中文	英譯
輸歐盟水產品官方管制行動方案	**Action Program for the Official Controls of Fishery Products Intended for Exporting to the European Union**
制修訂歷程	Chronicles of Promulgation and Amendments
中華民國 97 年 9 月 8 日行政院院臺農字第 0970037118 號函備查訂定全文 29 點	Promulgated on 08 Sep. 2008. Executive Yuan Ref. No. 0970037118
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第一章 訂定目的與適用範圍	**Chapter 1 The Objective and Scope**
一、為規範中華民國輸歐盟水產品各權責機關之官方管制作業，以確保輸歐盟水產品衛生安全符合歐盟法規，特訂定本行動方案。	1. This Action Program aims to regulate the official controls of fishery products (FPs) intended for exporting to the European Union (EU), in order to ensure FPs meet the EU regulations and health standards.
二、本行動方案之用詞定義如附件一。	2. The definitions of terms for this Action Program are listed in Annex I.
三、輸歐盟水產品之官方管制包括自生產至出口所有階段，一般採用之適當控制方法與技術包括監視、監測、查證、稽核、檢查、取樣、分析、測試及診斷等。	3. The tasks for official controls for FPs intended for exporting to the EU shall be implemented at all stages from primary production to exportation, performing control methods and techniques such as surveillance, monitoring, verification, audit, inspection, sampling, analysis, test and diagnosis.
第二章 官方管制權責分工與一般要求	**Chapter 2 Cooperation among Competent Authorities for Official Controls and General Requirements**
四、經濟部標準檢驗局（以下簡稱標準局）、農業部漁業署（以下簡稱漁業署）、農業部動植物防疫檢疫署（以下簡稱防檢署）、衛生福利部食品藥物管理署(以下簡稱食藥署)、經濟部國際貿易署（以下簡稱貿易署）及環境部，為促進水產品順利輸銷歐盟，特組成輸歐盟水產品專案小組(以下簡稱專案小組)，標準局為主要權責機關，漁業署、防檢署及食藥署為協辦權責機關。貿易署為協助機	4. To ensure compliance with the EU rules, a multi-governmental team (MGT) on FPs export to the EU, is formed by the Bureau of Standards, Metrology and Inspection (BSMI) of the Ministry of Economic Affairs (MOEA), the Fisheries Agency (FA) and the Animal and Plant Health Inspection Agency (APHIA) of the Ministry of Agriculture, Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and

關，提供貿易法規及貿易推廣等資訊。環境部為協助機關，提供飲用水水質標準及水質稽查結果等資訊。	Welfare, International Trade Administration (TITA) of MOEA, and the Ministry of Environment (MOENV). The BSMI is the central competent authority (the CCA), and the jointly competent authorities are consisted of FA, APHIA and TFDA. As the assistance authorities, the TITA serves to provide information on trade regulations and trade promotions, and the MOENV serves to provide the drinking water quality standards and audit outcomes.
五、專案小組由標準局局長擔任召集人，並由標準局、漁業署、防檢署及食藥署各指派一人擔任副召集人，共同督導相關業務及協調部會作業。	5. The convener of the MGT is the Director-General of BSMI. Furthermore, BSMI, FA, APHIA and TFDA shall each appoint a representative to be the deputy convener of the MGT responsible for supervising and coordinating the affairs of FPs intended to export to the EU.
六、專案小組下設工作小組，由權責機關指派若干人員組成，並推派一人擔任組長，以隨時聯繫確保輸歐盟水產品之官方管制正常運作，工作項目包括：	6. Under the MGT, a Working Group which consists of all competent authorities (CAs) is established, and the CAs shall appoint one person as the group leader. The Working Group is responsible for maintaining coordination between participating CAs, in order to ensure the proper conduct of official controls of FPs intended for exporting to the EU. The tasks include:
（一）每年至少召開會議一次，以檢討當年度成果及下年度計畫。	(1) To organized at least one meeting per year to review annual official control outcomes and the plan for the upcoming year;
（二）定期查詢歐盟法規之更新，以提供權責機關檢討訂定/修訂相關法令及程序。	(2) To review updates of the EU regulations periodically, and to provide findings to all participating CAs to assess whether current regulations and procedures need to be amended;
（三）對權責機關進行內部稽核，以確認管制措施結果符合原管制目標，並依結果採取適當措施。稽核應符合	(3) To perform internal audits in CAs to ensure the outcomes of official controls meet the objectives, and ensure that CAs have taken

