►M2 Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs◄M2 (OJ L88, p.29)

執委會 2007 年 3 月 28 日制定第 333/2007 號規章關於管控食品中微量元素和加工污染物含量之取樣和分析方法

Amended by COMMISSION REGULATION (EU) No 836/2011 of 19 August 2011 (L215 p.9) (**M1**)（第 1 次修訂）
Amended by COMMISSION REGULATION (EU) 2016/582 of 15 April 2016 (L101 p.3) (**M2**)（第 2 次修訂）
Amended by COMMISSION IMPLEMENTING REGULATION (EU) 2019/2093 of 29 November 2019 (L317 p.96) (**M3**)（第 3 次修訂）
Amended by COMMISSION IMPLEMENTING REGULATION (EU) 2021/705 of 28 April 2021 (L146 p.73) (**M4**)（第 4 修訂）
Amended by Commission Implementing Regulation (EU) 2022/685 of 28 April 2022 (L126 p.14) (**M5**)（第 5 修訂）（本次修正附錄自 2022.12.15 起適用）
(Based on the consolidation of 19 May, 2021)（本譯文係依參照歐盟 Eur-Lex 網站之該規章 2021 年 5 月 19 日合訂版，並納入 M5 修正內容進行編譯）

原(修正)條文	中譯文(條號點次請參照原條文)
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(以下簡稱歐盟)的條約，
Having regard to 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, in particular Article 11(4) thereof,	鑑於歐洲議會及理事會於2004年4月29日通過第882/2004號規章制定確保官方管制之執行符合飼料及食品法、動物健康及動物福利規定，特別是其第11(4)條，
Whereas:	茲以：
(1) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food provides that maximum levels must be set for certain contaminants in foodstuffs in order to protect public health.	理事會於1993年2月8日通過第315/93號規章制定食品污染物的歐盟程序，以規定食品中某些污染物必須被設定最大限量來保護公眾健康。
(2) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs establishes maximum levels for lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in certain foodstuffs.	歐盟執委會於2006年12月19日通過第1881/2006號規章制定食品中某些污染物的最大限量，建立在某些食品中鉛、鎘、汞、無機錫、3-單氯丙二醇(3-MCPD)及苯芘(BaP)的最高含量。
(3) Regulation (EC) No 882/2004 lays down general principles for the official control of foodstuffs. However, in certain cases more specific provisions are necessary to ensure that official controls are performed in a harmonised manner in the Community.	第882/2004號規章制定對食品官方管制之一般原則。然而，在某些情況下，需要更具體的規定來確保歐盟境內的官方管制是以一致的方式執行。
(4) The methods of sampling and analysis to be used for the official control of levels of lead, cadmium, mercury, 3-MCPD, inorganic tin and benzo(a)pyrene in certain foodstuffs are established in Commission Directive 2001/22/EC of 8 March 2001 laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs, Commission Directive 2004/16/EC of 12 February 2004 laying down the sampling methods and the methods of analysis for the official control of the levels of tin in canned foods and Commission Directive 2005/10/EC of 4 February 2005 laying down the sampling methods and the methods of analysis for the official control of the levels of benzo(a)pyrene in foodstuffs, respectively.	某些食品中鉛、鎘、汞、3-MCPD、無機錫及B(a)P含量的官方管制取樣及分析方法，分別制訂於2001年3月8日執委會2001/22/EC指令有關食品中鉛、鎘、汞及3-MCPD含量的官方管制取樣及分析方法、2004年2月12日執委會2004/16/EC指令有關罐頭食品中錫含量的官方管制取樣及分析方法及2005年2月4日執委會2005/10/EC指令有關食品中B(a)P含量的官方管制取樣及分析方法。
(5) Numerous provisions on sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs are similar. Therefore, in the interest of clarity of legislation, it is appropriate to merge those provisions in one single legislative act.	這些對於食品中鉛、鎘、汞、無機錫、3-MCPD和B(a)P含量的官方管制取樣及分析之規定是相似的。因此，為了立法的明確性，合併這些規定為單一立法案是適當的。
(6) Directives 2001/22/EC, 2004/16/EC and 2005/10/EC should therefore be repealed and replaced by a new	2001/22/EC、2004/16/EC及2005/10/EC指令因此

Regulation.	應被廢止並以新的規章來取代。
(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for the Food Chain and Animal Health,	本規章所制定之措施是符合食物鏈及動物健康常務委員會之意見。
HAS ADOPTED THIS REGULATION:	頒布本規章如下：
Article 1	*第1條*
1. ►M3 Sampling and analysis for the control of the levels of lead, cadmium, mercury, inorganic tin, inorganic arsenic, 3-monochloropropane-1,2-diol (3-MCPD), 3-MCPD fatty acid esters, glycidyl fatty acid esters, polycyclic aromatic hydrocarbons (PAH) and perchlorate listed in Sections 3, 4, 6 and 9 of the Annex to Regulation (EC) No 1881/2006 and for the control of the levels of acrylamide in accordance with Commission Regulation (EU) 2017/2158[1] shall be carried out in accordance with the Annex to this Regulation. ◄M3	列在第1881/2006號規章的附錄第3、4、6及9節中，對鉛、鎘、汞、無機錫、無機砷、3-MCPD、3-MCPD脂肪酸酯、甘油脂肪酸酯、多環芳香烴(PAHs)和高氯酸鹽含量管控，以及依據(EU)2017/2158規章對丙烯醯胺含量管控之取樣及分析方法，應依本規章附錄來執行。
2. Paragraph 1 shall apply without prejudice to the provisions of Regulation (EC) No 882/2004.	第1段應在不影響第(EC)882/2004號規章的規定下適用。
Article 2	*第2條*
Directives 2001/22/EC, 2004/16/EC and 2005/10/EC are hereby repealed.	2001/22/EC、2004/16/EC及2005/10/EC等指令特此被廢止。
References to the repealed Directives shall be construed as references to this Regulation.	這些廢止指令的參考文獻應仍為本規章所引用。
Article 3	*第3條*
This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.	本規章應自公告於歐盟官方公報後第20天生效。
It shall apply from 1 June 2007.	本規章應自2007年6月1日起適用。
This Regulation shall be binding in its entirety and directly applicable in all Member States.	本規章應完整並直接應用於所有會員國。

1 Commission Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food (OJ L 304, 21.11.2017, p. 24).

ANNEX *附錄*

PART A **DEFINITIONS**		A 部分 **定義**	
For the purposes of this Annex, the following definitions shall apply:		為本附錄目的，下列定義應適用：	
lot:	►M5 an identifiable quantity of food delivered at one time and determined by the official to have common characteristics (such as origin, variety, species, catchment area, type of packing, packer, consignor or markings); ◄M5	批(次)	一次交(出)貨並由官員確認具有共同特徵(諸如來源、種類、魚種、捕撈區域、包裝型態、包裝者、出貨者或標記)之可識別數量的食品；
sublot:	designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separated and identifiable;	子批/次批/小批(次)	一大批(母體)中的指定部分，以便應用取樣方法在該指定的部分。每一小批必須是可以物理性進行分離及可識別的；
incremental sample:	a quantity of material taken from a single place in the lot or sublot;	增量樣品	從單一地點自批或小批中抽取一定數量的材料；
aggregate sample:	the combined total of all the incremental samples taken from the lot or sublot; aggregate samples shall be considered as representative of the lots or sublots from which they are taken;	聚合樣品	從批或小批中抽取之所有增量樣品的匯集；聚合樣品應視為其所取自之批或小批的代表；
laboratory sample:	a sample intended for the laboratory;	實驗室樣品	供實驗室用之樣品；
►M5 comparable size or weight:	the difference in size or weight does not exceed 50%. ◄M5	相當的大小或重量	大小或重量之差異不超過50%。

