11./ Decision 93/51/EEC 關於適用於生產熟製甲殼類和軟體貝類的微生物標準

8 OJ L 165, 21.6.2001, p. 48. Decision as amended by Decision 2004/379/EC (OJ L 144, 30.4.2004, p. 1)./ Decision 2001/471/EC 按照關於鮮肉生產和上市健康條件的 64/433/EEC 指令和關於影響鮮禽肉生產和上市健康問題的 71/118/EEC 指令，制定對經營者在廠場中執行一般衛生的定期檢查之規定

9 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)./ 2000/13/EC 關於會員國對食品標籤、介紹和廣告相關法律的近似規定

the use of alternative indicator organisms, on condition that these schemes provide equivalent guarantees of food safety.	供等效食品安全保證的允許使用條件。
(25) Trends in test results should be analysed, as they are able to reveal unwanted developments in the manufacturing process enabling the food business operator to take corrective actions before the process is out of control.	應分析測試結果的趨勢，因其能揭示製造過程中不必要的發展，使FBO能夠在過程失控前採取矯正措施。
(26) The microbiological criteria set in this Regulation should be open to review and revised or supplemented, if appropriate, in order to take into account developments in the field of food safety and food microbiology. This includes progress in science, technology and methodology, changes in prevalence and contamination levels, changes in the population of vulnerable consumers, as well as the possible outputs from risk assessments.	為了考慮到食品安全和食品微生物學領域的發展，若適合，本規章中設定的微生物標準應可公開審視及修正或補充。此包括科學、技術和方法學的演變、盛行率和污染程度的變化、弱勢消費族群的變化，以及風險評估的可能結果。
(27) In particular, criteria for pathogenic viruses in live bivalve molluscs should be established when the analytical methods are developed sufficiently. There is a need for development of reliable methods for other microbial hazards too, e.g. *Vibrio parahaemolyticus*.	特別是當分析方法已充分開發時，應建立活雙枚貝類中致病性病毒的標準。也有對其他微生物危害(例如*腸炎弧菌*)開發可靠方法的需要。
(28) It has been demonstrated that the implementation of control programmes can markedly contribute to a reduction of the prevalence of salmonella in production animals and products thereof. The purpose of 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 agents[10] is to ensure that proper and effective measures are taken to control salmonella at relevant stages of the food chain. Criteria for meat and products thereof should take into account the expected improvement in the salmonella situation at the level of primary production.	已證明管控計畫的實施能顯著地有助於降低經濟動物及其相關產品中沙門氏菌的流行。歐洲議會和理事會於2003年11月17日第2160/2003號規章[10]的目的是確保採取適當且有效的措施來控管在食物鏈相關階段的沙門氏菌。肉類及其相關製品的標準應考慮到在初級生產階段沙門氏菌情況的預期改善。
(29) For certain food safety criteria, it is appropriate to grant the Member States a transitional derogation, enabling them to comply with less stringent criteria but provided that the foodstuffs would only be marketed on the national market. The Member States should notify the Commission and other Member States where this transitional derogation is used.	對某些食品安全標準而言，給予會員國過渡期部分豁免是適當的，以使他們在遵守不太嚴格標準下，能夠讓食品只在國內市場銷售。會員國應將使用過渡期部分豁免處告知執委會和其他會員國。
(30) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,	本規章措施係依據食物鏈與動物健康常設委員會意見，
HAVE ADOPTED THIS REGULATION:	已通過本規章：
Article 1 **Subject-matter and scope**	*第1條* **主題和範圍**
This Regulation lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. The competent authority shall verify compliance with the rules and criteria laid down in this Regulation in accordance with Regulation (EC) No 882/2004, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis.	本規章制訂了某些微生物的微生物標準，以及FBOs在實施第852/2004號規章第4條中所指的一般和特定衛生措施時應遵守的實施細則。在不影響為檢測和測量其他微生物、毒素或代謝物的目的而進行進一步取樣和分析的權利或者作為過程查證的情況下，主管機關應對疑似不安全食品或在風險分析的背景下，依第882/2004號規章查證對本規章制定的規定和標準的符合性。
This Regulation shall apply without prejudice to other specific rules for the control of micro-organisms laid down in Community legislation and in particular the health standards for foodstuffs laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council[11], the rules on parasites laid down under Regulation (EC) No 854/2004 of the European Parliament and of the Council[12] and the microbiological criteria laid down under Council Directive 80/777/EEC[13].	本規章應在不影響歐盟立法中所制定微生物管控的其他具體規定下適用，特別是歐洲議會和理事會第853/2004號規章中規定的食品衛生標準、歐洲議會和理事會第854/2004號規章所規定的寄生蟲規定和理事會80/777/EEC指令所規定的微生物標準。
Article 2 **Definitions**	*第2條* **定義**
The following definitions shall apply:	下列定義應適用：
(a) 'micro-organisms' means bacteria, viruses, yeasts, moulds, algae, parasitic	「微生物」是指細菌、病毒、酵母菌、黴

10 OJ L 325, 12.12.2003, p. 1/ Regulation (EC) No 2160/2003 關於沙門氏菌和其他特定食源性人畜共通病原體的控管
11 OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.
12 OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.
13 OJ L 229, 30.8.1980, p. 1.

protozoa, microscopic parasitic helminths, and their toxins and metabolites;	菌、藻類、寄生原蟲、微型寄生蠕蟲及其毒素和代謝物；
(b) 'microbiological criterion' means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch;	「微生物標準」是指界定一產品、一批食材或一過程可接受性的標準，其是基於微生物及/或它們毒素/代謝物的含量，在每單位質量、體積、面積或批次中的存在、不存在或數量；
(c) 'food safety criterion' means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market;	「食品安全標準」是指界定一產品或一批食材可用於進入市場的可接受性標準；
(d) 'process hygiene criterion' a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law;	「過程衛生標準」是指一個指出可接受之生產過程活動的標準。此標準並不適用於上市產品。為維持生產過程的衛生狀態符合食品法，它設置了一個指標性污染值，高於該值就需要採取矯正措施；
(e) 'batch' means a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period;	「批」是指在一限定生產期內在一既知場所生產並在幾乎相同環境下以給定的過程中獲得的一群或一組可識別產品；
(f) 'shelf-life' means either the period corresponding to the period preceding the 'use by' or the minimum durability date, as defined respectively in Articles 9 and 10 of Directive 2000/13/EC; §9 The date of minimum durability of a foodstuff shall be the date until which the foodstuff retains its specific properties when properly stored. §10 In the case of foodstuffs which, from the microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the "use by" date.	「保存期限」是指對應於「使用期限」之前的期限或最短保存日期，如在2000/13/EC指令第9條和第10條所分別定義的； §9 食品的最短保存日期應為食品在適當儲存時保持其特定特性的日期 §10 從微生物學觀點來看極易腐敗而因此可能在短期內對人體健康構成立即危害的食品，最短保存日期應由「使用期限」替代
(g) 'ready-to-eat food' means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern;	「即食食品」是指生產者或製造商欲直接供人食用的食品，其無需經烹煮或其他有效去除或降低關注微生物至可接受程度的處理；
(h) 'food intended for infants' means food specifically intended for infants, as defined in Commission Directive 91/321/EEC[14];	「供嬰兒食用食品」是指專門供嬰兒食用的食品，如在執委會91/321/EEC指令所定義的；
(i) 'food intended for special medical purposes' means dietary food for special medical purposes, as defined in Commission Directive 1999/21/EC[15];	「供特殊醫療用途的食品」是指特殊醫療用途的膳食食品，如在執委會1999/21/EC指令所定義的；
(j) 'sample' means a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced it;	「樣品」是指由1個或幾個單位的1組組合或由不同方式在一群體中或在一個重要數量的物質中選取的一部分物質，旨在提供有關所研究群體或物質的既定特徵的資訊，以及為關注的有問題群體或物質或關注的生產過程提供判決基礎；
(k) 'representative sample' means a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample;	「代表性樣品」是指保持其所取自批次特徵的樣品。特別是單純隨機取樣樣品的情況，其每個聚合樣品的批次的項目或增量樣品被賦予相同機率；
(l) 'compliance with microbiological criteria' means obtaining satisfactory or acceptable results set in Annex I when testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective action, in accordance with food law and the instructions given by the competent authority;	「符合微生物標準」是指依據食品法和主管機關指定指導說明書，當通過取樣、進行分析和矯正措施之執行，針對附件I所設標準限量值進行測試時，獲得令人滿意或可接受的結果；
▼M4	
(m) the definition of 'sprouts' in Article 2(a) of Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts[16]; ◄M4	「芽菜」的定義，在執委會2013年3月11日第208/2013號實施規章關於芽菜和用於生產芽菜種子的可追溯性要求的第2(a)條中；
▼M9	
(n) 'a broad range of foods', as referred to in EN ISO 16140-2, means food as defined by the first subparagraph of Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[17];	「範圍廣泛的食品」，如EN ISO 16140-2所述，是指歐洲議會和理事會第178/2002號規