公正且符合利益迴避及透明化之原則。	appropriate actions according to the outcomes. Audits should be impartial and avoid conflicts of interest, as well as performed in a transparent manner;
（四）統籌規劃輸銷歐盟水產品相關法規之教育訓練。	(4) To coordinate and conduct trainings on regulatory provisions for FPs exporting to the EU; and
（五）輸歐盟水產品發生嚴重食品風險情事時，立即執行危機處理，以確保產品安全。	(5) In case of any food safety risk emerged, to perform crisis management and take actions immediately to ensure the safety of FPs.
七、輸歐盟水產品之官方管制由權責機關依權責執行，其分工如下：	7. The official controls of FPs intended for exporting to the EU are conducted by the CAs according to their responsibilities as follows:
（一）漁業署主管水產品生產階段之衛生管理。	(1) FA is the competent authority for the hygiene management of the primary production of FPs.
（二）防檢署主管動物用藥品及法定動物傳染病管理。	(2) APHIA regulates veterinary medicines and statutory zoonotic diseases.
（三）標準局主管輸歐盟水產品自加工至出口階段之衛生管理。	(3) BSMI is responsible for the hygiene management of FPs intended for exporting to the EU from the manufacturing stage to exporting stage.
（四）食藥署主管國內食品安全衛生法規、水產品製造業者衛生管理與提供歐盟食品及飼料快速警示系統通報案件資訊。	(4) TFDA regulates domestic food safety regulations, hygiene management of FPs manufacturers and reporting cases from EU Rapid Alert System for Food and Feed (RASFF).
八、權責機關應依下列原則執行官方管制措施：	8. The CAs shall perform official controls based on the following principles:
（一）制定書面作業程序。	(1) To establish documented or written procedures and arrangements;
（二）符合機密保護原則並維持高度之透明性。	(2) To comply with the principle of confidentiality, while maintaining high transparency;
（三）官方管制人員執行相關作業時應符合利益迴避原則。	(3) To ensure that the staffs performing official controls and related activities shall be free from any conflict of interests;

（四）除非確有必要或因官方管制活動性質需要，不得事先告知業者。	(4) To perform official controls to the food business operators without prior notice, unless such prior notice is necessary for the controls to be carried out or the nature of the official control activities requires otherwise;
（五）應基於風險以適當頻率對業者進行官方管制。風險考量因素包括生產場所與活動類型、可能影響產品安全與動物健康之流程、業者違規紀錄或任何可能顯示不符合法規的資訊，以及國內外不合格水產品資訊通報等。	(5) To perform official controls based on risks and with appropriate frequency, identified risks including production sites and activity nature, the procedures of production or manufacturing of FPs that potentially affect product safety and animal health, the food business operator's past records with regard to compliance or any suspicion of non-compliance, and any domestic or international reports of non-compliance; and
（六）執行官方管制應作成紙本或電子化紀錄，包括官方管制之標的、標準及結果。發現有不符合事項時，應以書面通知並要求業者採取行動。	(6) To draw up written records on hard copy or digital form for every performed official control, including the objective, standards and outcomes, to inform the food business operators by a written notice when non-conformity is found, and to require the food business operators to take corrective actions.
九、權責機關應將廠場登錄狀況及年度官方管制類型、數量與結果等相關資訊公告於網站，以確保官方管制資訊之透明化。	9. In order to ensure the transparency of the performance of official controls, the CAs shall make relevant information available to the public on the internet, including the approval or registration status of establishments, and the type, number and outcome of annual official controls.
第三章 官方管制人員之資格及訓練	**Chapter 3 Qualification and Trainings for Staffs Performing Official Controls**
十、執行官方管制人員應為漁撈、水產養殖、畜牧、獸醫、食品相關科系畢業，或從事相關工作一年以上持有工作證明者。	10. The staffs performing official controls shall have a degree related to fishing industry, aquaculture, animal husbandry, veterinary medicine or food, or have at least one year of relevant working experiences with