PART B **SAMPLING METHODS**	B 部分 **取樣方法**
B.1. GENERAL PROVISIONS	一般規定
B.1.1. **Personnel**	**人員**
Sampling shall be performed by an authorised person as designated by the Member State.	取樣應由會員國指定之授權人員執行。
B.1.2. **Material to be sampled**	**取樣對象**
Each lot or sublot which is to be examined shall be sampled separately.	每一被檢查之批或小批應分別取樣。
B.1.3. **Precautions to be taken**	**預防措施**
In the course of sampling, precautions shall be taken to avoid any changes which would affect the levels of contaminants, adversely affect the analytical determination or make the aggregate samples unrepresentative.	在取樣過程中，應採取預防措施以避免任何可能影響污染物含量、對分析測定有不利影響或使聚合樣品失去代表性的變化。
B.1.4. **Incremental samples**	**增量樣品**
As far as possible, incremental samples shall be taken at various places distributed throughout the lot or sublot. Departure from such procedure shall be recorded in the record provided for under point B.1.8. of this Annex.	增量樣品應盡可能均勻取自批或小批的各部分。與此程序有所不同之取樣，應紀錄於本附錄B. 1. 8. 所指的紀錄中。
B.1.5. **Preparation of the aggregate sample**	**聚合樣品之製備**
The aggregate sample shall be made up by combining the incremental samples.	聚合樣品應由各增量樣品所匯集而成。
B.1.6. **Samples for enforcement, defence and referee purposes**	**為執法、辯護及仲裁目的之樣品**
The samples for enforcement, defence and referee purposes shall be taken from the homogenised aggregate sample	為執法、辯護及仲裁目的之樣品應取自均質之聚合樣品，除非其與會員國為顧及食品業者權益所訂的規定

unless this conflicts with the rules of the Member States as regards the rights of the food business operator.	有所衝突。
B.1.7. **Packaging and transmission of samples**	**樣品之包裝及遞送**
Each sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the sample which might arise during transportation or storage.	每一樣品應置於乾淨的、惰性的容器中，以提供樣品適當的防護，避免受到污染物的污染、分析物質被容器內壁吸收致損耗以及運送過程中的損傷。應採取一切必要的預防措施以避免於運送或儲存過程中可能致使樣品組成份產生任何變化。
►M1 In case of sampling for PAH analysis plastic containers shall be avoided if possible as they could alter the PAH content of the sample. Inert, PAH-free glass containers, adequately protecting the sample from light, shall be used wherever possible. Where this is practically impossible, at least direct contact of the sample with plastics shall be avoided, e.g. in case of solid samples by wrapping the sample in aluminium foil before placing it in the sampling container. ◄M1	在取樣分析PAH的例子，應盡可能避免使用塑膠容器因其可能會改變樣品中PAH含量。應盡可能充分保護樣品免受光照，使用惰性、無PAH的玻璃容器。在實際執行有困難時，至少應避免樣品與塑膠材質直接接觸，例如固態樣品的例子，在放入取樣容器前先用鋁箔包裹樣品。
B.1.8. **Sealing and labelling of samples**	**樣品之密封及標示**
Each sample taken for official use shall be sealed at the place of sampling and identified following the rules of the Member States.	每一個供官方使用所抽取的樣品應於取樣地點即予密封並依各會員國規定予以標識。
A record shall be kept of each sampling, permitting each lot or sublot to be identified unambiguously (reference to the lot number shall be given) and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.	應保有每一次取樣的紀錄，使每一批或小批可明確地識別(應給予取樣編號)並註記取樣日期和地點以及任何對分析員有助益之額外資訊。
B.2. ►M1 SAMPLING PLANS	取樣計畫
B.2.1. **Division of lots into sublots**	**劃分批為小批**
Large lots shall be divided into sublots on condition that the sublot may be separated physically. For products traded in bulk consignments (e.g. cereals) Table 1 shall apply. For other products Table 2 shall apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%. ◄M1	大的批(次)應在得以物理性分離小批的的情況下，劃分為子/次/小批(次)。對以散裝託運交易之產品(例如穀物)，適用表1規定。其他產品則適用表2規定。考量批的重量不總是小批重量的確切倍數，小批重量最高可超過表中所述重量之20%。
▼M4	
B.2.2. **Number of incremental samples**	**增量樣品的數量**
For food, other than food supplements, dried spices or herbs, dried fungi, algae or lichen, the aggregate sample shall be at least 1 kilogram or 1 litre, except where it is not possible, e.g. when the sample consists of 1 package or unit.	除食品補充劑、乾香料或香草、乾真菌、藻類或地衣外，食品的聚合樣品應至少為1公斤或1公升，除非不可能，例如當樣品是單個包裝或單位組成時。
For food supplements, dried spices or herbs, dried fungi, algae or lichen the aggregate sample shall be at least 100 grams or 100 millilitres.	食品補充劑、乾香料或香草、乾真菌、藻類或地衣的聚合樣品應至少為100公克或100毫升。
For food, other than food supplements, the minimum number of incremental samples to be taken from the lot or sublot shall be in accordance with Table 3.	除食品補充劑外的食品，自批或小批抽取增量樣品之最小數量應符合表3規定。
In the case of bulk liquid products, the lot or sublot shall be thoroughly mixed in so far as possible and in so far it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of contaminants shall be assumed within a given lot or sublot. Therefore the number of incremental samples from a lot or sublot to form the aggregate sample shall be three.	以散裝液體產品為例，應儘可能在不影響產品品質條件下，在批或小批取樣前立即地以人工或機械方式徹底混合。此係假設污染物質均勻的分布於此批或小批中。因此，自1批或小批中抽取3個增量樣品以匯集為1個聚合樣品是足夠的。
Where the lot or sublot consists of individual packages or units, for food, other than food supplements, the number of	若批或小批係由個別包裝或單位組成，則對於除食品補充劑外的食品，抽取的包裝或單位(增量樣品)數量

packages or units (incremental samples) to be taken to form the aggregate sample shall be in accordance with Table 4a.	應符合表4a規定以匯集成聚合樣品。
The incremental samples shall be of similar weight/volume. For food, other than food supplements, dried spices or herbs, dried fungi, algae or lichen, the weight/volume of an incremental sample shall be at least 100 grams or 100 millilitres, resulting in an aggregate sample of at least about 1 kilogram or 1 litre.	增量樣品應有相近的重量/體積。除食品補充劑、乾香料或香草、乾真菌、藻類或地衣外，食品的一個增量樣品的重量或體積應至少為100公克或100毫升，以匯集成至少約1公斤或1公升的一個聚合樣品。
For dried spices or herbs, dried fungi, algae or lichen, the weight/volume of an incremental sample shall be at least 35 grams or 35 millilitres, resulting in an aggregate sample of at least 100 grams or 100 millilitres.	對於乾香料或香草、乾真菌、藻類或地衣，一個增量樣品的重量或體積應至少為35公克或35毫升，以匯集成至少約100公克或100毫升的一個聚合樣品。
The maximum levels for inorganic tin apply to the contents of each can, but for practical reasons an aggregate sampling approach may be used. If the result of the test for an aggregate sample of cans is less than but close to the maximum level of inorganic tin and if it is suspected that individual cans might exceed the maximum level, then further investigations shall be conducted.	無機錫的最大限量適用於每罐內容物，但基於務實理由得使用匯集取樣的方法。倘罐製品之聚合樣品的檢驗結果低於但接近於最大限量，致可能有單個罐製品超過最大限量之疑慮，則有必要執行進一步調查。(譯註：實務上，不會逐一單個罐頭進行檢驗，故檢驗結果趨近最大限量值時，須採取必要確認措施。)
For food supplements the minimum number and size of the incremental samples shall be in accordance with Table 4b.	對於食品補充劑，增量樣品之最小數量和大小應符合表4b。
Where it is not possible to carry out the method of sampling set out in this point B.2. because of the unacceptable commercial consequences (e.g. because of packaging forms, damage to the lot) or where it is practically impossible to apply the method of sampling provided for in this point B.2., an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or sublot and is fully documented. This shall be recorded in the record provided for in point B.1.8.	如因無法接受的商業情形(如因包裝型式、批次貨品損壞)而無法執行本點B.2規定的取樣方法，或是實務上無法應用本點B.2的取樣方法時，可以採用其他替代取樣方法，該方法應足以代表取樣批或小批並被完整記錄。此應被記錄於B.1.8.規定的紀錄中。

Table 1

Subdivision of lots into sublots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
≥ 1 500	500 tonnes
> 300 and < 1 500	3 sublots
≥ 100 and ≤ 300	100 tonnes
< 100	—

表 1

散裝託運交易產品劃分批至小批

批重量(噸)	小批之重量或數量
≥ 1,500	500 噸
＞ 300 和 ＜ 1,500	3 小批
≥ 100 和 ≤ 300	100 噸
＜ 100	—

Table 2

Subdivision of lots into sublots for products not traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
≥ 15	15-30 tonnes
< 15	—

表2

非散裝託運交易產品劃分批至小批

批重量(噸)	小批之重量或數量
≥ 15	15~30 噸
＜ 15	—

Table 3

Minimum number of incremental samples to be taken from the lot or sublot of food, other than food supplements

Weight or volume of lot/sublot (in kilogram or litre)	Minimum number of incremental samples to be taken
< 50	3
≥ 50 and ≤ 500	5
> 500	10

表3

食品自批或小批抽取增量樣品之最小數量，食品補充劑除外

批/小批之重量或體積(公斤或公升)	增量樣品之最小數量
＜ 50	3
50 ≤ 和 ≤ 500	5
500 ＜ 50	10

Table 4a

Number of packages or units (incremental samples) to be taken to form the aggregate sample where the lot or sublot consists

表4a

當批或小批係由個別包裝或單位組成的食品，抽取包裝或單位數量(增量樣品)以匯集成聚合樣品，食品補

of individual packages or units of food, other than food supplements

充劑除外

Number of packages or units in the lot/sublot	Number of packages or units to be taken
≤ 25	at least 1 package or unit
26-100	about 5 %, at least 2 packages or units
> 100	about 5 %, at maximum 10 packages or units

批/小批之包裝或單位數量	抽取之包裝或單位數量
≤ 25	至少 1 包/單位
26~100	約 5%，至少 2 包/單位
> 100	約 5%，至多 10 包/單位

