

Tse-Xin Organic Certification Corporation

慈心有機驗證股份有限公司

Equivalent Standard for Operation in

Non-EU Countries Certification Manual

非歐盟國家業者之有機等同性標準驗證手冊



TOC

2023.11.10

CONTENTS 目錄

PART A. Guide for Performing Quality Management 品質管理作業要點	1
I. Certification operation 業務執行	2
II. Certification 驗證	4
III. Documentation and records 文件化及紀錄	18
IV. Confidentiality 保密性	22
V. Information 資訊	22
VI. Inspection and Testing, Reporting, and Exclusion from Sale 查驗與檢測、報告、及禁止銷售	24
VII. Prevent Conflicts of Interest 避免利益衝突	25
VIII. Compliance 符合性	27
IX. Compliant and Appeal process 申訴抱怨程序	30
X. Labels, Labeling, and Market Information 標籤、標示及市場資訊	33
PART B. Equivalent Standard for Operators in Non-EU Countries	37
Section A: TOC Organic Standard (Production Standard)	40
1 Objectives	40
2 Scope	40
2.1 Agricultural products for the EU market	40
2.2 Operators	40
2.3 Framework of relevant law	40
3 Objectives for organic production	41
4 Principles of organic production	41
4.1 Overall principles	41
4.2 Specific principles applicable to farming	42
4.3 Specific principles applicable to processing of organic food	42
5 General Production Rules	43
5.1 Compliance with standards	43
5.2 Adherence to the control system	43
5.2.1 Minimum control requirements	43
5.2.2 Modification of control arrangements	45
5.2.3 Control visits	45
5.2.4 Access to facilities	46
5.2.5 Control requirements	46
5.2.6 Measures in case of suspicion of infringements and irregularities	48
5.2.7 Exchange of information	49
5.3 Prohibition on the use of GMOs	50
5.4 Prohibition on the use of ionizing radiation	50
5.5 Supervisory activities relating to control bodies	50

5.6	Catalogue of measures in case of irregularities and infringements	52
6	Farm Production.....	52
6.1	General farm production rules.....	52
6.2	Conversion	52
6.2.1	General requirements	52
6.2.2	Conversion – Plants and plant products	53
6.3	Parallel production	53
6.3.1	Parallel production – Plant production	53
6.4	Plant production rules.....	54
6.4.1	Seeds	54
6.4.2	Soil management and amendments	56
6.4.3	Pest prevention and treatment	57
6.4.4	Contamination	58
6.4.5	Storage of input products	58
6.4.6	Cleaning and disinfection.....	58
6.5	Mushroom production	58
6.6	Wild plant collection	59
7	Production of Processed Food	59
7.1	General rules	59
7.2	Rules for the production of processed food	59
7.3	Split operations.....	60
7.4	Product composition.....	60
7.4.1	Use of certain products and substances in processing of food.....	60
7.4.2	Use of certain non-organic ingredients of agricultural origin in processing food.....	61
7.4.3	Authorization of non-organic food ingredients of agricultural origin	61
7.5	Collection, packaging, transport and storage of products	62
7.5.1	Collection of products and transport to preparation units.....	62
7.5.2	Packaging and transport of products to other operators or units	62
7.5.3	Reception of products from other units and other operators.....	63
7.5.4	Storage of products.....	63
8	Labelling	64
8.1	Use of terms referring to organic production	64
8.2	Compulsory indications.....	65
8.3	Organic production logos	66
8.4	Organic logo of the European Union.....	66
8.4.1	Conditions for the use of the code number and place of origin	66
8.5	In-conversion products of plant origin	66
9	Record keeping responsibilities of operators.....	67
9.1	General.....	67