	supporting documents.
十一、 權責機關應依業務特性對官方管制人員培訓，並訂定年度訓練計畫，訓練範疇如附件二。 前項人員訓練皆須留有紀錄，並予以保存備查。	11. The CAs shall organize and conduct trainings for the staffs performing official controls based on their assigned duties, and develop an annual training scheme. The areas of the training are described in Annex II. The above-mentioned trainings for each staff shall be recorded and the record be kept for reference.
十二、 權責機關應對執行官方管制之人員進行考核，考核結果有不符合項目者，應進行再教育訓練等適當之調整措施。	12. The CAs shall evaluate the qualification of staffs performing official controls. To take corrective measures such as re-training, where appropriate, if any non-satisfied result is found.
第四章 官方實驗室之管理	**Chapter 4 Management of Official Laboratories**
十三、 權責機關應指定實驗室執行官方管制行動所採樣品之分析、測試或診斷。除水生動物疾病診斷依照世界動物衛生組織（WOAH）規範外，應要求實驗室依據 ISO/IEC 17025 運作及取得認證。	13. The CAs shall designate laboratories to analyze, test, or diagnose on samples taken from official controls. Laboratories should be accredited and perform tasks in accordance with ISO/IEC 17025, except that the task for aquatic animal disease diagnosis shall be conducted according to the requirements of the World Organization for Animal Health (WOAH).
十四、 權責機關應要求實驗室採取符合歐盟、國際或我國認可或建議之方法、基準或規範，在經過確效程序確認其適用性後，執行分析、測試及診斷。	14. The CAs shall require designated laboratories to adopt methods, criteria, or protocols recognized or recommended by EU, international organizations or national government, and ensure that they have been validated for analytical, testing, and diagnostic needs.
十五、 權責機關應要求實驗室參加實驗室間比對或能力試驗，以評估其分析、測試或診斷之能力。	15. The CAs shall require designated laboratories to participate in inter-laboratory comparative tests or proficiency tests, in order to evaluate their competence to carry out analysis, testing,

	and diagnosis.
十六、 權責機關應定期或於必要時對實驗室進行稽核，如發現缺失，得命其限期改正。實驗室未依限完成改正者，權責機關得終止其指定資格或部分之受委託工作。	16. The CAs shall audit designated laboratories regularly or when necessary, and if any defect is found, the CAs shall require the designated laboratory to implement corrective measures in a given deadline. If the defect is not corrected by the deadline, the CAs shall terminate the designation of the laboratory, or partially withdraw the delegated tasks.
第五章 官方管制措施委託之管理	**Chapter 5 Management of the Delegated Official Control Measures**
十七、 輸歐盟水產品之官方管制除不符合事項之處置外，得以書面方式委託其他機關（構）、法人或民間團體等(以下簡稱受委託單位)辦理。	17. Except for the intensified official controls for the cases of non-compliance, the delegation of official control tasks of FPs intended for exporting to the EU to a delegated body (DB), such as relevant government agency or body, juristic person or organization, shall be in made written form.
十八、 權責機關應確認受委託單位具有適當專業技能、充足人員、設施及設備，得以公正且符合利益迴避原則從事受委託之工作。	18. The CAs shall ensure that the DBs have the expertise, a sufficient number of qualified staffs, equipment and infrastructure required to perform the delegated tasks impartially and avoid conflicts of interest.
十九、 權責機關應要求受委託單位定期或必要時回報執行受託工作之管控結果。 管控結果顯示不符合或有不符合之虞者，受委託單位應立即通知權責機關。 必要時，權責機關得要求受委託單位配合調查或提供必要合作及協助。	19. The CAs shall require the DBs to report the outcome of delegated official control tasks regularly or when requested. The DB shall inform the delegating CAs immediately if the resulted of delegated official control tasks is non-compliant or likely to be non-compliant. When necessary, the CAs may require the DBs to cooperate in the investigation or provide assistance.
二十、 權責機關應要求執行水產品生產廠場驗證或符合性評鑑工作之受委託	20. The CAs shall require the DBs responsible for certifying or carrying out conformity