Table 4b

The minimum number and size of the incremental samples for food supplements

表4b

食品補充劑增量樣品之最小數量和大小

Lot size (number of packages)	Number of packages (incremental samples) to be taken for sample	Size of the incremental sample
1-50	1	Entire content of the package
51-250	2	Entire content of the package
251-1 000	4	From each retail package taken for sample, half of the content of the package
> 1 000	4+1 packages per 1 000 retail packages with a maximum of 25 retail packages	≤ 10 packages: from each retail package, half of the content of the package > 10 packages: from each package, an equal amount is taken to result in a sample with the equivalent of the content of 5 packages
Unknown (only applicable for e-commerce)	1	Entire content of the package

批量(包裝數量)	抽取作為樣品之包裝數量(增量樣品)	增量樣品之大小
1~50	1	包裝中的完整內容物
51~250	2	包裝中的完整內容物
251~1, 000	4	從每個零售包裝中抽取內容物的一半
> 1, 000	每1, 000個零售包裝取4+1包，最多25包	≤ 10包：從每個零售包裝中抽取內容物的一半 > 10包：從每個包裝中抽取適量內容物以匯集成約5包量的樣品
不明(僅電子商務適用)	1	包裝中的完整內容物

▲M4

▼M1 ▼M5

B.2.3. **Specific provisions for the sampling of lots containing whole fish of comparable size or weight**

對含有相當大小或重量全魚的批次進行抽樣的具體規定

The number of incremental samples to be taken from the lot is set out in Table 3. The aggregate sample uniting all incremental samples shall be at least 1 kilogram (see point B.2.2).

從批次中抽取的增量樣品數量列於表3。所有增量樣品的聚合樣品應至少為1公斤(見B. 2. 2點)。

— Where the lot to be sampled contains small fish (individual fish weighing < 1 kilogram), the whole fish is taken as incremental sample to form the aggregate sample. Where the resulting aggregate sample weighs more than 3 kilograms, the incremental samples may consist of the middle parts of the fish, weighing each at least 100 grams, forming the aggregate sample. The whole part to which the maximum level is applicable, is used for homogenisation of the sample.

在要抽樣的批次中含有小魚(單一魚體重量＜1公斤)時，則取整條魚作為增量樣品成聚合樣品。若得到的聚合樣品重量會超過3公斤時，則增量樣品(每個重量至少100公克)可由魚體中間部分組成，匯集成聚合樣品。最高含量適用於整個部分(譯註：魚體中間部分會是全魚污染物含量最高部位，具有代表性)用作為樣品的均質化。

The middle part of the fish is where the centre of gravity is. This is located in most cases at the dorsal fin (in case the fish has a dorsal fin) or halfway between the gill opening and the anus.

魚體中間部分是其重心所在處。多數情況是位於背鰭處(在魚有背鰭的情況下)或鰓孔和肛門的中間處。

— Where the lot to be sampled contains larger fish (individual fish weighing ≥ 1 kilogram), the incremental sample consists of the middle part of the fish. Each incremental sample weighs at least 100 grams.

在要抽樣的批次中含有較大的魚(單一魚體重量≥1公斤)，則增量樣品由魚體中間部分組成。每個增量樣品至少重100公克。

For fish of intermediate size (≥ 1 kilogram and < 6 kilograms) the incremental sample is taken as a slice of the fish from backbone to belly in the middle part of the fish.

對於中等大小的魚(≥ 1公斤和< 6公斤)，增量樣品取自從魚體中間部分的脊椎到腹部的魚片。

For very large fish (≥ 6 kilograms), the incremental

對於非常大的魚(≥ 6公斤)，增量樣品取自魚體中間

sample is taken from the right side (frontal view) dorso-lateral muscle meat in the middle part of the fish. Where the taking of such a piece of the middle part of the fish would result in a significant economic damage, the taking of three incremental samples of at least 350 grams each may be considered as being sufficient independent of the size of the lot or alternatively three incremental samples of at least 350 grams each from an equal part (175 grams) of the muscle meat close to the tail part and the muscle meat close to the head part of each fish may be considered as being sufficient independent of the size of the lot.	部分的右側(正面視圖)背外側肌肉的肉。在抽取此一塊魚體中間部分會導致重大經濟損失時，則無關乎批次大小地抽取3個至少350公克的增量樣品可以認為是足夠的，或選擇無關乎批次大小地從每條魚尾端的肌肉和頭部附近的肌肉取等量(175公克)為增量樣品，抽取3個至少350公克的增量樣品可以認為是足夠的。
B.2.4. **Specific provisions for sampling of lots of fish containing whole fish of different size and/or weight**	**對含有不同大小和/或重量全魚的批次進行抽樣的具體規定**
The provisions of point B.2.3 as regards sample constitution shall apply.	應適用B. 2. 3點關於樣品組成的規定。
Where a size or weight class/category is predominant (about 80 % or more of the lot), the sample is taken from fish with the predominant size or weight. This sample is to be considered as being representative for the whole lot.	在某大小或重量等級/類別占多數(約批次的80%或以上)時，則樣品當取自該大小或重量的魚體。此樣品被認為對整個批次具有代表性。
Where no particular size or weight class/category predominates, then it shall be ensured that the fish selected for the sample are representative for the lot. Specific guidance for such cases is provided in "Guidance document on sampling of whole fish of different size and/or weight"[2].	在沒有特定大小或重量等級/類別占多數時，則應確保選作為樣品的魚對批次具有代表性。此類情況的具體指引參見「對不同大小和/或重量全魚的取樣指導文件」(譯註：增譯於本規章譯文後)。
B.2.5. **Specific provisions for the sampling of terrestrial animals**	**對陸生動物抽樣的具體規定**
For meat and offal of porcine, bovine, ovine, caprine and equine animals a sample of 1 kilogram shall be taken from at least one animal. If needed to obtain a sample quantity of 1 kilogram, equal sample quantities shall be taken from more than one animal.	對於豬、牛、羊、山羊和馬的肉和內臟，應從至少1隻動物身上抽取1公斤的樣品。若需要獲得1公斤的樣品量，應從不止1隻動物身上抽取等量樣品。
For poultry meat equal quantities shall be sampled from at least three animals in order to obtain an aggregate sample of 1 kilogram. For poultry offal equal quantities shall be sampled from at least three animals in order to obtain an aggregate sample of 300 grams.	對於禽肉，應從至少3隻動物身上抽取等量樣品，以獲得1公斤的聚合樣品。對於家禽內臟，應從至少3隻動物身上抽取等量樣品，以獲得300公克的聚合樣品。
For meat and offal of farmed game animals and wild terrestrial animals a sample of 300 grams shall be taken from at least one animal. If needed to obtain a sample quantity of 300 grams, equal sample quantities shall be taken from more than one animal. ◀M5	對於養殖野味和野生陸生動物的肉和內臟，應從至少1隻動物身上抽取300公克的樣品。若需要獲得300公克的樣品量，應從不止1隻動物身上抽取等量樣品。
B.3. SAMPLING AT RETAIL STAGE	**在零售階段之抽樣**
Sampling of foodstuffs at retail stage shall be done where possible in accordance with the sampling provisions set out in point B.2.2 of this Annex.	零售階段食品之抽樣，應盡可能依本附錄B. 2. 2點的取樣規定執行。
Where it is not possible to carry out the method of sampling set out in point B.2.2 because of the unacceptable commercial consequences (e.g. because of packaging forms, damage to the lot, etc.) or where it is practically impossible to apply the abovementioned method of sampling, an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or sublot and is fully documented. ◀M1	如因無法接受的商業情形(如包裝型式、批次貨品損壞等)而無法執行B. 2. 2點規定之取樣方法，或是實務上無法應用上述取樣方法時，可採用其他替代取樣方法，該方法應足以代表取樣批或小批並被完整記錄。
PART C **SAMPLE PREPARATION AND ANALYSIS**	C 部分 **樣品製備及分析**

2 https://ec.europa.eu/food/safety/chemical-safety/contaminants/sampling-and-analysis