14 OJ L 175, 4.7.1991, p. 35.
15 OJ L 91, 7.4.1999, p. 29.
16 See page 16 of this Official Journal./ 見本官方公報第 16 頁

ISO 16140-2:2016 Microbiology of the food chain — Method validation — Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method	章第2條第1項所定義的食品； ISO 16140-2:2016 食物鏈微生物學—方法確效—第2部分：根據參考方法對替代(自用)方法確效的方案
(o) 'independent certification body' means a body which is independent from the organisation that manufactures or distributes the alternative method and which provides a written assurance, in the form of a certificate, testifying that the validated alternative method meets the requirements of EN ISO 16140-2;	「獨立驗證機構」是指獨立於產生或流通替代方法之組織的機構，並以證書形式提供書面保證，來證明經確效的替代方法符合EN ISO 16140-2的要求；
(p) 'production process assurance of the manufacturer' means a production process whose management system guarantees that the validated alternative method remains conform to the characteristics required by EN ISO 16140-2 and ensures that mistakes and defects in the alternative method are prevented; ◄M9	「製造商的生產過程保證」是指一生產過程，其管理體系保證使用經確效符合EN ISO 16140-2要求特性的替代方法並確認防止替代方法中的錯誤和缺失；
▼M10	
(q) 'reptile meat' means reptile meat as laid down in point (16) of Article 2 of Commission Delegated Regulation (EU) 2019/625[18]. ◄M10	「爬行動物肉」是指執委會2019/625授權規章第2條(16)點規定的爬行動物肉。
Article 3 **General requirements**	*第3條* **通則**
1. Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. To this end the food business operators at each stage of food production, processing and distribution, including retail, shall take measures, as part of their procedures based on HACCP principles together with the implementation of good hygiene practice, to ensure the following:	FBOs應確保食品符合附件I所訂的相關微生物標準。為此，在食品生產、加工和分銷(包括零售)每個階段的FBOs應採取基於HACCP原則以及實施GHP作為其程序一部分的措施，以確保以下內容：
(a) that the supply, handling and processing of raw materials and food stuffs under their control are carried out in such a way that the process hygiene criteria are met,	在他們掌控下的原料和食材供應、處理和加工，是以符合過程衛生標準的方式進行，
(b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.	在合理可預見的分銷、儲存和使用條件下，可以符合適用產品整個保存期限的食品安全標準。
2. As necessary, the food business operators responsible for the manufacture of the product shall conduct studies in accordance with Annex II in order to investigate compliance with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of *Listeria monocytogenes* and that may pose a *Listeria monocytogenes* risk for public health.	必要時，負責產品製造的FBOs為調查整個保存期限得符合標準，應按附件II進行研究。特別是，對於能夠支持*Listeria*生長並可能對公眾健康構成*Listeria*風險的即食食品。
Food businesses may collaborate in conducting those studies.	食品產業間可以合作進行這些研究。
Guidelines for conducting those studies may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.	進行那些研究的指引可能包括在第852/2004號規章第7條所指的良好作業指引中。
Article 4 **Testing against criteria**	*第4條* **依據標準進行測試**
1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.	當在確效或查證其是正確的基於HACCP原則和GHP來運作程序時，FBOs應按附件I規定的微生物標準進行適當的測試。
2. Food business operators shall decide the appropriate sampling frequencies, except where Annex I provides for specific sampling frequencies, in which case the sampling frequency shall be at least that provided for in Annex I. Food business operators shall make this decision in the context of their procedures based on HACCP principles and good hygiene practice, taking into account the instructions for use of the foodstuff.	FBOs應決定適當的取樣頻率，除非附件I規定了具體的取樣頻率，在此情況取樣頻率至少應為附件I規定的頻率。FBOs應同時考慮到食材的使用說明，依據基於HACCP原則和GHP所訂的程序情況來做出此決定。
The frequency of sampling may be adapted to the nature and size of the food	在食品安全不會受到危害的前提下，取樣頻

17 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)./ 2002 年 1 月 28 日歐洲議會和理事會第 178/2002 號規章規定了食品法的一般原則和要求，建立了歐洲食品安全局並製定了食品安全方面的程序

18 Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supple menting Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18)./ 2019 年 3 月 4 日的執委會授權規章（EU）2019/625，補充歐洲議會和理事會關於特定動物和貨物的貨物進入聯盟的要求的規章（EU）2017/625 供人類食用

businesses, provided that the safety of foodstuffs will not be endangered.	率可以按食品企業的性質和規模進行調整。
Article 5 **Specific rules for testing and sampling**	*第5條* **對測試和取樣之具體規定**
1. The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods.	分析方法和取樣計畫以及附件 I 中的方法應作為參考方法。
2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method. ISO 18593 Microbiology of food and animal feeding stuffs – Horizontal methods for sampling techniques from surfaces using contact plates and swabs	當取樣是為確保符合標準之必要時，樣品應取自用於食品生產中的加工區域和設備。應以ISO 18593作為取樣之參考方法。 ISO 18593 食品和動物飼料的微生物學 – 使用平板和拭子從接觸表面取樣技術的方法
Food business operators manufacturing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme.	即食食品(可能對公眾健康構成*Listeria*風險)的製造FBOs，應將對加工區域和設備的*Listeria*取樣檢查列為其取樣方案之一部分。
►M9 Food business operators manufacturing dried infant formulae or dried foods for special medical purposes intended for infants below six months, which pose a *Cronobacter* spp. risk shall monitor the processing areas and equipment for Enterobacteriaceae as part of their sampling scheme. ◄M9	(略，因供6個月以下嬰兒食用的乾式食品具*克羅諾桿菌*屬污染風險，製造FBOs應對加工區域和設備進行腸桿菌科的監測)
3. The number of sample units of the sampling plans set out in Annex I may be reduced if the food business operator can demonstrate by historical documentation that he has effective HACCP-based procedures.	若FBO能以紀錄文件證明其具備有效的HACCP為基礎的程序，可以減少附件 I 規定的取樣計畫之樣品單位數量。
4. If the aim of the testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in Annex I shall be respected as a minimum.	若測試目的是專門評估某一批食品或某一個過程的可接受性，應至少遵從附件 I 規定的取樣計畫。
5. Food business operators may use other sampling and testing procedures, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses.	若能證明主管機關滿意這些程序可提供至少等效的保證，FBOs可以使用其他取樣和測試程序。那些程序可包括替代取樣點和趨勢分析的使用。
Testing against alternative micro-organisms and related microbiological limits as well as testing of analytes other than microbiological ones shall be allowed only for process hygiene criteria.	針對替代微生物和相關微生物限量值的測試以及微生物以外分析物的測試，應僅允許用於過程衛生標準。
►M9 The use of alternative analytical methods is acceptable provided they are:	可以接受使用替代分析方法的前提是：
— validated against the specific reference method provided for in Annex I in accordance with the protocol set out in standard EN ISO 16140-2, and	依據ISO 16140-2規定方案，以附件 I 規定的指定參考方法進行確效，以及
— validated for the food category specified in the relevant microbiological criterion set in Annex I the compliance with which is verified by the food business operator, or validated for a broad range of food as referred to in EN ISO 16140-2.	對附件 I 所列特定食品類別的相關微生物標準進行確效，FBO已查證其符合性或對ISO 16140-2所述範圍廣泛的食品進行確效。
Proprietary methods may be used as alternative analytical methods, provided they are:	自用方法可作為替代分析方法的前提是：
— validated, in accordance with the protocol set out in standard EN ISO 16140-2, against the specific reference method provided for verifying compliance with the microbiological criteria laid down in Annex I, as provided for in the third subparagraph, and	按照ISO 16140-2規定方案，以第3小段所述，根據為查證是否符合附件 I 規定的微生物標準而提供的特定參考方法進行確效，以及
— certified by an independent certification body.	由獨立的驗證機構驗證。(按：此段為下述所指之第4小段第2個縮進段)
The certification of the proprietary method referred to in the second indent of the fourth subparagraph shall:	第4小段第2個縮進段所稱自用方法之驗證，應：
— be subject, at least every 5 years, to reassessment through renewal procedures,	至少每5年經由更新的程序進行重新評估，
— show that the production process assurance of the manufacturer was evaluated, and	顯示製造商的生產過程保證已被評估，並且
— include a summary of or a reference to the validation results of the proprietary method and a statement on the quality management of the production process of the method.	包括對自用方法確效結果之總結或參考文件和對該方法產生過程之品管聲明。
Food business operators may use other analytical methods than those validated or certified as provided for in the third, fourth and fifth subparagraphs, where	除第3、第4和第5小段規定的已查證或驗證分析方法外，FBOs可以使用其他分析方法，