單位依據 ISO/IEC 17065、ISO/IEC 17021 或 ISO/TS 22003 運作及取得認證。	assessment for establishments that produce FPs to be accredited and perform delegated official control tasks in accordance with ISO/IEC 17065, ISO/IEC 17021 or ISO/TS 22003.
二十一、權責機關應查證受委託單位履行委託工作之情形，包括人員之見證評鑑。如發現受委託單位不能妥適執行委託工作，或無法對被發現的缺失採取適當且即時之補救措施時，應立即終止全部或部分委託工作。	21. The CAs shall verify the DBs' implementation progress on the delegated duties, including performing an on-site witness audit. The CAs shall fully or partially withdraw the delegation without delays where the DBs fail to properly perform the delegated tasks, or fail to take appropriate and timely actions to remedy the shortcomings identified.
第六章 廠場查核	**Chapter 6 Official Controls on Establishments**
二十二、權責機關執行廠場檢查或稽核時，應查證廠場已建立、執行與維持適當之良好衛生作業流程，並有相關文件及紀錄，確保生產各階段符合我國及歐盟相關法規要求。	22. The CAs shall assess or audit that the establishments have established, implemented and maintained the procedures on good hygiene operating practices, and possess related documents and records, in order to ensure that all stages of production are in accordance with domestic regulations as well as EU's.
前項廠場如為凍結漁船、運搬船及加工廠，另應查證已建立、執行與維持符合危害分析重要管制點系統程序。	If the above-mentioned establishments are freezer vessels, reefer vessels and processing plants, the CAs shall also assess or audit whether their procedures have been established, implemented and maintained based on the principles of Hazard Analysis and Critical Control Points (HACCP).
查證項目得依廠場實際生產情況適當調整，必要時可取樣以供官方實驗室分析。	Tasks of official controls should be adjusted appropriately according to the nature and production status of the establishments, when necessary, samples taken from the establishments may be delivered to official laboratories for analyses.
第七章 水產品衛生管理	**Chapter 7 Hygiene Management for FPs**

二十三、權責機關應依生產各階段之特性執行水產品與水質衛生管理。 前項所稱之衛生管理應符合歐盟有關產品追溯性、官能檢查、鮮度指標、組織胺、微生物、寄生蟲、有毒水產品、環境污染物、食品添加物、包材與標識，以及潔淨海水、潔淨水與飲用水等廠場用水之規定。	23. The CAs shall conduct official controls on hygiene for FPs as well water quality, depending on the characteristics of the different stages of production. The above-mentioned official controls on hygiene shall comply with EU's requirements, including traceability, organoleptic check, freshness index, histamine, microorganism, parasites, toxic fishery species, contaminants, food additives, packaging materials and labelling as well as requirements for clean sea water, clean water and drinking water used by the establishments.
二十四、權責機關應訂定及執行養殖水產品殘留物年度監測計畫，並於每年三月三十一日前併同上年度監測計畫結果彙送歐盟執委會。	24. The CAs shall develop and enforce an annual residues monitoring plan for aquaculture, and should submit the plan and the results of the previous year to the European Commission before March 31st every year.
二十五、權責機關應依據歐盟規範或符合國際認可方式，執行樣品採樣、處理及標示，以確保具官方管制代表性。	25. The CAs shall perform sampling, handling, and marking of samples taken based on EU's specifications or internationally recognized methods to ensure the representativeness of official controls.
第八章 不符合之處置	**Chapter 8 Actions for Non-Compliant Cases**
二十六、權責機關執行官方管制發現不符合規定之情事且直接影響輸歐盟水產品之衛生安全時，應採取行動並通知相關主管機關以追溯不符合事項發生之來源、影響程度及責任。權責機關應採取適當行動，確認不符合事項已改善。 食藥署接獲歐盟食品及飼料快速警示系統通報我國輸歐盟水產品案件後，應即時通知標準局依前項規定	26. The CAs shall take actions and notify relevant CAs to trace and confirm the source of the non-compliance as well as any impacts and responsibilities brought about, when non-compliance which may directly affect product safety is found while carrying out the official controls. The CAs shall take appropriate actions to ensure that the non-compliance has been remedied. When receiving reports from the Rapid Alert System for Food and Feed (RASFF)