C.1. LABORATORY QUALITY STANDARDS	實驗室品質標準
Laboratories shall comply with the provisions of Article 12 of Regulation (EC) No 882/2004►M1 _____ ◄M1.	實驗室應符合第882/2004號規章第12條規定。
Laboratories shall participate in appropriate proficiency testing schemes which comply with the 'International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories'[3] developed under the auspices of IUPAC/ISO/AOAC.	實驗室應參與適當的能力試驗方案，該方案係遵循在IUPAC/ISO/AOAC主持下制定的「(化學)分析實驗室能力試驗之國際調和協議」。
Laboratories shall be able to demonstrate that they have internal quality control procedures in place. Examples of these are the 'ISO/AOAC/IUPAC Guidelines on Internal Quality Control in Analytical Chemistry Laboratories'[4].	實驗室應能證明其具有內部品質控管程序。例如「ISO/AOAC/IUPAC對分析化學實驗室之內部品質控管指引」。
Wherever possible the trueness of analysis shall be estimated by including suitable certified reference materials in the analysis.	若可能，分析之真值應透過在分析時加入適當之驗證參考物質(CRM)予以估算。
C.2. SAMPLE PREPARATION	樣品製備
C.2.1. **Precautions and general considerations**	**注意事項及一般考量**
►M5 The basic requirement is to obtain a representative and homogeneous laboratory sample without introducing secondary contamination.	基本要求是在不會引入二次污染情形下取得具代表性和均質的實驗室樣品。
The whole part to which the maximum level is applicable shall be used for homogenisation of the sample.	最高含量適用於整個部分(譯註：意指魚體中間部分是全魚污染物質含量最高部位，具有代表性)用作為樣品的均質化。
For products other than fish all of the sample material received by the laboratory shall be used for the preparation of the laboratory sample.	對於魚以外的產品，實驗室收到的所有樣品材料應用作為實驗室樣品的製備。
For fish all of the sample material received by the laboratory shall be homogenised. From the homogenised aggregate sample, a representative part/ quantity shall be used for the preparation of the laboratory sample.	對於魚，實驗室收到的所有樣品材料均應均質化。從均質的聚合樣品中，應使用有代表性的部分/數量來製備實驗室樣品。
Compliance with maximum levels laid down in Regulation (EC) No 1881/2006 shall be established on the basis of the levels determined in the laboratory samples. ◄M5	符合第1881/2006號規章所制定之最大限量值應被設定為實驗室樣品檢測數值之基準。
C.2.2. **Specific sample preparation procedures**	**具體之樣品製備程序**
C.2.2.1. ►M2 Specific procedures for lead, cadmium, mercury, inorganic tin and inorganic arsenic	鉛、鎘、汞、無機錫及無機砷之具體程序
The analyst shall ensure that samples do not become contaminated during sample preparation. Wherever possible, apparatus and equipment coming into contact with the sample shall not contain those metals to be determined and be made of inert materials, e.g. plastics such as polypropylene, polytetrafluoroethylene (PTFE) etc. These should be acid cleaned to minimise the risk of contamination. High quality stainless steel may be used for cutting edges.	分析員應確保樣品製備過程樣品不會被污染。若可能，與樣品接觸之儀器及設備應不含有欲測定之金屬且是由惰性材料所製成，例如聚丙烯、聚四氟乙烯(PTFE)等塑膠材質。它們可以用酸來清洗以降低污染之風險。高品質之不銹鋼可作為切割工具。
There are many satisfactory specific sample preparation procedures which may be used for the products under consideration. For those aspects not specifically covered by this Regulation, the CEN Standard 'Foodstuffs. Determination of elements and their chemical species. General considerations and specific requirements'[5] has been found to be satisfactory but other sample preparation methods may be equally valid.	有許多令人滿意的特定樣品製備程序可於考量後使用。那些未被本規章所涵蓋的程序亦是令人滿意的，如CEN標準「食品－元素及其化學物之測定，一般考量及具體要求」，但其他樣品製備方法可能同樣有效。
In the case of inorganic tin, care shall be taken to ensure that all the material is taken into solution as losses are	以無機錫為例，應小心並確認所有加入溶液中的物質不會發生損耗，特別是因為水解成不溶性的水合氧化

3 'The international harmonized protocol for the proficiency testing of analytical chemistry laboratories' by M. Thompson, S.L.R. Ellison and R. Wood, Pure Appl. Chem., 2006, 78, 145-96.
4 Edited by M. Thompson and R. Wood, Pure Appl. Chem., 1995, 67, 649-666.
5 Standard EN 13804:2013, 'Foodstuffs. Determination of elements and their chemical species. General considerations and specific requirements', CEN, Rue de Stassart 36, B-1050 Brussels.

known to occur readily, particularly because of hydrolysis to insoluble hydrated Sn(IV) oxide species. ◄M2	錫(IV)物質。
C.2.2.2. ►M1 Specific procedures for polycyclic aromatic hydrocarbons	PAHs之具體程序
The analyst shall ensure that samples do not become contaminated during sample preparation. Containers shall be rinsed with high purity acetone or hexane before use to minimise the risk of contamination. Wherever possible, apparatus and equipment coming into contact with the sample shall be made of inert materials such as aluminium, glass or polished stainless steel. Plastics such as polypropylene or PTFE shall be avoided because the analytes can adsorb onto these materials. ◄M1	分析員應確保樣品製備過程樣品不會被污染。容器應在使用前以高純度的丙酮或己烷潤洗來降低污染的風險。若可能，與樣品接觸之儀器及設備應以惰性材料所製成，如鋁、玻璃或精製的不銹鋼。而諸如聚丙烯或PTFE等塑膠材質應避免使用因其會吸收分析物質。
►M2 For the analysis of PAH in cocoa and cocoa derived products, the determination of the fat content is performed in accordance with AOAC Official method 963.15 for the determination of the fat content of cocoa beans and derived products. Equivalent fat determination procedures can be applied for which it can be demonstrated that the used fat determination procedure provides an equal (equivalent) fat content value. ◄M2	在分析可可和其衍生產品中的PAH，脂肪含量的測定係依據AOAC官方方法963.15來進行。等效的脂肪含量測定程序能運用於可證明所使用的脂肪測定程序提供相等(等同)的脂肪含量值。
C.2.3. **Treatment of the sample as received in the laboratory**	**實驗室之收樣處理**
The complete aggregate sample shall be finely ground (where relevant) and thoroughly mixed using a process that has been demonstrated to achieve complete homogenisation.	完整的聚合樣品應被精細地研磨(倘若相關)並使用已被證明可得到完全均質化的方式徹底地混合。
C.2.4. **Samples for enforcement, defence and referee purposes**	**為執法、辯護及仲裁目的之樣品**
The samples for enforcement, defence and referee purposes shall be taken from the homogenised material unless this conflicts with the rules of the Member States on sampling as regards the rights of the food business operator.	對執法、辯護及仲裁目的之樣品應取自均質之物質，除非其與會員國為顧及食品業者權益所訂的取樣規定有所衝突。
C.3. METHODS OF ANALYSIS	分析方法
C.3.1. **Definitions**	**定義**
The following definitions shall apply:	下列定義應適用：
r = Repeatability the value below which the absolute difference between single test results obtained under repeatability conditions (i.e., same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95 %) and hence $r = 2{,}8 \times s_r$.	可重複性，在重複性條件下(如相同樣品、同操作者、同儀器、同實驗室及短暫的時間間隔)獲得的單獨測試結果之間的絕對差值，可被預期落在一特定概率(一般為95%)內，且其值=$2.8 \times s_r$。
s_r = Standard deviation calculated from results generated under repeatability conditions.	標準差，在重複性條件下產生的結果所計算得到的值。 補充：指一組數值自平均值分散開來的程度，公式為 $SD = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}}$
RSD_r = Relative standard deviation calculated from results generated under repeatability conditions $[(s_r/\bar{x}) \times 100]$.	相對標準差，在重複性條件下產生的結果所計算得到的值，公式為$(s_r/\bar{X}) \times 100$。 補充： 第一組數據(10.1、10.2、10.3、10.4、10.5)， $\bar{X}$=10.4，SD=0.158，RSD=1.5； 第二組數據(0.1、0.2、0.3、0.4、0.5)， $\bar{X}$=0.3，SD=0.158，RSD=52.7； 2組數據雖有相同SD，然以RSD則能呈現其實驗的精密度
R = Reproducibility the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); R =	再現性，在可再現的條件下(如不同實驗室的操作人員使用標準化的測試方法就相同的材料所得到的結果)獲得的單獨測試結果之間的絕對差值，可被預期落在一特定概率(一般為95%)內，且其值= $2.8 \times s_R$。

	$2,8 \times s_R$.	
s_R =	Standard deviation, calculated from results under reproducibility conditions.	標準差，在再現性條件下計算所導得的值。
RSD_R =	Relative standard deviation calculated from results generated under reproducibility conditions [$(s_R/\bar{x})\times100$].	相對標準差，在再現性條件下產生的結果所計算得到的值，公式為($s_R/\bar{X}$) × 100。
▼M3		
LOD =	Limit of detection, smallest measured content, from which it is possible to deduce the presence of the analyte with reasonable statistical certainty.	偵測極限，指以合理之統計確定度來推斷分析物質可能存在之可被檢出的最小可測得之含量或濃度。 補充： 偵測極限其值等於3倍的空白樣品中位數值之標準差(n > 20)。 偵測極限可以通過空白樣品或偵測極限附近的樣品測定值的標準差以及偵測極限附近的標準曲線的斜率算出。 公式 LOD=3.3σ/slope σ：空白樣品測定值的標準差 slope：偵測極限附近標準曲線的斜率
LOQ =	Limit of quantification, lowest content of the analyte which can be measured with reasonable statistical certainty. ◄M3	定量極限，指以合理之統計確定度所可被測得的分析物質最低含量。 補充： 若準確度及精確度二者於偵測極限值附近之濃度範圍為一常數值，則定量極限其值等於10倍的空白樣品中位數值之標準差(n > 20)。 定量極限可以通過空白樣品或被測物定量限界附近的樣品測定值的標準差以及定量極限附近的標準曲線的斜率算出。 公式 LOQ=10σ/slope σ：空白樣品測定值的標準差 slope：定量極限附近標準曲線的斜率
$HORRAT^{6}_{r}$ =	►M1 The observed RSD_r divided by the RSD_r value estimated from the (modified) Horwitz equation[7] (cf. point C.3.3.1 (Notes to the performance criteria)) using the assumption r = 0,66 R.	RSD_r觀察值除以使用假設r=0.66R之(修正的)Horwitz方程式估算得到的RSD_r值(參見C.3.3.1點之性能標準註釋)。
$HORRAT_R$ =	The observed RSD_R divided by the RSD_R value estimated from the (modified) Horwitz equation (cf. point C.3.3.1 (Notes to the performance criteria)).	RSD_R觀察值除以使用(修正的)Horwitz方程式估算得到的RSD_R值(參見C.3.3.1點之性能標準註釋)。
u =	Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model[8] ◄M1	量測不確定度，在量測模組中，由標準量測不確定度(使用個別標準量測不確定度計算所得)和輸入數量所組成。
U =	The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).	擴張量測不確定度，在95%信賴水準下使用擴充係數2(U=2u)。
Uf =	Maximum standard measurement uncertainty.	最大標準量測不確定度