such methods have been validated in accordance with internationally accepted protocols and their use has been authorised by the competent authority. ◄M9	該等方法已按照國際公認方案進行確效並且獲主管機關授權使用。
Article 6 **Labelling requirements**	*第6條* **標籤要求**
1. When the requirements for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked of all species set down in Annex I are fulfilled, the batches of those products placed on the market must be clearly labelled by the manufacturer in order to inform the consumer of the need for thorough cooking prior to consumption.	當滿足附錄 I 設定之所有種類供煮熟食用的碎肉、肉製品和肉產品中*沙門氏菌*的要求時，這些上市批次產品必須由製造商清楚地標示告知消費者在食用前需要徹底烹煮。
2. As from 1 January 2010 labelling as referred to in paragraph 1 in respect of minced meat, meat preparations and meat products made from poultrymeat will no longer be required.	自2010年1月1日起，對禽類碎肉、肉製品和肉產品不再需要進行第1段所述的標示。
Article 7 **Unsatisfactory results**	*第7條* **不滿意的結果**
1. When the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators shall take the measures laid down in paragraphs 2 to 4 of this Article together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers.	當測試結果對應於附件 I 所列標準是不令人滿意時，FBOs應採取本條第2至4段規定的措施併行其基於HACCP程序的矯正措施和其他為保護消費者健康所必要的行動。
In addition, they shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place.	此外，他們應採取措施找出不滿意結果的原因，以防止再次發生不可接受的微生物污染。這些措施可能包括修正基於HACCP的程序或其他現有的食品衛生管控措施。
2. When testing against food safety criteria set out in Chapter 1 of Annex I provides unsatisfactory results, the product or batch of food stuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002. However, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.	當對應於附件 I 第1章所列食品安全標準所進行的測試為不滿意結果時，應依照第178/2002號規章第19條規定回收或召回該食材產品或批次。但是，已上市而尚未進入零售階段且不符合食品安全標準的產品，可以提交進一步加工處理來消除有問題危害。此處理只能由零售階段以外的FBOs來執行。
The food business operator may use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and provided that this use has been decided within the procedures based on HACCP principles and good hygiene practice and authorised by the competent authority.	FBO可以將該批次用於最初預定用途以外處，前提是此使用不會對公眾或動物健康構成風險並且此使用是在基於HACCP原則和GHP的程序內決定的，並獲得主管機關的授權。
3. A batch of mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in Section V of Annex III to Regulation (EC) No 853/2004, with unsatisfactory results in respect of the *Salmonella* criterion, may be used in the food chain only to manufacture heat-treated meat products in establishments approved in accordance with Regulation (EC) No 853/2004.	使用第853/2004號規章附件 III 第 V 節第 III 章第3段中提及的技術所生產的一批機械分離肉(MSM)，在*沙門氏菌*標準方面有令人不滿意的結果，只能在依據第853/2004號規章核可廠場中用於製造熱處理肉產品的食品鏈。
4. In the event of unsatisfactory results as regards process hygiene criteria the actions laid down in Annex I, Chapter 2 shall be taken.	至於加工衛生標準有令人不滿意的結果，應採取附件 I 第2章規定的措施。
Article 8 **Transitional derogation**	*第8條* **過渡性部分豁免**
1. A transitional derogation is granted until 31 December 2009 at the latest pursuant to Article 12 of Regulation (EC) No 852/2004 as regards compliance with the value set in Annex I to this Regulation for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked placed on the national market of a Member State.	依據第852/2004號規章第12條規定的過渡性部分豁免，關於符合本法規附件 I 規定的欲供作會員國國內市場上販售在食用前需要徹底煮熟的碎肉、肉製品和肉製品中*沙門氏菌*的限量值，最遲在2009年12月31日前生效。
2. The Member States using this possibility shall notify the Commission and other Member States thereof. The Member State shall:	使用這種可能性的會員國應將其通知執委會和其他會員國。會員國應：
(a) guarantee that the appropriate means, including labelling and a special mark, which cannot be confused with the identification mark provided for in Annex II, Section I to Regulation (EC) No 853/2004, are in place to ensure that the derogation applies only to the products concerned when placed on	保證採取適當方式，包括不會與第853/2004號規章附錄 II 第 I 節規定的識別標記混淆的標示和1個特殊標記，以確保部分豁免僅適用於進入國內市場的有關產品，及供歐盟內

the domestic market, and that products dispatched for intra-Community trade comply with the criteria laid down in Annex I;	部貿易集散之產品符合附錄 I 所訂的標準；
(b) provide that the products to which such transitional derogation applies shall be clearly labelled that they must be thoroughly cooked prior to consumption;	規定適用此類過渡性部分豁免的產品應清楚標明在食用前必須徹底煮熟；
(c) undertake that when testing against the Salmonella criterion pursuant to Article 4, and for the result to be acceptable as regards such transitional derogation, no more than one out of five sample units shall be found to be positive.	承諾當依據第4條針對沙門氏菌標準進行測試時，不得有超過1/5單位的樣品被檢出為陽性，以使此類過渡性部分豁免的結果可以被接受。
Article 9 **Analyses of trends**	*第9條* **趨勢分析**
Food business operators shall analyse trends in the test results. When they observe a trend towards unsatisfactory results, they shall take appropriate actions without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks.	FBOs應對測試結果分析趨勢。當觀察到有傾向不滿意結果的趨勢時，他們即應採取適當行動來改正情況以避免微生物風險的發生。
Article 10 **Review**	*第10條* **審視**
This Regulation shall be reviewed taking into account progress in science, technology and methodology, emerging pathogenic micro-organisms in foodstuffs, and information from risk assessments. In particular, the criteria and conditions concerning the presence of salmonella in carcases of cattle, sheep, goats, horses, pigs and poultry shall be revised in the light of the changes observed in salmonella prevalence.	應考慮科學、技術和方法的進步、新興食品病原微生物和風險評估資訊，對本規章進行審視。特別是，關於牛、綿羊、山羊、馬、豬和家禽屠體中存在沙門氏菌的標準和條件，應根據觀察到的沙門氏菌盛行率變化進行修正。
Article 11 **Repeal**	*第11條* **廢止**
Decision 93/51/EEC is repealed.	廢止93/51/EEC決定。
Article 12	*第12條*
This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.	本規章應於在*歐盟官方公報*公布後的第20天生效。
It shall apply from 1 January 2006.	自2006年1月1日起適用。
This Regulation shall be binding in its entirety and directly applicable in all Member States.	整體而言，本規章應具約束力並直接適用所有會員國。

▼M1

ANNEX I

Microbiological criteria for foodstuffs

附錄 I

對食品的微生物標準

Chapter 1. Food safety criteria/ 食品安全標準

	Food category/ 食品類別	Micro-organisms/their toxins, metabolites/ 微生物及其毒素或代謝物	Sampling plan[1] / 取樣計畫 n	Sampling plan[1] / 取樣計畫 c	Limits[2]/ 限量值 m	Limits[2]/ 限量值 M	Analytical reference method[3]/ 分析參考方法	Stage where the criterion applies/ 標準適用階段
1.1	Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes[4]/ （略）	*Listeria monocytogenes*	10	0	►M9 Not detected ◄ in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2	Ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes/ 能支持 *Listeria* 生長的即食食品(嬰兒和特殊醫療用途者除外)	*Listeria monocytogenes*	5	0	100 cfu/g[5]		EN/ISO 11290-2[6]	Products placed on the market during their shelf-life/ 上市後，保存(有效)期限內
					►M9 Not detected ◄ in 25 g[7]		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it/離廠前(在食品離開生產者即時管控之前)
1.3	Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes [4] [8] / 不能支持 *Listeria* 生長的即食食品(嬰兒和特殊醫療用途者除外)	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2[6]	
1.4	Minced meat and meat preparations intended to be eaten raw/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g		►M9 EN ISO 6579-1 ◄	
1.5	►M2 Minced meat and meat preparations made from poultry meat intended to be eaten cooked/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g		►M9 EN ISO 6579-1 ◄◄M2	
1.6	Minced meat and meat preparations made from other species than poultry intended to be eaten cooked/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 10 g		►M9 EN ISO 6579-1 ◄	
1.7	Mechanically separated meat (MSM) [9]/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 10 g		►M9 EN ISO 6579-1 ◄	
1.8	Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g		►M9 EN ISO 6579-1 ◄	
1.9	►M2 Meat products made from poultry meat intended to be eaten cooked/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g		►M9 EN ISO 6579-1 ◄◄M2	Products placed on the market during their shelf-life/ 上市後，保存期限內
1.10	Gelatine and collagen/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g		►M9 EN ISO 6579-1 ◄	
1.11	Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation [10]/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g		►M9 EN ISO 6579-1 ◄	
1.12	Milk powder and whey powder/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g		►M9 EN ISO 6579-1 ◄	
1.13	Ice cream [11], excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g		►M9 EN ISO 6579-1 ◄	
1.14	Egg products, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g		►M9 EN ISO 6579-1 ◄	
1.15	Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk/ （略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25g or ml		►M9 EN ISO 6579-1 ◄	
1.16	Cooked crustaceans and molluscan	*Salmonella*	5	0	►M9 Not detected ◄		►M9 EN ISO 6579-	