採取適當處置。	regarding the FPs intended for exporting from Taiwan to the EU, the TFDA shall notify the BSMI immediately to take appropriate actions mentioned above.
二十七、權責機關執行本行動方案發現其他影響水產品衛生安全情事，應通報相關主管機關，得由主管機關依相關法規採取以下措施：	27. Where any non-compliance is discovered while conducting this Action Program, the CAs shall notify relevant CAs to take the following regulatory measures according to the relevant regulations:
（一）確保水產品的衛生安全所須採行之矯正行動以符合法規要求。	(1) To ensure that the corrective measures for the hygiene safety of FPs are implemented, in order to comply with the regulatory requirements;
（二）限制或禁止該水產品流入市場、進口或出口。	(2) To restrict or prohibit specific FPs from entering the market, importing or exporting;
（三）監視或必要之回收、下架、改製或銷毀該水產品。	(3) To monitor the FPs, and if necessary, FPs should be recalled, withdrawn, reprocessed, or destroyed;
（四）命令廠場暫停其生產，停止全部或部分營運一段期間。	(4) To order the establishments to cease production of some or all FPs for a period;
（五）暫停、撤銷或廢止廠場之核可或登錄。	(5) To cease, revoke, or terminate the approval or registration of the establishments; and
（六）其他主管機關認為適當之處置方法。	(6) To take other actions agreed by relevant CAs.

附件一 用詞定義	Annex I Definitions of Terms for the Action Program
一、水產品（Fishery product）： 指除雙枚貝類、棘皮類、海鞘類、海洋腹足類、哺乳類、爬蟲類及蛙類等以外的所有野生或養殖之海水或淡水動物，包括此類動物之所有可供人食用形式、部位及其製品。	1. Fishery Product: any wild or farmed marine or freshwater animals, including their edible parts and processed products thereof except for bivalves, echinoderms, tunicates, gastropods, mammals, reptiles and frogs.
二、權責機關（Competent authority）： 指具有能力組織及執行官方管制之中央級機構，或其他被授權之機構。	2. Competent Authority: any organizations of central level or other authorized institutions that conduct official controls.
三、官方管制（Official control）： 指權責機關為判定輸歐盟水產品是否遵循歐盟食品及動物健康與福祉相關法規所做之任何形式控制。	3. Official Control: any procedures or actions that the competent authorities implement to determine whether fishery products intended for exporting to the EU meet EU's regulations for food safety, animal health and welfare.
四、監視（Surveillance）： 指權責機關對輸歐盟水產品持續性蒐集及分析關於水產品產業、業者或其活動相關之資訊，以確保官方管制之規劃、實施、檢查及行動，符合歐盟相關規定要求。	4. Surveillance: the act of the competent authorities to collect and analyze information regarding fishery businesses, operators and their activities on a continued basis, in order to ensure the official controls for fishery products intended for exporting to EU, such as planning, implementation, inspection and action, meet the EU's requirements.
五、監測（Monitoring）： 指權責機關為確保輸歐盟水產品符合歐盟法規規定，執行一個有計畫或系列之觀察或量測，以得知水產品及水生動物健康狀況是否符合歐盟法規要求。	5. Monitoring: the act of the competent authorities to conduct a planned or a series of observation or measurement, in order to confirm whether fishery products intended for exporting to the EU, as well as the health of aquatic animals, are in compliance with EU's regulations.
六、查證（Verification）： 指以稽核或檢查方式並考量客觀證據，來判定是否符合特定規範之核對工作。	6. Verification: the determination of whether the subject of interest meets specific requirements by