▼M2

C.3.2. **General requirements** 一般要求

Methods of analysis used for food control purposes shall comply with the provisions of Annex III to Regulation (EC) No 882/2004.	用於食品管控目的之分析方法應符合第882/2004號規章附錄Ⅲ之規定。
Methods for analysis for total tin are appropriate for control on inorganic tin levels.	總錫之分析方法適用於對無機錫含量之管控。
For the analysis of lead in wine, the methods and rules established by the OIV[9] apply in accordance with Article 80(5) of Regulation (EU) No 1308/2013[10].	（略，對葡萄酒中鉛含量的分析）
Methods for analysis for total arsenic are appropriate for screening purpose for control on inorganic arsenic levels. If the total arsenic concentration is below the maximum level for inorganic arsenic, no further testing is required and the	總砷之分析方法適用於對無機砷含量的篩選管控。若總砷濃度低於無機砷最大限量值，則無須進一步檢測並視為樣品是符合無機砷的最高限量值。若總砷濃度

6 Horwitz W. and Albert, R., 2006, The Horwitz Ratio (HorRat): A useful Index of Method Performance with respect to Precision, Journal of AOAC International, Vol. 89, 1095-1109.
7 M. Thompson, Analyst, 2000, p. 125 and 385-386.
8 International vocabulary of metrology – Basic and general concepts and associated terms (VIM), JCGM 200:2008.
9 Organisation internationale de la vigne et du vin.
10 Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

sample is considered to be compliant with the maximum level for inorganic arsenic. If the total arsenic concentration is at or above the maximum level for inorganic arsenic, follow-up testing shall be conducted to determine if the inorganic arsenic concentration is above the maximum level for inorganic arsenic. ◄M2

達到或高於無機砷最大限量值，則應採取進一步檢測以判定無機砷的濃度是否高於無機砷最大限量值。

C.3.3. **Specific requirements**

特定要求

C.3.3.1. Performance criteria

性能標準

►M1 Where no specific methods for the determination of contaminants in foodstuffs are prescribed at European Union level, laboratories may select any validated method of analysis for the respective matrix provided that the selected method meets the specific performance criteria set out in Tables 5, 6 and 7.

在歐盟階層並未規定測定食品中污染物質的方法，實驗室可對各別的基質選擇任何有效的分析方法，該方法符合表5至7所訂定的特定性能標準。

It is recommended that fully validated methods (i.e. methods validated by collaborative trial for the respective matrix) are used where appropriate and available. Other suitable validated methods (e.g. in-house validated methods for the respective matrix) may also be used provided that they fulfil the performance criteria set out in Tables 5, 6 and 7.

建議使用適當而有效地並經充分驗證的方法(例如經由對個別基質進行協同試驗所驗證之方法)。也可使用其他適合之驗證方法(如經由對個別基質進行內部驗證之方法)，該方法符合表5至7所訂定的性能標準。

Where possible, the validation of in-house validated methods shall include a certified reference material. ◄M1

可能的話，內部驗證方法的確認應包含一個驗證參考物質。

(a) ►M4 Performance criteria for methods of analysis for lead, cadmium, mercury, inorganic tin and inorganic arsenic

鉛、鎘、汞、無機錫及無機砷分析方法之性能標準

Table 5

表5

Parameter	Criterion			
Applicability	Foods specified in Regulation (EC) No 1881/2006			
Specificity	Free from matrix or spectral interferences			
Repeatability (RSD_r)	$HORRAT_r$ less than 2			
Reproducibility (RSD_R)	$HORRAT_R$ less than 2			
Recovery	The provisions of point D.1.2. apply			
LOD	= three tenths of LOQ			
LOQ	Inorganic tin	≤ 10 mg/kg		
	Lead	ML ≤ 0,02 mg/kg	0,02 < ML < 0,1 mg/kg	ML ≥ 0,1 mg/kg
		≤ ML	≤ two thirds of the ML	≤ one fifth of the ML
	Cadmium, mercury, inorganic arsenic	ML ≤ 0,02 mg/kg	0,02 < ML < 0,1 mg/kg	ML is ≥ 0,1 mg/kg
		≤ two fifths of the ML	≤ two fifths of the ML	≤ one fifth of the ML

參數	標準			
適用性	在第1881/2006號規章中規定的食品			
特異性	無基質或光譜干擾物質			
重複性 RSD_r	$HORRAT_r$小於2			
再現性 RSD_R	$HORRAT_R$小於2			
回收率	適用D.1.2.點規定			
偵測極限	等於LOQ的3/10			
定量極限	無機錫	(數值請參左側原文規定值)		
	鉛			
	鎘 汞 無機砷			

▲M4

(b) ►M3 Performance criteria for methods of analysis for 3-monochloropropane-1,2-diol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters:

(略，3-MCPD、3-MCPD脂肪酸酯、甘油脂肪酸酯等分析方法之性能標準)

— Performance criteria for methods of analysis for 3-MCPD in foods specified in point 4.1 of the Annex to Regulation (EC) No 1881/2006

(略，3-MCPD)

Table 6a

表6a

Parameter	Criterion
Applicability	Foods specified in point 4.1 of the Annex to Regulation (EC) No 1881/2006
Specificity	Free from matrix or spectral interferences
Field blanks	Less than LOD

參數	標準
適用性	於第 1881/2006 號規章中規定的食品
特異性	無基質或光譜干擾
環境空白對照組	小於 LOD
重複性(RSD_r)	為自(修正的)Horwitz 方程式推導出來 RSD_R之的 0.66 倍
再現性(RSD_R)	自(修正的)Horwitz 方程式推導出來

Repeatability (RSDr)	0,66 times RSD_R as derived from (modified) Horwitz equation
Reproducibility (RSDR)	as derived from (modified) Horwitz equation
Recovery	75-110 %
Limit of Detection (LOD)	≤ 5 µg/kg (on dry matter basis)
Limit of Quantification (LOQ)	≤ 10 µg/kg (on dry matter basis)

回收率	75-110%
偵測極限	≤ 5μg/kg（以乾物為基準）
定量極限	≤ 10μg/kg（以乾物為基準）

— Performance criteria for methods of analysis for 3-MCPD in foods specified in point 4.3 of the Annex to Regulation (EC) No 1881/2006

（略，3-MCPD）

Table 6b

表6b

Parameter	Criterion
Applicability	Foods specified in point 4.3 of the Annex to Regulation (EC) No 1881/2006
Specificity	Free from matrix or spectral interferences
Field blanks	Less than LOD
Repeatability (RSD_r)	0,66 times RSD_R as derived from (modified) Horwitz equation
Reproducibility (RSD_R)	as derived from (modified) Horwitz equation
Recovery	75-110 %
Limit of Detection (LOD)	≤ 7 µg/kg
Limit of Quantification (LOQ)	≤ 14 µg/kg

（略）

— Performance criteria for methods of analysis for 3-MCPD fatty acid esters, expressed as 3-MCPD, in foods specified in point 4.3 of the Annex to Regulation (EC) No 1881/2006

（略，3-MCPD脂肪酸酯）

Table 6c

表6c

Parameter	Criterion
Applicability	Foods specified in point 4.3 of the Annex to Regulation (EC) No 1881/2006
Specificity	Free from matrix or spectral interferences
Repeatability (RSD_r)	0,66 times RSD_R as derived from (modified) Horwitz equation
Reproducibility (RSD_R)	as derived from (modified) Horwitz equation
Recovery	70-125 %
Limit of Detection (LOD)	Three tenths of LOQ
Limit of Quantification (LOQ) for foods specified in 4.3.1 and 4.3.2	≤ 100 µg/kg in oils and fats
Limit of Quantification (LOQ) for foods specified in 4.3.3 and in 4.3.4 with a fat content < 40 %	≤ two fifths of the ML
Limit of Quantification (LOQ) for foods specified in 4.3.4 with a fat content ≥ 40 %	≤ 15 µg/kg fat