	shellfish/ 煮熟的甲殼類和軟體貝類				in 25 g	1 ◄
1.17	Live bivalve molluscs and live echinoderms, tunicates and gastropods/（略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g	►M9 EN ISO 6579-1 ◄
1.18	Sprouted seeds (ready-to-eat) ►M4 [23] ◄/（略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g	►M9 EN ISO 6579-1 ◄
1.19	Precut fruit and vegetables (ready-to-eat) /（略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g	►M9 EN ISO 6579-1 ◄
1.20	►M9 Unpasteurised [24] fruit and vegetable juices (ready- to-eat) ◄/（略）	*Salmonella*	5	0	►M9 Not detected ◄ in 25 g	►M9 EN ISO 6579-1 ◄
1.21	Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphy lococci criteria in Chapter 2.2 of this Annex/（略）	Staphylococcal enterotoxins	5	0	Not detected in 25 g	►M9 EN ISO 19020 ◄
1.22	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age/（略）	*Salmonella*	30	0	►M9 Not detected ◄ in 25 g	►M9 EN ISO 6579-1 ◄
1.23	Dried follow-on formulae/（略）	*Salmonella*	30	0	►M9 Not detected ◄ in 25 g	►M9 EN ISO 6579-1 ◄
1.24	►M2 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age [14]/（略）	*Cronobacter* spp. ►M9 *(Enterobacter sakazakii)* ◄	30	0	►M9 Not detected ◄ in 10 g	►M9 EN ISO 22964 ◄◄M2
1.25	►M7 Live bivalve molluscs and live echinoderms, tunicates and marine gastropods/（略）	*E. coli* [15]	5[16]	1	230 MPN/ 100 g of flesh and intravalvular liquid / 700 MPN/ 100g of flesh and intravalvular liquid	EN/ISO 16649-3 ◄M7
1.26	Fishery products from fish species associated with a high amount of histidine[17]/來自易生組織胺魚種之水產製品	Histamine	9[18]	2	100 mg/kg / 200 mg/kg	►M9 EN ISO 19343 ◄
1.27	►M5 Fishery products, except those in food category 1.27a, which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine [17]/ 1.27a 類別除外，經鹽漬處理酵素熟成並由易生組織胺魚種製成之水產品	Histamine	9[18]	2	200 mg/kg / 400 mg/kg	►M9 EN ISO 19343 ◄◄M5
1.27a	►C5 Fish sauce produced by fermentation of fishery products/ 由水產品發酵製成的魚露	Histamine	1	0	400 mg/kg	►M9 EN ISO 19343 ◄◄C5
1.28	►M3 Fresh poultry meat [20] ◄M3/（略）	►M9 *Salmonella* Typhimurium [21] *Salmonella* Enteritidis ◄	5	0	►M9 Not detected ◄ in 25 g	►M9 EN ISO 6579-1 (for detection) White- Kauffmann-Le Minor scheme (for serotyping) ◄
1.29	►M4 Sprouts [23]/（略）	Shiga toxin producing *E. coli* (STEC) O157, O26, O111, O103, O145 and O104:H4	5	0	►M9 Not detected ◄ in 25 grams	CEN/ISO TS 13136 [22] ◄M4
1.30	►M10 Reptile meat/（略）	*Salmonella*	5	0	Not detected in 25 g	EN ISO 6579-1 ◄M10

[1] n = number of units comprising the sample; c = number of sample units giving values between m and M. — n = 組成樣品的單位數；c = 組成樣品單位數其檢出值介於 m、M 之間。

[2] ►M10 For points 1.1-1.24, 1.27a, 1.28-1.30 m = M. ◄M10 — 對 1.1~1.24、1.27a、1.28~1.30 等點， m = M。

[3] The most recent edition of the standard shall be used. — 應使用最新版本的標準。

[4] Regular testing against the criterion is not required in normal circumstances for the following ready-to-eat foods: — 下列即食食品在正常情況下無需應對本標準進行定期檢測：

— those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (for example, products heat treated in their final package), — 有經熱處理或其他有效處理去除 *Listeria* 的產品，且在處理後不可能再污染（例如：產品在最終包裝中進行熱處理），

— fresh, uncut and unprocessed vegetables and fruits ►M9 ———— ◄ — 新鮮、未切割和未加工的蔬菜和水果，

— bread, biscuits and similar products, — 麵包、餅乾和相似產品，

— bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products, — 瓶裝或包裝水、軟飲料、啤酒、蘋果酒、葡萄酒、烈酒和相似產品，

— sugar, honey and confectionery, including cocoa and chocolate products, — 糖、蜂蜜和糖果，包括可可和巧克力產品，

— live bivalve molluscs, — 活雙枚貝類，

—►M2 food grade salt. ◄ — 食品級鹽。

[5] This criterion shall apply if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that must be low enough to guarantee that the limit of 100 — 若製造商能證明產品在整個保存期限內不會超過限量值 100 cfu/g，並令主管機關滿意，應適用本標準。業者可固定過程中的中間限值，該值須足夠低

cfu/g is not exceeded at the end of shelf-life.	以保證在保存期限結束時不會超過 100cfu/g。
(6) 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.	1ml 接種物接種於 1 個直徑 140 mm 的培養皿或 3 個直徑 90 mm 的培養皿上。
(7) This criterion shall apply to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.	本標準應適用於離開生產者即時管控之前(即離廠前)的產品，當他(業者)不能證明產品在整個保存期限內不會超過限量值 100 cfu/g，並令主管機關滿意時。
(8) Products with pH ≤ 4,4 or aw ≤ 0,92, products with pH ≤ 5,0 and aw ≤ 0,94, products with a shelf-life of less than five days shall be automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.	pH ≤ 4.4或a_w ≤ 0.92的產品、pH ≤ 5.0且a_w ≤ 0.94的產品、保存期限少於5天的產品，自動視為屬於此類產品(不支持*Listeria*生長)。其他類別的產品也能歸於此類，但須經科學論證。
(9) This criterion shall apply to mechanically separated meat (MSM) produced with the techniques referred to in paragraph 3 of Chapter III of Section V of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council.	本標準應適用於使用第853/2004號規章附錄Ⅲ第Ⅴ節第Ⅲ章第3段提及的生產機械分離肉(MSM)技術。
(10) Excluding products when the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and a_w of the product where appropriate, there is no salmonella risk.	當製造商能證明並令主管機關滿意，由於適當的產品熟成時間和產品的a_w，故不存在沙門氏菌風險時，則排除該等產品。
(11) Only ice creams containing milk ingredients.	僅限含乳成分的冰淇淋。
►M4 ——— ◄ ►M9 ——— ◄	
(14) Parallel testing for Enterobacteriaceae and ►M9 *Cronobacter* spp. ◄ shall be conducted, unless a correlation between these micro-organisms has been established at an individual plant level. If Enterobacteriaceae are detected in any of the product samples tested in such a plant, the batch must be tested for ►M9 *Cronobacter* spp. ◄ It shall be the responsibility of the manufacturer to demonstrate to the satisfaction of the competent authority whether such a correlation exists between Enterobacteriaceae and ►M9 *Cronobacter* spp. ◄	除非已在個別加工廠層級建立了這些微生物間的相關性，否則應進行腸桿菌科和*克羅諾桿菌屬*的平行檢測。若在此類工廠測試的任何產品樣品中檢測到腸桿菌科，則必須測試該批次的*克羅諾桿菌屬*。製造商有責任向主管機關證明腸桿菌科和*克羅諾桿菌屬*之間是否存在這種相關性。
(15) *E. coli* is used here as an indicator of faecal contamination.	此處使用*大腸桿菌*作為糞便污染指標菌。
(16) ►M7 Each sample unit comprises a minimum number of individual animals according to EN/ISO 6887-3. ◄	按照EN/ISO 6887-3，每個樣品單位由最少數量的個別動物組成。
(17) Particularly fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae*.	特別是下列所屬魚種：*鯖科、鯡科、鯷科、鰯科、扁鯵科、秋刀魚科*。
(18) ►M5 Single samples may be taken at retail level. In such a case the presumption laid down in Article 14(6) of Regulation (EC) No 178/2002, according to which the whole batch should be deemed unsafe, shall not apply, unless the result is above M. ◄	可在零售階段抽取單一樣品。在此情況，依據第178/2002號規章第14(6)條規定，推定整批產品應被視為不安全，除非結果大於M。
►M9 ——— ◄	
(20) ►M3 This criterion shall apply to fresh meat from breeding flocks of *Gallus gallus*, laying hens, broilers and breeding and fattening flocks of turkeys.	本標準應適用於*紅原雞*雞群、蛋雞、肉雞和火雞種育肥雞群的鮮肉。
(21) As regards monophasic *Salmonella typhimurium* only ►C3 1,4,[5],12:i:- ◄ is included.	僅關於單相*沙門氏鼠傷寒桿菌*包括在內。
(22) ►M4 Taking into account the most recent adaptation by the European Union reference laboratory for *Escherichia coli*, including Verotoxigenic *E. coli* (VTEC), for the detection of STEC O104:H4.	考慮到歐盟參考實驗室最近為檢測STEC O104:H4對*E. coli*（包括VTEC)所做的調整。
(23) Excluding sprouts that have received a treatment effective to eliminate *Salmonella* spp. and STEC. ◄	不包括已接受有效消除*沙門氏菌*屬和STEC處理的芽菜。
(24) ►M9 The term unpasteurised means that the juice has not been subjected to pasteurisation obtained by time-temperature combinations or to other processes validated to achieve an equivalent bactericidal effect to pasteurisation as regards its effect on *Salmonella*. ◄	未經巴氏滅菌名詞是指果汁未經通過時間-溫度組合獲得的巴氏滅菌，或經對*沙門氏菌*影響方面達到與巴氏滅菌等效殺菌效果之確效的其他處理過程。