9.2	Plant production records.....	68
10	Documentary Evidence	68
11	Import into the Union and the Certificate of Inspection.....	68
11.1	Subject matter.....	68
11.2	Verification in the third country	69
11.3	Issuance of the certificate of inspection	70
11.4	Format of the certificate of inspection and use of TRACES	71
11.5	Official controls on consignments.....	72
11.6	Special customs procedures.....	75
11.7	Contingency arrangements for TRACES in case of unavailability and in case of force majeure.....	76
11.8	Use of the certificate of inspection and extract of the certificate of inspection by customs authorities.....	77
11.9	Information to be provided by a competent authority, control authority or control body in a third country on suspected or established non-compliances on consignments	77
12	Documents and notifications required for import into the Union.....	78
12.1	Subject matter.....	78
12.2	Prior notification of arrival.....	78
12.3	Certificate of inspection and extract of the certificate of inspection	79
12.4	Documentary accounts	80
12.5	Description of the production units and activities	80
12.6	Notification of suspected or established non-compliance	81
12.7	Transitional provisions for paper certificates of inspection and extracts thereof.....	81
Section B: Annexes		83
ANNEX I. Fertilizers and soil conditioners referred to in Article 3(1) of Regulation (EC) 889/2008.....		84
ANNEX II. Pesticides — plant protection products referred to in Article 5(1) of Regulation (EC) 889/2008		88
ANNEX III. Certain products and substances for use in production of processed organic food referred to in Article 27(1)(a) of Regulation (EC) 889/2008.....		92
ANNEX IV. Ingredients of agricultural origin which have not been produced organically referred to in Article 28 of Regulation (EC) 889/2008		100
ANNEX V. Products and substances used in farming and criteria for their authorization		101
ANNEX VI. Logo and code number		102
ANNEX VII. Model of documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007 referred to in Article 68 of Regulation (EC) No 889/2008		104
ANNEX VII a. Model of complementary documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007 referred to in Article		

68(2) of the Standard	105
ANNEX VIII. Model of a vendor declaration referred to in Article 69 of Regulation (EC) 889/2008	106
ANNEX IX. Definitions	107
PART C. Appendices 附錄	111
Appendix I. TOC Fee Schedule in Taiwan Dollars 本公司費用表(新台幣)	112
Appendix II. Sampling Procedures for Residue Testing 殘留檢測採樣程序	114

PART A. Guide for Performing Quality Management

品質管理作業要點

TOC

I. Certification operation 業務執行

A. The Tse-Xin Organic Certification Corporation (hereinafter referred to as “TOC”) is currently performing organic crops, processing food and aquatic plants processing products certification in Taiwan, R.O.C., TOC also was accredited by USDA to perform certification operation for the scope of organic crops, wild crops and handling operations in Taiwan and other countries. 慈心有機驗證股份有限公司(以下簡稱「TOC」)目前在中華民國台灣執行有機作物、水產植物加工品及加工驗證業務，並經美國 USDA 認證在台灣及其他國家執行有機作物、野生作物及加工驗證業務。

B. Object

This TOC Organic Equivalent Standard for Operators in Non-EU Countries (hereinafter refer to as “TOC Organic Standard” or “the Standard”) has been adapted from Regulation (EC) N° 834/2007 and Regulation (EC) N° 889/2008. It is a standard for organic operators who work outside the European Union and who wish to be certified as meeting requirements that are equivalent to the requirements of the Regulations of the European Union. 慈心非歐盟國家業者有機等同性標準(以下簡稱「慈心有機標準」或「本標準」)依循歐盟條例 834/2007 及 889/2008。這是對歐盟以外作業且需求被驗證為符合歐盟等同標準的有機經營業者之標準。

The TOC Organic Standard combines the propositions and provisions of the said EU Regulations for certification of organic products and it adapts them for application in non-EU countries. The Standard establishes rules for organic production and its certification which is equivalent to the rules set by the Regulations of the European Union for operators within the European Union. 慈心有機標準結合歐盟對有機產品驗證法規的主張與條款並適用於非歐盟國家。該標準所訂定之有機生產與其驗證的規則等同於歐盟制定給歐盟境內經營業者的規定。

The Standard provides the basis for the sustainable development of organic production while ensuring the effective functioning of the market, guaranteeing fair competition, ensuring consumer confidence and protecting consumer interests. 本標準提供有機生產永續發展之基礎，同時確保市場有效功能，保證公平競爭，確保消費者信心與保護消費者利益。

It establishes common objectives and principles to support the rules set out under the Standard concerning: 本標準並建立有關之共同目標與原則，以支撐本標準訂立之規定如下：

1. All stages of production, preparation and distribution of organic products and their control; and 有機產品之生產、調製與配銷之所有階段及其控管；及
2. The use of indications referring to organic production in labeling and advertising. 有機生產標示與廣告之使用指示。