（略）

— Performance criteria for methods of analysis for glycidyl fatty acid esters, expressed as glycidol, in foods specified in point 4.2 of the Annex to Regulation (EC) No 1881/2006

（略，甘油脂肪酸酯）

Table 6d

表6d

Parameter	Criterion
Applicability	Foods specified in point 4.2 of the Annex to Regulation (EC) No 1881/2006

（略）

Specificity	Free from matrix or spectral interferences
Repeatability (RSD_r)	0,66 times RSD_R as derived from (modified) Horwitz equation
Reproducibility (RSD_R)	as derived from (modified) Horwitz equation
Recovery	70-125 %
Limit of Detection (LOD)	Three tenths of LOQ
Limit of Quantification (LOQ) for foods specified in 4.2.1 and 4.2.2	≤ 100 µg/kg in oils and fats
Limit of Quantification (LOQ) for foods specified in 4.2.3 with a fat content < 65 % and in 4.2.4 with a fat content < 8 %	≤ two fifths of the ML
Limit of Quantification (LOQ) for foods specified in 4.2.3 with a fat content ≥ 65 % and in 4.2.4 with a fat content ≥ 8 %	≤ 31 µg/kg fat

▲M3

(c) ►M1 Performance criteria for methods of analysis for polycyclic aromatic hydrocarbons:

PAH分析方法之性能標準

The four polycyclic aromatic hydrocarbons to which these criteria apply are benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene.

這些標準適用於4種PAHs：benzo(a)pyrene、benz(a)anthracene、benzo(b)fluoranthene 及 chrysene

Table 7

表7

Parameter	Criterion
Applicability	Foods specified in Regulation (EC) No 1881/2006
Specificity	Free from matrix or spectral interferences, verification of positive detection
Repeatability (RSD_r)	$HORRAT_r$ less than 2
Reproducibility (RSD_R)	$HORRAT_R$ less than 2
Recovery	50-120 %
LOD	≤ 0,30 µg/kg for each of the four substances
LOQ	≤ 0,90 µg/kg for each of the four substances

參數	標準
適用性	於第 1881/2006 號規章中規定的食品
特異性	無基質或光譜干擾，確效陽性檢測
重複性(RSD_r)	$HORRAT_r$ 值小於 2
再現性(RSD_R)	$HORRAT_R$ 值小於 2
回收率	50-120%
偵測極限	每 1 種均 ≤ 0.30 µg/kg
定量極限	每 1 種均 ≤ 0.90 µg/kg

▲M1

(d) ►M3 Performance criteria for methods of analysis for acrylamide:

丙烯醯胺分析方法之性能標準

Table 8

表8

Parameter	Criterion
Applicability	All foods
Specificity	Free from matrix or spectral interferences
Field blanks	Less than Limit of Detection (LOD)
Repeatability (RSD_r)	0,66 times RSD_R as derived from (modified) Horwitz equation
Reproducibility (RSD_R)	as derived from (modified) Horwitz equation
Recovery	75-110 %
Limit of Detection (LOD)	Three tenths of LOQ
Limit of Quantification (LOQ)	For foods with benchmark levels < 125 µg/kg: ≤ two fifths of the benchmark level, however not required to be lower than 20 µg/kg For foods with benchmark level ≥ 125 µg/kg: ≤ 50 µg/kg

（略）

(e) Performance criteria for methods of analysis for perchlorate:

高氯酸鹽分析方法之性能標準

Table 9

表9

Parameter	Criterion
Applicability	All foods

（略）

Specificity	Free from matrix or spectral interferences
Repeatability (RSD_r)	0,66 times RSD_R as derived from (modified) Horwitz equation
Reproducibility (RSD_R)	as derived from (modified) Horwitz equation
Recovery	70-110 %
Limit of Detection (LOD)	Three tenths of LOQ
Limit of Quantification (LOQ)	≤ two fifths of the ML

(f) Notes to the performance criteria: 性能標準之註解

The Horwitz equation[11] (for concentrations 1,2 x 10^{-7} ≤ C ≤ 0,138) and the modified Horwitz equation[12] (for concentrations C < 1,2 × 10^{-7}) are generalised precision equations which are independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

Horwitz方程式(對濃度值為1.2x10^{-7} ≤ C ≤ 0.138)及修正的Horwitz方程式(對濃度值為C < 1.2x10^{-7})是廣義而精確的方程式，與分析物和基質無關，但對大多數常規分析方法而言，是完全視濃度而定。

Modified Horwitz equation for concentrations C < 1,2 × 10^{-7}: (以下略)

$$RSD_R = 22\ \%$$

where:

— RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions [$(s_R/\bar{x})$ x 100]

— C is the concentration ratio (i.e. 1 = 100g/100g, 0,001 = 1 000 mg/kg). The modified Horwitz equation applies to concentrations C < 1,2 × 10^{-7}.

Horwitz equation for concentrations 1,2 x 10^{-7} ≤ C ≤ 0,138:

$$RSD_R = 2C^{(-0,15)}$$

where:

—RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions [$(s_R/\bar{x})$ x 100]

—C is the concentration ratio (i.e. 1 = 100g/100g, 0,001 = 1 000 mg/kg). The Horwitz equation applies to concentrations 1,2 x 10^{-7} ≤ C ≤ 0,138. ◄M3

C.3.3.2. ►M1 'Fitness-for-purpose' approach 「適合目的」的方法

For in-house validated methods, as an alternative a 'fitness-for-purpose' approach[13] may be used to assess their suitability for official control. Methods suitable for official control must produce results with a combined standard measurement uncertainty (u) less than the maximum standard measurement uncertainty calculated using the formula below:

對於內部驗證的方法，作為另一種「適合目的」之替代方法，可以用來評估其對官方管制之適合性。適用官方管制之方法必須產生小於以下列公式計算得到最大標準量測不確定度(Uf)的組合標準量測不確定度(u)的結果：

$$Uf = \sqrt{(LOD/2)^2 + (\alpha C)^2}$$

$$Uf = \sqrt{(LOD/2)^2 + (\alpha C)^2}$$

where: 而

— Uf is the maximum standard measurement uncertainty (µg/kg). Uf：最大標準量測不確定度(µg/kg)；

— LOD is the limit of detection of the method (µg/kg). The LOD must meet the performance criteria set in point C.3.3.1 for the concentration of interest. LOD：方法之偵測極限(µg/kg)。LOD須滿足C.3.3.1點關於標的濃度設定的性能標準。

— C is the concentration of interest (µg/kg); C：標的濃度(µg/kg)；

— α is a numeric factor to be used depending on the value of C. The values to be used are given in ►M3 Table10. ◄M3 ◄M1 α：為一常數，視濃度值而定。一般使用表10所列數值。

▼M3

Table 10 *表10*

►M1 Numeric values to be used for α as constant in formula 本點公式之常數α值，視標的濃度而定

11 W. Horwitz, L.R. Kamps, K.W. Boyer, J.Assoc.Off.Analy.Chem.,63, 1980, 1344-1354.
12 M. Thompson, Analyst, 125, 2000, 385-386.
13 M. Thompson and R. Wood, Accred. Qual. Assur., 2006, p. 10 and 471-478.

set out in this point, depending on the concentration of interest

C (µg/kg)	α
≤ 50	0,2
51-500	0,18
501-1 000	0,15
1 001 -10 000	0,12
> 10 000	0,1

濃度(μg/kg)	常數 α 值
≤ 50	0.2
51 – 500	0.18
501 – 1,000	0.15
1,001 – 10,000	0.12
>10,000	0.1

The analyst shall note the 'Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation'[14]. ◄M1

分析者應注意「分析結果、量測不確定度、回收率因子及與歐盟食品和飼料法規規定之間關係的報告」。

PART D
REPORTING AND INTERPRETATION OF RESULTS

D 部分
報告及結果解釋

D.1. REPORTING

報告

D.1.1. **Expression of results**

結果表示

The results shall be expressed in the same units and with the same number of significant figures as the maximum levels laid down in Regulation (EC) No 1881/2006.

結果應以第1881/2006號規章所訂定最大限量之相同計量單位及有效位數來表示。

D.1.2. **Recovery calculations**

回收率計算

If an extraction step is applied in the analytical method, the analytical result shall be corrected for recovery. In this case the level of recovery must be reported.

分析方法若有應用萃取步驟，則分析結果應以回收率進行修正，同時，回收率值應予以列出。

►M1 In case no extraction step is applied in the analytical method (e.g. in case of metals), the result may be reported uncorrected for recovery if evidence is provided by ideally making use of suitable certified reference material that the certified concentration allowing for the measurement uncertainty is achieved (i.e. high accuracy of the measurement), and thus that the method is not biased. In case the result is reported uncorrected for recovery this shall be mentioned. ◄M1

在分析方法並未使用萃取步驟(例如金屬分析)時，分析結果可不經回收率修正，理想上可經由使用合適的CRM來證明，而獲得允許量測不確定度(如高準確度之測量)的驗證濃度以及該方法沒有偏頗。未以回收率修正檢驗結果之情形，應於報告中敘明。

D.1.3. **Measurement uncertainty**

量測不確定度

The analytical result shall be reported as x +/– U whereby x is the analytical result and U is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u).