Interpretation of the test results	**測試結果的解釋**
►M7 The limits given refer to each sample unit tested. ◄	所訂限值作為每個樣品單位測試之參考值。
The test results demonstrate the microbiological quality of the batch tested[19].	測試結果證明當批測試產品的微生物品質。
L. monocytogenes in ready-to-eat foods intended for infants and for special medical purposes:	供嬰兒和供特殊醫療用途的即食食品中的*Listeria*：
— satisfactory, if all the values observed indicate the absence of the bacterium,	滿意的，若觀測到的所有測值顯示不存在該菌，
— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.	不滿意的，若在任何樣品單位中檢測到該菌存在。
L. monocytogenes in ready-to-eat foods able to support the growth of *L. monocytogenes* before the food has left the immediate control of the producing food business operator when he is not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:	當業者無法對在離開生產者即時管控之前，證明在整個保存期限內不會超過限量值100 cfu/g的能支持*Listeria*生長的即食食品：
— satisfactory, if all the values observed indicate the absence of the bacterium,	滿意的，若觀測到的所有測值顯示不存在該菌，
— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.	不滿意的，若在任何樣品單位中檢測到該菌存在。

19 The test results may be used also for demonstrating the effectiveness of the hazard analysis and critical control point principles or good hygiene procedure of the process. /測試結果也可用於證明加工過程HACCP原則或GHP的有效性。

►M7 *L. monocytogenes* in other ready-to-eat foods:	其他即食食品中的*Listeria*：
— satisfactory, if all the values observed are ≤ the limit,	滿意的，若觀測到的所有測值是小於或等於(≤)限量值，
— unsatisfactory, if any of the values are > the limit.	不滿意的，若任一檢值是大於(>)限量值。
E. coli in live bivalve molluscs and live echinoderms, tunicates and marine gastropods:	活雙枚貝類和活棘皮動物、被囊類和海洋腹足類動物中的*大腸桿菌*：
— satisfactory, if all the five values observed are ≤ 230 MPN/100 g of flesh and intravalvular liquid or if one of the five values observed is > 230 MPN/100 g of flesh and intravalvular liquid but ≤ 700 MPN/100 g of flesh and intravalvular liquid,	滿意的，若觀測到所有肉和瓣膜內液體的5個測值是小於或等於(≤)230 MPN/100 g，或是5個中有1個肉和瓣膜內液體的測值是大於(>)230 MPN/100 g但小於或等於(≤)700 MPN/100 g，
— unsatisfactory, if any of the five values observed are > 700 MPN/100 g of flesh and intravalvular liquid or if at least two of the five values observed are > 230 MPN/100 g of flesh and intravalvular liquid. ◄M7	不滿意的，若觀測到5個中任1個肉和瓣膜內液體的測值是大於(>)700 MPN/100 g，或是5個中有2個以上肉和瓣膜內液體的測值是大於(>)230 MPN/100 g。
— satisfactory, if all the values observed are ≤ the limit,	滿意的，若觀測到的所有測值是小於或等於(≤)限量值，
— unsatisfactory, if any of the values are > the limit.	不滿意的，若任一檢值是大於(>)限量值。
Salmonella in different food categories:	不同食品類別中的*沙門氏菌*：
— satisfactory, if all the values observed indicate the absence of the bacterium,	滿意的，若觀測到的所有測值顯示不存在該菌，
— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.	不滿意的，若在任何樣品單位中檢測到該菌存在。
Staphylococcal enterotoxins in dairy products:	乳製品中的葡萄球菌腸毒素：
— satisfactory, if in all the sample units the enterotoxins are not detected,	滿意的，若所有樣品單位均未檢測到腸毒素，
— unsatisfactory, if the enterotoxins are detected in any of the sample units.	不滿意的，若任1樣品單位檢測到腸毒素。
►M9 *Cronobacter* spp. ◄ in dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age:	供6個月以下嬰兒食用的乾式嬰兒配方及供特殊醫學用途膳食食品中的*克羅諾桿菌屬*：
— satisfactory, if all the values observed indicate the absence of the bacterium,	滿意的，若觀測到的所有測值顯示不存在該菌，
— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.	不滿意的，若在任何樣品單位中檢測到該菌存在。
►M5 Histamine in fishery products:	水產品中的組織胺：
Histamine in fishery products from fish species associated with a high amount of histidine except fish sauce produced by fermentation of fishery products:	除經發酵水產品產製的魚露外，來自易生組織胺相關魚種的水產品中的組織胺：
— satisfactory, if the following requirements are fulfilled:	滿意的，若滿足以下要求：
1. the mean value observed is ≤ m	觀測到的平均測值小於或等於(≤)m
2. a maximum of c/n values observed are between m and M	觀測到c/n的最大值在m和M之間
3. no values observed excess the limit of M.	沒有任何觀測到的測值超過 M值。
— unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more of the values observed are > M.	不滿意的，若觀測到的平均測值超過m值或是有c/n值是超過m和M之間或是觀測到1個或多個測值大於(>)M。
Histamine in fish sauce produced by fermentation of fishery products:	發酵水產品產製魚露中的組織胺：
— satisfactory, if the value observed is ≤ the limit,	滿意的，若觀測到的測值小於或等於(≤)限量值，
— unsatisfactory, if the value observed is > the limit. ◄M5	不滿意的，若觀測到的測值大於(>)限量值。

Chapter 2. Process hygiene criteria/生產過程衛生標準

2.1 *Meat and products thereof*（肉及其相關製品，略）

Food category	Micro-organisms	Sampling plan[1] n	Sampling plan[1] c	Limits[2] m	Limits[2] M	Analytical reference method[3]	Stage where the criterion applies	Action in case of unsatisfactory results
2.1.1 Carcases of cattle, sheep, goats and horses[4] 2.1.2 Carcases of pigs[4] (unit for limit = log cfu/ cm² daily mean log)	Aerobic colony count			3.5 4.0	5.0	EN ISO 4833-1	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1.5 2.0	2.5 3.0	EN ISO 21528-2		
2.1.3 Carcases of cattle, sheep, goats and horses	*Salmonella*	50[5]	2[6]	Not detected in the area tested per carcase		EN ISO 6579-1	Carcases after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
2.1.4 Carcases of pigs			3[6]					Improvements in slaughter hygiene and