	conducting an audit or an inspection, as well as evaluating the objective evidence.
七、稽核（Audit）： 指有系統、獨立及文件化獲取客觀證據並客觀地評估，以決定某活動及其結果符合或滿足所制定計畫或要求事項程度之過程。	7. Audit: the process of obtaining objective evidence in a systematic, independent and documented manner and making an objective evaluation, in order to determine the extent to which an activity and its results meet or satisfy the established plan or requirements.
八、檢查（Inspection）： 指權責機關為確保輸歐盟水產品符合歐盟法規規定，派員對廠場關於水產品生產管理之各類文件、設施、設備、紀錄與任何相關資源之檢查，或為查證受委託單位正確執行委託任務所進行之檢查。	8. Inspection: the act of the competent authorities assigning its staffs to inspect the various documents, facilities, equipment, records and any related sources of establishments regarding the production of fishery products, or to verify whether the delegated bodies conduct the entrusted task correctly or not, in order to ensure fishery products intended for exporting to the EU are in compliance with EU's regulations.
九、取(採)樣（Sampling）： 指從水產品自生產至出口相關階段中，取得相關之產品或任何物質(包括從環境取得之物質或用水)，透過分析、測試或診斷以確認是否符合歐盟法規規定。	9. Sampling: the act of obtaining fishery products or any substances (including substances or water taken from the environment) at any stage from production to exportation, to ensure that such products are in compliance with EU's regulations by conducting analyses, tests or diagnoses.
十、分析（Analysis）： 指一種調查與判斷力，以鑑別問題或爭議之過程，塑造問題、研究並解釋結果，最後提出適當建議。	10. Analysis: a process of investigation and evaluation to identify issues or disputes, to model and research issues, as well as to interpret the results and then propose appropriate recommendations.
十一、測試（Test）： 指在實驗室依科學方法取得並確認樣品中某物質的存在、質量或真實性之	11. Test: the manner using scientific methods to obtain and confirm the existence, quality,

方式。	quantity or authenticity of certain substances within a sample in the laboratory.
十二、診斷（Diagnose）： 依據水生動物病史、檢查及實驗室數據或結果，來確定疾病發生情形或過程。	12. Diagnose: the confirmation of incidence or process of a the occurrence of disease based on aquatic animals' medical history, examination as well as laboratory data or results.
十三、歐盟食品及飼料快速警示系統（Rapid Alert System for Food and Feed, RASFF）： 指歐盟執委會所建置的一套資訊系統工具，以因應歐盟境內食品鏈發現公共衛生風險時，得以快速發布訊息，以供相關國家採取適當行動。	13. The Rapid Alert System for Food and Feed (RASFF): the information system established by European Commission to quickly release information for relevant countries to take appropriate actions, in response to serious public health risks detected relating to food chain within the EU.
十四、機密保護原則（Confidentiality）： 指執行官方管制之人員不得對非涉該管制事項相關權責機關以外人員，透露於執行業務所接觸到的任何機密資訊，包括個人資料及檔案。	14. Confidentiality: the obligation of staffs or officials implementing the official controls not to disclose to non-authorized personnel any confidential information involved in official controls, including personal information and files.
十五、透明性（Transparency）： 指權責機關沒有任何偏見地向公眾公開相應之訊息。	15. Transparency: the principle of the competent authority to disclose information to the public without prejudice.
十六、不符合（Non-Compliance）： 指不符合國內外水產品衛生安全或水生動物健康法規，以致造成產品衛生安全不同程度危害之可能性。	16. Non-Compliance: the possibility of non-compliance with international and domestic requirements for fishery product safety or the health of aquatic animals, that may pose risks to product hygiene and safety.
十七、廠場（Establishment）： 指與輸歐盟水產品相關之養殖場、漁船、卸魚場、魚市場、加工廠及倉儲廠等場所。	17. Establishment: the facilities related to fishery products intended for exporting to EU, such as aquaculture farms, fishing vessels, landing sites, fish markets, processing plants, and cold stores.