在95%信賴水準下使用擴充係數2(U=2u)，分析結果應以x±U來表示，x表分析結果，U表示擴張量測不確定度。

►M1 The analyst shall note the 'Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation'[15]. ◄M1

分析者應注意「分析結果、量測不確定度、回收率因子及與歐盟食品和飼料法規規定之間關係的報告」。

D.2. INTERPRETATION OF RESULTS

結果解釋

D.2.1. **Acceptance of a lot/sublot**

批/小批的允收

The lot or sublot is accepted if the analytical result of the laboratory sample does not exceed the respective maximum level as laid down in Regulation (EC) No 1881/2006 taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.

若實驗室樣品分析結果未超過各別於第1881/2006號規章所制定的最大限量值(並考慮到擴張量測不確定度及有萃取步驟的分析方法之結果經回收率修正)，該批或小批得以允收(核判合格)。

14 http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf
15 http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf

D.2.2. **Rejection of a lot/sublot**	**批/小批的拒收**
The lot or sublot is rejected if the analytical result of the laboratory sample exceeds beyond reasonable doubt the respective maximum level as laid down in Regulation (EC) No 1881/2006 taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.	若實驗室樣品分析結果合理的懷疑超過在第1881/2006號規章所制定的最大限量值(並考慮到擴張量測不確定度及有萃取步驟的分析方法之結果經回收率修正)，該批或小批得以拒收(核判不合格)。
D.2.3. **Applicability**	**適用性**
The present interpretation rules shall apply for the analytical result obtained on the sample for enforcement. In case of analysis for defence or reference purposes, the national rules shall apply.	現行的解釋規則應適用於強制性管制樣品之分析結果。對用於辯護或參考目的之分析，則應適用國家規定。

【全魚取樣指南】

Guidance on sampling of whole fishes of different size and/or weight	**對不同大小和/或重量全魚的取樣指南**
For batches of fishes of different size and/or weight, in case no particular size or weight class/category predominates, the following sample procedure is proposed:	對於不同大小和/或重量魚的批次，在沒有特定大小或重量等級/類別占多數情形下，建議採用下列抽樣程序：
1) In case the size and/or weight of the fishes present in the lot differs more than 50 % but less than 100 %: two separate representative samples are taken from each size or weight class/category within a lot.	在批次中存在的魚的大小和/或重量差異超過50%但小於100%的情形：從每個大小或重量等級/類別中抽取2個單獨的代表性樣品。
2) In case the size and/or weight of the fishes present in the lot differs more than 100%: three separate representative samples are taken from each size or weight class/category within a lot.	在批次中存在的魚的大小和/或重量差異超過100%的情形：從每個大小或重量等級/類別中抽取3個單獨的代表性樣品。
The laboratory may perform a sequential analysis on the samples of the different size/weight classes/categories of one lot, whereby the sample representing the largest fishes is analysed first.	實驗室可以對1個批次的不同大小/重量等級/類別的樣品依序進行分析，首先從代表最大魚類的樣品開始分析。
-In case the analytical result of this sample is compliant with the maximum level, the whole lot is considered to be compliant.	在該樣品的分析結果符合最大限量時，則認為整批符合要求。
-In case the analytical result of this sample is exceeding the EU maximum level, then the sample taken from the medium size fishes is analysed.	在該樣品的分析結果超過EU最大限量時，則取中型魚的樣品進行分析。
-In case this analytical result is compliant then no analysis is necessary of the sample taken from the smallest size fishes (in case the lot is divided into three size classes).	在該分析結果符合要求時，則無需對從最小型魚所採集的樣品進行分析(若該批次分為3個大小等級)。
-In case the analytical result of the sample of the medium size fishes is non-compliant with the EU maximum level, in case of three separate samples, then the sample from the smallest size fishes is analysed.	在中型魚樣品的分析結果不符合EU最大限量時，若是3個獨立的樣品，則分析最小型魚的樣品。
Based on the analytical results of one or more samples, the whole or parts of the lot can be accepted or rejected.	基於1個或多個樣品的分析結果，能判定接受或拒絕整批或部分批次。
EXAMPLES	範例
1) In case the size and/or weight of the fishes present in the lot differs more than 50 % but less than 100 %: two separate representative samples are taken from each size or weight class/category within a lot.	**在批次中存在的魚的大小和/或重量差異超過50%但小於100%的情形：從每個大小或重量等級/類別中抽取2個單獨的代表性樣品。**
Example: 5 ton lot of fishes with weights from 2 kg to 3.5 kg.	示例：一批5噸的魚，重量從2公斤到3.5公斤。
A first aggregate sample is taken of the smaller sized (lot relative) fishes, which weigh about 2-2.75 kg: 10 incremental samples (fishes) are taken. Each incremental sample is constituted from the muscle meat of the middle part of the fish (slice backbone to belly, symmetrically taken around line B in Figure 1) and weighs about 100 grams. This results in one aggregate sample of about 1 kg to be homogenised and analysed separately.	第1個聚合樣品是從約2-2.75公斤重量類別(相對該批次)較小尺寸的魚中採集的：抽取10個魚的增量樣品。每個增量樣品由魚中間部分的肌肉組成(從脊椎到腹部的魚片，沿著圖1的B線對稱地採樣)，重約100公克。此將產生1個約1kg可被均質化且單獨分析的聚合樣品。
A second aggregate sample is taken of the larger sized (lot relative) fishes, which weigh about 2.75 -3.5 kg : 10 incremental samples (fishes) are taken. Each incremental sample is constituted from the muscle meat of the middle part of the fish (slice backbone to belly, symmetrically taken around line B in Figure 1) and weighs about 100 grams. This results in one aggregate sample of about 1 kg to be homogenised and analysed separately.	第2個聚合樣品是從約2.75-3.5kg重量類別(相對該批次)較大尺寸的魚中採集的：抽取10個魚的增量樣品。每個增量樣品由魚中間部分的肌肉組成(從脊椎到腹部的魚片，沿著圖1的B線對稱地採樣)，重約100公克。此將產生1個約1kg可被均質化且單獨分析的聚合樣品。

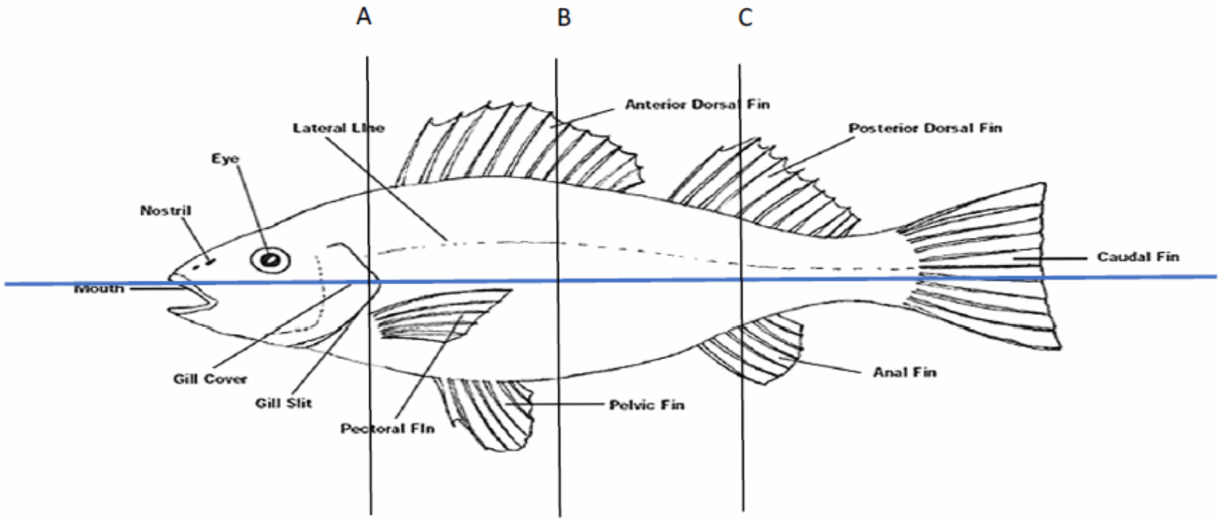

Figure 1: The different sections of a fish./ 圖1. 魚的不同部位

Nostril/鼻孔；Eye/眼；Lateral line/側線；Anterior dorsa fin/前背鰭；Posterior dorsal fin/後背鰭；Caudal fin/尾鰭；Mouth/口；Gill cover/鰓蓋；Gill slit/鰓裂；Pectoral fin/胸鰭；Polvic fin/腹鰭； Anal fin/臀鰭。