2.1.5 Poultry carcases of broilers and turkeys	*Salmonella* spp.[10]		5	Not detected in 25 g of a pooled sample of neck skin			Carcases after chilling	review of process controls, origin of animals and of the biosecurity measures in the farms of origin
2.1.6 Minced meat 2.1.7 MSM[9] (unit for limit = cfu/g)	Aerobic colony count[7]	5	2	5×10^5	5×10^6	EN ISO 4833-1	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	E. coli[8]	5	2	50	500	ISO 16649-1 or 2		
2.1.8 Meat preparations (unit for limit = cfu/g or cm^2)	*E. coli*[8]	5	2	500	5000			
2.1.9 Carcases of broilers *From 1.1.2025 c = 10	*Campylobacter* spp.	50[5]	15*	1 000 cfu/g		EN ISO 10272-2	Carcases after chilling	Improvements in slaughter hygiene, review of process controls, of animals' origin and of the biosecurity measures in the farms of origin

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) For points 2.1.3-2.1.5 and 2.1.9 m = M.
(3) The most recent edition of the standard shall be used.
(4) The limits (m and M) shall apply only to samples taken by the destructive method. The daily mean log shall be calculated by first taking a log value of each individual test result and then calculating the mean of these log values.
(5) The 50 samples shall be derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.
(6) The number of samples where the presence of salmonella is detected. The c value is subject to review in order to take into account the progress made in reducing the salmonella prevalence. Member States or regions having low salmonella prevalence may use lower c values even before the review.
(7) This criterion shall not apply to minced meat produced at retail level when the shelf-life of the product is less then 24 hours.
(8) *E. coli* is used here as an indicator of faecal contamination.
(9) These criteria apply to mechanically separated meat (MSM) produced with the techniques referred to in paragraph 3 of Chapter III of Section V of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council.
(10) Where *Salmonella* spp. is found, the isolates shall be further serotyped for *Salmonella* Typhimurium and *Salmonella* Enteritidis in order to verify compliance with the microbiological criterion set out in Row 1.28 of Chapter 1.

Interpretation of the test results

The limits given refer to each sample unit tested, excluding testing of carcases where the limits refer to pooled samples.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae and aerobic colony count in carcases of cattle, sheep, goats, horses and pigs:

— satisfactory, if the daily mean log is ≤ m,

— acceptable, if the daily mean log is between m and M,

— unsatisfactory, if the daily mean log is > M.

Salmonella in carcases:

— satisfactory, if the presence of *Salmonella* is detected in a maximum of c/n samples,

— unsatisfactory, if the presence of *Salmonella* is detected in more than c/n samples.

After each sampling session, the results of the last ten sampling sessions shall be assessed in order to obtain the n number of samples.

E. coli and aerobic colony count in minced meat, meat preparations and mechanically separated meat (MSM):

— satisfactory, if all the values observed are ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

— unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.

Campylobacter spp. in poultry carcases of broilers:

— satisfactory, if a maximum of c/n values are > m,

— unsatisfactory, if more than c/n values are > m.

2.2 *Milk and dairy products*（乳及乳製品，略）

Food category	Micro-organisms	Sampling plan[1]		Limits[2]		Analytical reference method[3]	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.1 Pasteurised milk and other pasteurised liquid dairy products[4]	Enterobacteriaceae	5	0	10 cfu/ml		EN ISO 21528-2	End of the manufacturing process	Check on the efficiency of heat-treatment and prevention of recontamination as well as the quality of raw materials
2.2.2 Cheeses made from milk or whey that has undergone heat treatment	*E. coli*[5]	5	2	100 cfu/g	10^3 cfu/g	ISO 16649-1 or 2	At the time during the manufacturing process when the E. coli count is expected to be highest[6]	Improvements in production hygiene and selection of raw materials
2.2.3 Cheeses made from raw milk	Coagulase-positive staphylococci			10^4 cfu/g	10^5 cfu/g	EN/ISO 6888-2	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improvements in production hygiene and selection of raw materials. If values>10^5 cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.4 Cheeses made from milk that has undergone a lower heat treatment than pasteurisation and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment[7]				10^2 cfu/g	10^3 cfu/g	EN/ISO 6888-1 or 2		
2.2.5 Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment[7]				10 cfu/g	10^2 cfu/g		End of the manufacturing process	Improvements in production hygiene. If values > 10^5 cfu/g are detected, the batch has to be tested for staphylococcal

								enterotoxins.
2.2.6 Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	*E. coli*[5]					ISO 16649-1 or 2		Improvements in production hygiene and selection of raw materials
2.2.7 Milk powder and whey powder[4]	Enterobacteriaceae	5	0	10 cfu/g		EN ISO 21528-2		Check on the efficiency of heat treatment and prevention of recontamination
	Coagulase-positive staphylococci	5	2	10 cfu/g	10^2 cfu/g	EN/ISO 6888-1 or 2		Improvements in production hygiene. If values > 10^5 cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
2.2.8 Ice cream[8] and frozen dairy desserts	Enterobacteriaceae	5	2	10 cfu/g	10^2 cfu/g	EN ISO 21528-2		Improvements in production hygiene
2.2.9 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Enterobacteriaceae	10	0	Not detected in 10 g		EN ISO 21528-1		Improvements in production hygiene to minimise contamination[9]
2.2.10 Dried follow-on formulae	Enterobacteriaceae	5	0					
2.2.11 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Presumptive *Bacillus cereus*	5	1	50 cfu/g	500 cfu/g	EN/ISO 7932[10]		Improvements in production hygiene. Prevention of recontamination. Selection of raw material.

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) For points 2.2.1, 2.2.7, 2.2.9 and 2.2.10 m=M.
(3) The most recent edition of the standard shall be used.
(4) The criterion shall not apply to products intended for further processing in the food industry.
(5) *E. coli* is used here as an indicator for the level of hygiene.
(6) For cheeses which are not able to support the growth of *E. coli*, the *E. coli* count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of *E. coli*, it is normally at the end of the ripening period.
(7) Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.
(8) Only ice creams containing milk ingredients.
(9) Parallel testing for Enterobacteriaceae and *Cronobacter* spp. shall be conducted, unless a correlation between these micro-organisms has been established at an individual plant level. If Enterobacteriaceae are detected in any of the product samples tested in such a plant, the batch has to be tested for *Cronobacter* spp. It shall be the responsibility of the manufacturer to demonstrate to the satisfaction of the competent authority whether such a correlation exists between Enterobacteriaceae and *Cronobacter* spp.
(10) 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in dried infant formulae, dried dietary foods for special medical purposes intended for infants below six months of age and dried follow-on formulae:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

E. coli, Enterobacteriaceae (other food categories) and coagulase-positive staphylococci:

— satisfactory, if all the values observed are ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

— unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.

Presumptive *Bacillus cereus* in dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age:

— satisfactory, if all the values observed are ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

— unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.

2.3 *Egg products*（蛋製品，略）

Food category	Micro-organisms	Sampling plan[1]		Limits		Analytical reference method[2]	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.3.1 Egg products	Enterobacteriaceae	5	2	10 cfu/g or ml	100 cfu/g or ml	EN ISO 21528-2	End of the manufacturing process	Check on the efficiency of heat treatment and prevention of recontamination

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in egg products:

— satisfactory, if all the values observed are ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

— unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.

2.4 *Fishery products/ 水產製品*

▼C4

Food category/ 食品類別	Micro-organisms/ 微生物	Sampling plan[1]/ 取樣計畫		Limits/ 限量值		Analytical reference method[2]/ 分析參考方法	Stage where the criterion applies/ 標準適用階段	Action in case of unsatisfactory results/ 不滿意結果時之行動
		n	c	m	M			
2.4.1 Shelled and shucked products of cooked crustaceans and molluscan shellfish/ 煮熟之帶殼和去殼甲殼類和軟體貝類產品	*E. coli*	5	2	1 MPN/g	10 MPN/g	ISO TS 16649-3	End of the manufacturing process / 製造過程結束	Improvements in production hygiene/ 改善生產衛生
	Coagulase-positive *staphylococci*	5	2	100 cfu/g	1,000 cfu/g	EN/ISO 6888-1 or 2		

[1] n = number of units comprising the sample; c = number of sample units giving values between m and M.

n = 組成樣品的單位數；c = 組成樣品單位數其檢出值介於m、M之間。

[2] The most recent edition of the standard shall be used.