十八、能力試驗（Proficiency Testing）： 指透過參加能力試驗執行機構所實施之實驗室間比對，以評估實驗室測試與(或)校正之能力。	18. Proficiency Testing: a testing and/or calibration the evaluation of the performance of laboratory by participating in the inter-laboratory comparison conducted by the proficiency testing agency.
十九、委託（Delegation）： 指權責機關將自身事物託付其他機關(構)、法人或民間團體等單位辦理之行政作為。	19. Delegation: the administrative actions of the competent authority delegating institutions, corporates or non-governmental bodies to deal with the official matters under its jurisdiction.
二十、見證評鑑（Witness）： 指現場觀察執行官方管制人員之行動，包括產品取樣、檢查或驗證活動等，以評估其專業行為與應用知識及技能之能力。	20. Witness: on-site observation of staffs conducting official controls, such as product sampling, inspection or verification, in order to assess their professionalism and the capability of applying knowledge and skills.
二十一、良好衛生作業（Good hygiene practices, GHP）： 指在考慮到水產品預期用途後，控制危害並確保適合供人食用的產品所必需之措施和條件，包括操作之設計要求、設備、生產運作控制(包含溫度、原料、供水系統、文件和回收指引等)、維護、公共衛生、個人衛生和教育訓練。	21. Good Hygienic Practices (GHP): the measures and conditions necessary to control hazards and ensure products suitable for human consumption after considering the intended use of fishery products, including operational design, equipment, production operation controls (such as temperature, raw materials, water supply systems, documents and recall guidelines etc.), maintenance, public health, personal hygiene and educational training.
二十二、危害分析重要管制點（Hazard analysis and critical control points, HACCP）： 指以科學為基礎所建立之管制系統，可鑑別特定危害及其管制措施以確保產品安全，此管制系統主要在於預防，而非仰賴最終產品之檢驗。	22. Hazard Analysis and Critical Control Points (HACCP): a control system established on the basis of science that can identify specific hazards and their control measures to ensure product safety. This control system is mainly for prevention rather than relying on examination of the final products.
二十三、潔淨海水（Clean Seawater）：	23. Clean Seawater:

指天然、人工或純淨的海水或微鹹水，不含能直接或間接影響水產品衛生安全品質之微生物、有害物質或有毒海洋浮游生物。	natural, artificial or purified seawater or brackish water that does not contain microorganisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting food sanitation and safety.
二十四、潔淨水（Clean Water）： 指清淨海水和相似品質之淡水。	24. Clean Water: clean seawater and fresh water of similar quality.
二十五、回收（Recall）： 指將產品從市場及消費者端移除。	25. Recall: the act of retrieving products from the market and consumers.
二十六、下架（Withdraw）： 指將產品從市場端移除。	26. Withdraw: the act of removing the product from the market.
二十七、改製（Reprocessing）： 指將受到污染的主要原料處理成為可被使用之狀態。	27. Reprocessing: the process of treating contaminated main raw materials to make them usable.

附件二 官方管制人員之訓練課程範疇	**Annex II Areas of Training for Staffs Performing Official Controls**
一、 不同的管制方法與技術，如檢查、查證、篩選、標靶篩選、取（採）樣、實驗室分析、測試及診斷。	1. Different control methods and techniques, such as inspection, verification, selection, targeted selection, sampling, laboratory analyses, tests and diagnoses.
二、 管制程序。	2. Official control procedures.
三、 關於動物健康要求之規範。	3. Requirements for animal health.
四、 關於產品生產、加工及運輸任何階段衛生安全要求之規範。	4. Requirements for hygiene and safety during any stage of production, processing, and transportation.
五、 對不符合規範事項之評估。	5. Evaluation of non-compliant cases.
六、 產品在生產、加工及運輸中之危害。	6. Potential hazards during production, processing and transportation.
七、 在生產、加工及運輸不同階段，對人類健康、動物健康、動物福祉及環境可能存在之風險。	7. Potential risks from production, processing and transportation that could impact human health, animal health, animal welfare and the environment.

八、 預防並降低動物副產品及衍生產品對人類與動物健康所造成之風險。	8. The way to prevent and minimize the risks to human and animal health caused by animal by-products and their derivatives.
九、 危害分析重要管制點（HACCP）及良好農業規範（Good agricultural practices）之應用評估。	9. The way to evaluate the application of Hazard Analysis and Critical Control Points (HACCP) and Good Agricultural Practices (GAP).
十、 管理系統，如業者對品質保證計畫之管理及對官方管制規範要求之評估。	10. Management system, such as the food business operators' management on quality assurance plan and evaluation of official control requirements.
十一、官方驗證系統。	11. Official certification systems.
十二、緊急事件之應變安排及溝通。	12. Communication and contingency arrangement for emergency cases.
十三、官方管制之法律程序及意涵。	13. Official control legislative procedures and their applications.
十四、書面審查，包括實驗室間比對試驗、認證及風險評估等文件紀錄。	14. Document review, including any records on inter-laboratory comparisons, accreditation and risk assessment, etc.
十五、依據歐盟官方管制規章，執行官方管制所需之任何訓練。	15. Implementation of EU's official control requirements.