A) Laboratory performs a sequential analysis:	實驗室依序進行分析的情形：
First the sample of the larger sized fishes is homogenised and analysed separately.	首先，將較大尺寸魚的樣品均質化及單獨分析。
-In case the analytical result is compliant, the whole lot is compliant.	在分析結果符合時，則整批判定合格。
-In case the analytical result is non-compliant, as a second step the sample of the smaller sized fishes is homogenised and analysed separately.	在分析結果不符合時，進行第2步驟—將較小尺寸魚的樣品均質化並單獨分析。
-- In case the analytical result of the sample of the smaller sized fishes is non-compliant, the whole lot is non-compliant.	若較小尺寸魚樣品的分析結果是不符合時，則整批判定不合格。
-- In case the analytical result of the sample of smaller sized fishes is compliant, then the smaller sized fishes (2-2.75 kg) have to be sorted out and these fishes are compliant. The remaining larger sized fishes (2.75-3.5 kg) are non-compliant.	若較小尺寸魚樣品的分析結果是符合時，則必須將此規格小魚(2-2.75公斤)挑揀出來並判定為合格。其餘較大尺寸魚(2.75-3.5公斤)則判定為不合格。
B) Laboratory analyses both samples at the same time:	實驗室同時分析2個樣品的情形：
-In case both analytical results are compliant, the whole lot is compliant.	在2者分析結果都是符合時，則整批判定合格。
-In case both analytical results are non-compliant, the whole lot is non-compliant.	在2者分析結果都是不符合時，則整批判定不合格。
-In case the sample of the smaller sized fishes (2-2.75 kg) is compliant and the sample of the larger sized fishes (2.75-3.5 kg) not, then the smaller sized fishes (2-2.75 kg) have to be sorted out and these small sized fishes are compliant. The remaining larger sized fishes (2.75-3.5 kg) are non-compliant.	若小魚樣品(2-2.75公斤)是符合，而大魚樣品(2.75-3.5公斤)是不符合時，則必須將小魚(2-2.75公斤)挑揀出來並判定為合格。其餘較大尺寸魚(2.75-3.5公斤)則判定為不合格。
2) In case the size and/or weight of the fishes present in the lot differs more than 100%: three separate representative samples are taken from each size or weight class/category within a lot	**在批次中存在的魚的大小和/或重量差異超過100%的情形：從每個大小或重量等級/類別中抽取3個單獨的代表性樣品**
Example: 10 ton lot of fishes with weights from 2 kg to 8 kg.	示例：一批10噸的魚，重量從2公斤到8公斤。
A first aggregate sample is taken of the smaller sized (lot relative) fishes, which weigh about 2-4 kg: 10 incremental samples (fishes) are taken, each incremental sample is constituted from the muscle meat of the middle part of the fish (slice backbone to belly, symmetrically taken around line B in Figure 1) and weighs about 100 grams. This results in one aggregate sample of about 1 kg, to be homogenised and analysed	第1個聚合樣品是從約2-4公斤重量類別(相對該批次)較小尺寸的魚中採集的：抽取10個魚的增量樣品。每個增量樣品由魚中間部分的肌肉組成(從脊椎到腹部的魚片，沿著圖1的B線對稱地採樣)，重約100公克。此將產生1個約1kg可被均質化且單獨分析的聚合樣品。

separately.	
A second aggregate sample is taken of the fishes of medium size (lot relative) of about 4-6 kg: 10 incremental samples (fishes) are taken, each incremental sample is constituted from the muscle meat of the middle part of the fish (slice backbone to belly) and weighs about 100 grams. This results in one aggregate sample of about 1 kg, to be homogenised and analysed separately.	第2個聚合樣品是從約4-6kg重量類別(相對該批次)中等尺寸的魚中採集的：抽取10個魚的增量樣品，每個增量樣品由魚中間部分的肌肉組成(從脊椎到腹部的魚片)，重約100公克。此將產生1個約1kg可被均質化且單獨分析的聚合樣品。
A third aggregate sample is taken of the larger sized (lot relative) fishes of about 6-8 kg: 3 incremental samples (fishes) are taken, each incremental sample is	第3個聚合樣品是從約6-8kg重量類別(相對該批次)較大尺寸的魚中採集的：抽取3個魚的增量樣品，每個增量樣品是
-constituted of the right side dorso-lateral muscle meat in the middle part of the fish (symmetrically around line B in Figure 1 and above the horizontal line in Figure 1) and weighs about 350 grams. This results in one aggregate sample of about 1 kg to be homogenised and analysed separately.	由魚中間部分右側背外側的肌肉組成(沿著圖1的B線並在水平線上方對稱地採樣)，重約350公克。此將產生1個約1kg可被均質化且單獨分析的聚合樣品。
OR	或是
-constituted of equal parts of 175 grams of the muscled meat close to the tail part (the region around line C in Figure 1) and the muscle meat close to the head part of one fish (the region of line A in Figure 1) which are combined to form an incremental sample of about 350 grams per fish. This results in one aggregate sample of about 1 kg to be homogenised and analysed separately.	由靠近尾部肌肉(沿著圖1中C線區域)和靠近魚頭肌肉(圖1的A線區域)等量175克組成，加起來形成每條魚約350公克的1個增量樣品。此將產生1個約1kg可被均質化且單獨分析的聚合樣品。
A) The laboratory performs a sequential analysis:	實驗室依序進行分析的情形：
First the sample of the larger sized fishes (6-8 kg) is homogenised and analysed separately.	首先，將較大尺寸魚(6-8公斤)的樣品均質化及單獨分析。
-In case the analytical result is compliant, the whole lot is compliant	在分析結果符合時，則整批判定合格。
-In case the analytical result is non-compliant, as a second step the sample of the medium sized fishes (4-6 kg) is homogenised and analysed separately.	在分析結果是不符合時，進行第2步驟—將中等尺寸魚(4-6公斤)的樣品均質化並單獨分析。
-- In case the analytical result of the sample of medium sized fishes (4-6 kg) is compliant, then the larger sized fishes (6-8 kg) have to be sorted out and these fishes (6-8 kg) are non-compliant. The remaining smaller (2-4 kg) and medium sized (4-6 kg) fishes are compliant.	若中等尺寸(4-6公斤)樣品的分析結果是符合時，則必須將較大型魚(6-8公斤)挑揀出來，這些6-8公斤的魚判定為不合格。其餘較小型(2-4公斤)和中型(4-6公斤)魚則判定為合格。
-- In case the analytical result of the sample of medium sized fishes (4-6 kg) is non-compliant, as a third step the sample of the smaller sized fishes (2-4 kg) is homogenised and analysed.	若中等尺寸(4-6公斤)樣品的分析結果是不符合時，進行第3步驟—對較小尺寸魚(2-4公斤)的樣品均質化並單獨分析。
-- -- In case the analytical result of the sample of smaller sized fishes (2-4 kg) is non-compliant, then the whole lot of fish is non-compliant	若小型魚(2-4公斤)樣品的分析結果是不符合時，則整批判定不合格。
-- -- In case the analytical result of the sample of smaller sized fishes (2-4 kg) is compliant, then the smaller fishes (2-4 kg) have to be sorted out and these fishes (2-4 kg) are compliant. The remaining medium (4-6 kg) and larger sized fishes (6-8 kg) are not compliant.	若小型魚(2-4公斤)樣品的分析結果是符合時，則必須將較小型魚(2-4公斤)挑揀出來，這些2-4公斤的魚判定為合格。其餘中型(4-6公斤)和大型(6-8公斤)魚則判定為不合格。
B) The laboratory analyses all three samples at the same time	實驗室同時分析3個樣品的情形：
- In case all three analytical results are compliant, the whole lot is compliant.	在3者分析結果全都是符合時，則整批判定合格。
- In case all three analytical results are non-compliant, the whole lot is non-compliant.	在3者分析結果全都是不符合時，則整批判定不合格。
- In case the sample of the smaller fishes (2-4 kg) is compliant and the sample of the medium sized (4-6 kg) and larger fishes (6-8 kg) not, then the smaller fishes (2-4 kg) have to be sorted out and these fishes are compliant. The remaining medium sized (4-6 kg) and	若小型魚(2-4公斤)樣品是符合，而中型(4-6公斤)和大型(6-8公斤)魚的樣品是不符合時，則必須將小魚(2-4公斤)挑揀出來並判定為合格。其餘中型(4-6公

larger sized fishes (6-8 kg) are non-compliant.	斤)和大型(6-8公斤)魚則判定為不合格。
- In case the sample of the smaller (2-4 kg) and medium sized fishes (4-6 kg) is compliant and the sample of the larger sized fishes (6-8 kg) not, then the larger sized fishes (6-8 kg) have to be sorted out and these fishes (6-8 kg) are non-compliant. The remaining smaller (2-4 kg) and medium sized fishes (4-6 kg) are compliant.	若小型魚(2-4公斤)和中型魚(4-6公斤)樣品是符合，而大型魚(6-8公斤)樣品是不符合時，則必須將大型魚(6-8kg)挑揀出來，這些6-8公斤的魚判定為不合格。其餘較小型(2-4公斤)和中型(4-6公斤)魚則判定為合格。

by SW