應使用最新版本的標準。

Interpretation of the test results	**測試結果的解釋**
The limits given refer to each sample unit tested.	所訂限值作為每個樣品單位測試之參考值。
The test results demonstrate the microbiological quality of the process tested.	測試結果證明(製造)過程測試的微生物品質。
E. coli in shelled and shucked products of cooked crustaceans and molluscan shellfish:	煮熟之帶殼和去殼甲殼類和軟體貝類產品中的*大腸桿菌*：
— satisfactory, if all the values observed are ≤ m,	滿意的，若觀測到的所有測值小於或等於(≤)m，
— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,	可接受的，若觀測到有1個c/n的最大值在m和M之間且其他測值是小於或等於(≤)m，
— unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.	不滿意的，若觀測到1個或多個測值大於(>)M或是有多個c/n值在m和M之間。
Coagulase-positive *staphylococci* in shelled and cooked crustaceans and molluscan shellfish:	煮熟之帶殼甲殼類和軟體貝類產品中的*金黃色葡萄球菌*：
— satisfactory, if all the values observed are ≤ m,	滿意的，若觀測到的所有測值小於或等於(≤)m，
— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,	可接受的，若觀測到有1個c/n的最大值在m和M之間且其他測值是小於或等於(≤)m，
— unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.	不滿意的，若觀測到1個或多個測值大於(>)M或是有多個c/n值在m和M之間。

2.5 *Vegetables, fruits and products thereof*（蔬菜、水果及其相關製品，略）

Food category	Micro-organisms	Sampling plan[1]		Limits		Analytical reference method[2]	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.5.1 Precut fruit and vegetables (ready-to-eat)	*E. coli*	5	2	100 cfu/g	10^2 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials
2.5.2 Unpasteurised[3] fruit and vegetable juices (ready- to-eat)								

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) The most recent edition of the standard shall be used.
(3) The term unpasteurised means that the juice has not been subjected to pasteurisation obtained by time-temperature combinations or to other processes validated to achieve an equivalent bactericidal effect to pasteurisation as regards its effect on *E.coli*.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

E. coli in precut fruit and vegetables (ready-to-eat) and in unpasteurised fruit and vegetable juices (ready-to-eat):

— satisfactory, if all the values observed are ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

— unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.

Chapter 3. Rules for sampling and preparation of test samples	**受測樣品(試樣)取樣及製備之規定**
3.1 *General rules for sampling and preparation of test samples*	*試樣取樣及製備之通則*
In the absence of more specific rules on sampling and preparation of test samples, the relevant standards of the ISO (International Organisation for Standardisation) and the guidelines of the Codex Alimentarius shall be used as reference methods. ◄M1	對受測樣品缺乏更具體的取樣和製備規定情形下，應使用ISO相關標準和Codex指引作為參考方法。
►M8 3.2 *Bacteriological sampling in slaughterhouses and at premises producing minced meat, meat preparations, mechanically separated meat and fresh meat*	*在肉相關製品(絞肉、肉製品、MSM和鮮肉)生產設施及屠宰場內之微生物檢體取樣*
Sampling rules for carcases of cattle, pigs, sheep, goats and horses	**牛、豬、綿羊、山羊和馬胴體取樣規定**
The destructive and non-destructive sampling methods, the selection of the sampling sites	可使用ISO 17604規定的破壞性和非破壞性取樣方

and the rules for storage and transport of samples to be used are set out in standard ISO 17604.	法、取樣部位的選擇以及樣品儲存和運輸規定。
Five carcases shall be sampled at random during each sampling session. Sample sites must be selected taking into account the slaughter technology used in each plant.	略(隨機對5個胴體取樣，依每個工廠使用的屠宰技術選擇取樣部位)
When sampling for analyses of *Enterobacteriaceae* and aerobic colony counts, four sites of each carcase shall be sampled. Four tissue samples representing a total of 20 cm^2 shall be obtained by the destructive method. When using the non- destructive method for this purpose, the sampling area shall cover a minimum of 100 cm^2 (50 cm^2 for small ruminant carcases) per sampling site.	略(對*腸桿菌科*和好氧菌落數的分析進行取樣之規定，破壞性的為每個胴體取4處總面積為20 cm^2的組織樣品，非破壞性的每個胴體採樣區域應至少覆蓋100 cm^2，小型反芻動物為50 cm^2)
When sampling for *Salmonella* analyses, an abrasive sponge sampling method shall be used. Areas most likely to be contaminated shall be selected. The total sampling area shall cover a minimum of 400 cm^2.	略(對*沙門氏菌*的分析進行取樣之規定，使用海綿拭子選擇最有可能被污染的區域，總採樣區域應至少覆蓋400 cm^2)
When samples are taken from the different sampling sites on the carcase, they shall be pooled before examination.	略(不同取樣部位的樣品應在檢驗前匯集合併)。
Sampling rules for poultry carcases and fresh poultry meat	**家禽胴體和鮮禽肉取樣規定**
Slaughterhouses shall sample whole poultry carcases with neck skin for *Salmonella* and *Campylobacter* analyses. Cutting and processing establishments other than those adjacent to a slaughterhouse cutting and processing meat received only from this slaughterhouse, shall also take samples for *Salmonella* analysis. When doing so, they shall give priority to whole poultry carcases with neck skin, if available, but ensuring that also poultry portions with skin and/or poultry portions without skin or with only a small amount of skin are covered, and that choice shall be risk-based.	略(屠宰場應對整隻帶頸皮之禽胴體取樣分析*沙門氏菌*和*彎曲桿菌*。分切和加工廠收樣時應對*沙門氏菌*取樣分析，並以帶皮部位為風險優先取樣部位)
Slaughterhouses shall include in their sampling plans poultry carcases from flocks with an unknown *Salmonella* status or with a status known to be positive for *Salmonella Enteritidis* or *Salmonella Typhimurium*.	略(屠宰場應訂各種沙門氏菌菌群的取樣計畫)
When testing against the process hygiene criteria set out in Row 2.1.5 and Row 2.1.9 of Chapter 2 for *Salmonella* and *Campylobacter* in poultry carcases in slaughterhouses and the tests for *Salmonella* and *Campylobacter* are carried out in the same laboratory, neck skins from a minimum of 15 poultry carcases shall be sampled at random after chilling during each sampling session. Before examination, the neck skin samples from at least three poultry carcases from the same flock of origin shall be pooled into one sample of 26 g. Thus, the neck skin samples form 5 × 26 g final samples (26 g are needed to perform analyses for *Salmonella* and *Campylobacter* from one sample in parallel). The samples shall be kept after sampling and transported to the laboratory at a temperature not lower than 1 °C and not higher than 8 °C and the time between the sampling and the testing for *Campylobacter* shall be of less than 48 hours in order to ensure maintenance of sample integrity. Samples that have reached a temperature of 0 °C shall not be used to verify compliance with the *Campylobacter* criterion. The 5 × 26 g samples shall be used to verify the compliance with process hygiene criteria set out in Row 2.1.5 and Row 2.1.9 of Chapter 2 and the food safety criterion set out in Row 1.28 of Chapter 1. In order to prepare the initial suspension at the laboratory, the 26 g test portion shall be transferred to nine volumes (234 ml) buffered peptone water (BPW). The BPW shall be brought to room temperature before adding. The mixture shall be treated in a stomacher or pulsifier for approximately one minute. Foaming shall be avoided by removing the air from the stomacher bag as much as possible. 10 ml (~ 1 g) of this initial suspension shall be transferred to an empty sterile tube and 1 ml of the 10 ml shall be used for the enumeration of *Campylobacter* on selective plates. The rest of the initial suspension (250 ml ~ 25 g) shall be used for the detection of *Salmonella*.	略(依第2章所列衛生標準在同一試驗室進行*沙門氏菌*和*彎曲桿菌*檢測之取樣、混樣及樣品保存運送溫度-時間等規定)
When testing against the process hygiene criteria set out in Row 2.1.5 and Row 2.1.9 of Chapter 2 for *Salmonella* and *Campylobacter* in poultry carcases in slaughterhouses and the tests for *Salmonella* and *Campylobacter* are carried out in two different laboratories, neck skins from a minimum of 20 poultry carcases shall be sampled at random after chilling during each sampling session. Before examination, the neck skin samples from at least four poultry carcases from the same flock of origin shall be pooled into one sample of 35 g. Thus, the neck skin samples form 5 × 35 g samples, which in turn shall be split in order to obtain 5 × 25 g final samples (to be tested for *Salmonella*) and 5 × 10 g final samples (to be tested for *Campylobacter*). The samples shall be kept after sampling and transported to the laboratory at a temperature not lower than 1 °C and not higher than 8 °C and the time between the sampling and the testing for *Campylobacter* shall be of less than 48 hours in order to ensure maintenance of sample integrity. Samples that have reached a temperature of 0 °C shall not be used to verify compliance with the *Campylobacter* criterion. The 5 × 25 g samples shall be used to verify the compliance with process hygiene criteria set out in Row 2.1.5 of Chapter 2 and the food safety criterion set out in Row 1.28 of Chapter 1. The 5 × 10 g final samples shall be used to verify the compliance with the process hygiene criterion set out in Row 2.1.9 of Chapter 2.	略(依第2章所列衛生標準在2間不同試驗室進行*沙門氏菌*和*彎曲桿菌*檢測之取樣、混樣及樣品保存運送溫度-時間等規定)
For the *Salmonella* analyses for fresh poultry meat other than poultry carcases, five samples of at least 25 g of the same batch shall be collected. The sample taken from poultry portions with skin shall contain skin and a thin surface muscle slice in case the amount of skin is not sufficient to form a sample unit. The sample taken from poultry portions without skin or with only a small amount of skin shall contain a thin surface muscle slice or slices added to any skin present to make a sufficient sample unit. The slices of	略(對鮮禽肉進行*沙門氏菌*檢測之取樣規定，儘可能帶皮或肌肉表面切片)

meat shall be taken in a way that includes as much as possible of the surface of the meat.	
Guidelines for sampling	**取樣指引**
More detailed guidelines on the sampling of carcases, in particular concerning the sampling sites, may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.	略(歐盟在第852/2004號規章第7條提到會員國要有相關良好作業指引供業者參考)
Sampling frequencies for carcases, minced meat, meat preparations, mechanically separated meat and fresh poultry meat	**胴體、各式肉製品的取樣頻率**
The food business operators of slaughterhouses or establishments producing minced meat, meat preparations, mechanically separated meat or fresh poultry meat shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.	略(FBOs應每週至少取樣1次進行微生物分析，每週取樣日期應更改以確保涵蓋一周中的每一天)
As regards the sampling of minced meat and meat preparations for *E. coli* and aerobic colony count analyses and the sampling of carcases for *Enterobacteriaceae* and aerobic colony count analyses, the frequency may be reduced to fortnightly testing if satisfactory results are obtained for six consecutive weeks.	略(*腸桿菌科/大腸桿菌*和好氧菌落數的分析，若連續6週獲得滿意的結果，可以減少頻率至隔週1次)
In the case of sampling for *Salmonella* analyses of minced meat, meat prepara tions, carcases and fresh poultry meat, the frequency may be reduced to fort nightly if satisfactory results have been obtained for 30 consecutive weeks. The *Salmonella* sampling frequency may also be reduced if there is a national or regional *Salmonella* control programme in place and if this programme includes testing that replaces the sampling laid down in this paragraph. The sampling frequency may be further reduced if the national or regional *Salmonella* control programme demonstrates that the *Salmonella* prevalence is low in animals purchased by the slaughterhouse.	略(*沙門氏菌*的分析，若連續30週獲得滿意的結果，可以減少頻率至隔週1次；若有國家或區域*沙門氏菌*管控計畫，則依該等計畫調整頻率)
In the case of sampling for *Campylobacter* analysis of poultry carcases, the frequency may be reduced to fortnightly if satisfactory results have been obtained for 52 consecutive weeks. The *Campylobacter* sampling frequency may be reduced, after authorisation by the competent authority, if there is an official or officially recognised national or regional *Campylobacter* control programme in place and if this programme includes sampling and testing equivalent to the sampling and testing required for verifying compliance with the process hygiene criterion set out in Row 2.1.9 of Chapter 2. If low contam ination level of flocks is set for *Campylobacter* in the control programme, the sampling frequency may be further reduced if this low contamination level of *Campylobacter* is reached over a 52-week period in the farms of origin of the broilers purchased by the slaughterhouse. In case the control programme shows satisfactory results during a specific period of the year, frequency of analysis of *Campylobacter* may also be adjusted to seasonal variations after authorisation by the competent authority.	略(*彎曲桿菌*的分析，若連續52週獲得滿意的結果，可以減少頻率至隔週1次；若有國家或區域*彎曲桿菌*管控計畫，則依該等計畫及依主管機關授權的季節調整頻率)
However, when justified on the basis of a risk analysis and consequently auth orised by the competent authority, small slaughterhouses and establishments producing minced meat, meat preparations and fresh poultry meat in small quantities may be exempted from these sampling frequencies. ◄M8	略(若依風險分析證明並獲得主管機關授權的小型屠宰場和生產廠場可免除這些取樣頻率)
►M4 3.3 *Sampling rules for sprouts*	*芽菜的取樣規定(略)*
For the purposes of this Section, the definition of batch in Article 2(b) of Implementing Regulation (EU) No 208/2013 will apply.	
A. General rules for sampling and testing	
1. Preliminary testing of the batch of seeds	
Food business operators producing sprouts shall carry out a preliminary testing of a representative sample of all batches of seeds. A representative sample shall include at least 0,5 % of the weight of the batch of seeds in sub samples of 50 g or be selected based on a structured statistically equivalent sampling strategy verified by the competent authority.	
For the purposes of performing the preliminary testing, the food business operator must sprout the seeds in the representative sample under the same conditions as the rest of the batch of seeds to be sprouted.	
2. Sampling and testing of the sprouts and the spent irrigation water	
Food business operators producing sprouts shall take samples for microbiological testing at the stage where the probability of finding Shiga toxin producing *E. coli* (STEC) and *Salmonella* spp. is the highest, in any case not before 48 hours after the start of the sprouting process.	
Samples of sprouts shall be analysed according to the requirements in rows 1.18 and 1.29 of Chapter 1.	
However, if a food business operator producing sprouts has a sampling plan, including sampling procedures and sampling points of the spent irrigation water, they may replace the sampling requirement under the sampling plans set out in rows 1.18 and 1.29 of Chapter 1 with the analysis of 5 samples of 200 ml of the water that was used for the irrigation of the sprouts.	
In that case requirements set out in rows 1.18 and 1.29 of Chapter 1 shall apply to the	

analysis of the water that was used for the irrigation of the sprouts, with the limit of absence in 200 ml.	
When testing a batch of seeds for the first time, food business operators may only place sprouts on the market if the results of the microbiological analysis comply with rows 1.18 and 1.29 of Chapter 1, or the limit of absence in 200 ml if they analyse spent irrigation water.	
3. Sampling frequency	
Food business operators producing sprouts shall take samples for microbiological analysis at least once a month at the stage where the probability of finding Shiga toxin producing *E. coli* (STEC) and *Salmonella* spp. is the highest, in any case not before 48 hours after the start of the sprouting process.	
B. Derogation from the preliminary testing of all batches of seeds set out in point A.1 of this Section	
When justified on the basis of the following conditions and authorised by the competent authority, food business operators producing sprouts may be exempted from the sampling set out in point A.1 of this Section:	
(a) the competent authority is satisfied that the food business operator implements a food safety management system in that establishment, which may include steps in the production process, which reduces the microbiological risk; and,	
(b) historical data confirms that during at least 6 consecutive months prior to granting the authorisation, all batches of the different types of sprouts produced in the establishment comply with the food safety criteria set out in rows 1.18 and 1.29 of Chapter 1. ◄M4	

ANNEX II	*附錄 II*
The studies referred to in Article 3(2) shall include:	第3(2)條中提及的研究應包括：
— specifications for physico-chemical characteristics of the product, such as pH, a_w, salt content, concentration of preservatives and the type of packaging system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life, and	產品物化特性之規格，諸如pH、a_w、鹽含量、防腐劑濃度和包裝系統類型，同時考慮到儲存和加工條件、污染的可能性和預期的保存期限，以及
— consultation of available scientific literature and research data regarding the growth and survival characteristics of the micro-organisms of concern.	查閱現有關於關注微生物生長和生存特徵的科學文獻和研究數據。
When necessary on the basis of the abovementioned studies, the food business operator shall conduct additional studies, which may include:	必要時在前述研究基礎上，FBO應進行額外的研究，可以是：
— predictive mathematical modelling established for the food in question, using critical growth or survival factors for the micro-organisms of concern in the product,	使用產品中關注微生物的臨界生長或存活因子，對有關食品建立預測性的數學模型。
— tests to investigate the ability of the appropriately inoculated micro-organism of concern to grow or survive in the product under different reasonably foreseeable storage conditions,	在產品中適當地接種關注微生物，以調查在不同合理而可預見的儲存條件下之生長或存活能力的檢測。
— studies to evaluate the growth or survival of the micro-organisms of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use.	評估可能存在於保存期限內產品中關注微生物在合理而可預見的分銷、儲存和使用條件下的生長或存活情形的研究。
The above mentioned studies shall take into account the inherent variability linked to the product, the micro-organisms in question and the processing and storage conditions.	上述研究應考慮與產品相關的內部變異性、有關微生物和加工及儲存條件。

by SW