C. Scope 範圍

The Standard shall apply to the following products originating from agriculture where such products are placed on the EU market or are intended to be placed on the EU market: 本標準適用於以下源自農業的產品，該類產品必須是在歐盟市場陳列或準備在歐盟市場陳列販賣：

1. Unprocessed agricultural products; 未加工農產品；
2. Processed agricultural products for use as food. 供食用加工農產品。



II. Certification 驗證

- A. person seeking to receive or maintain organic certification must: 欲取得或維持有機驗證者，必須：
1. Comply with the Standard and EU relevant regulations. 依循本標準及歐盟相關法規規定。
 2. Establish, implement, and update annually an organic production and handling system plan (OSP) that is submitted to TOC as provided for in the Standard Ref. 5.2.1 “Minimum Control Requirement”). 建立、執行並每年提報更新的有機生產與處理系統計畫(驗證申請書)予本公司，此計畫需依本標準第5.2.1條「最低管理要求」之規定執行。
 3. Each year, before the date indicated by the control authority or control body, the operator shall notify the control authority or control body of its schedule of production of crop products, giving a breakdown by parcel. (The Standard Ref. 5.2.5.0) 每年，在主管機關或驗證機構指定的日期之前，經營者應當通知主管機關或驗證機構，其作物生產的時間表，並按田區區分。(本標準第5.2.5.0條)
 4. Access to facilities (The Standard Ref. 5.2.4) 進入場地 (本標準第5.2.4條)
 - 4.1. Give the certification body, for control purposes, access to all parts of the unit and all premises, as well as to the accounts and relevant supporting documents. 為管制目的，讓驗證機構進入所有生產單位與場地並可取得帳冊與相關配套文件檔案。
 - 4.2. Provide the certification body with any information reasonably necessary for the purposes of the control. 為管制目的，提供驗證機構任何合理必要的資料。
 - 4.3. Submit, when requested by the certification body, the results of its own quality assurance programs. 當驗證機構要求時，提交自己的品質保證計劃成果。
 5. Maintain all records of certify operation in compliance with the requirements of the Standard Ref. 9 (Record keeping responsibilities of operators). 驗證作業紀錄的保存，需依本標準第9條「經營業者記錄保存責任」之規定執行。
 6. Submit the applicable certification fees charged by TOC (Appendix I). 繳付驗證費用 (如附錄1)。
 7. Immediately notify TOC concerning any: 有下列情況應即時通知本公司：
 - 7.1 The operator responsible shall notify any change in the description or of the measures referred to in Art. 5.2.1 and in the initial control arrangements set out in the Standard Ref. 5.2.5.1, 5.2.5.2, 5.2.5.3, to the certification body in due time. 業者對於本標準第5.2.1條的說明或措施規定以及本標準第5.2.5.1~5.2.5.3條所訂定原始管理計畫的任何變動均應在限定時間內通知驗證機構。

7.2 Application, including drift, of a prohibited substance to any field, production units, site, facility, livestock or product that is part of an operation. 施用禁用物質(包括禁用物質之漂移)於作業內的田區、生產單位、場地、設施、禽畜或產品。

7.3 Change in a certified operation or any portion of a certified operation that may affect its compliance with regulations of the Standard. 驗證作業或任何其中一部分的改變，此改變可能影響其是否符合本標準之規範。

B. Application for certification 驗證申請

1 A person seeking certification of a production or handling operation must submit an application for certification. The application must include the following information: 欲取得生產或處理作業驗證者需提出申請，申請應包含下列資料：

1.1 Complete “Organic System Plan”, including: 填寫「有機驗證申請書」，內容包括：

1.1.1 The control arrangements implemented and subsequently maintain. (The Standard Ref. 5.2.1.(a)) 管理計畫與後續維護 (本標準第5.2.1(a)條)

1.1.2 A declaration signed by the responsible operator which include an undertaking by the operator as described in the Standard Ref. 5.2.1.(b). 一份由業者權責人簽署的聲明書，該聲明書包括業者的承諾如本標準第5.2.1.(b)條所述。

1.1.3 The Standard Ref. 5.2.1.(c) (本標準第5.2.1(c)條)

1.1.3.1 Name and address of operator. 業者名稱與地址。

1.1.3.2 Location of premises and, where appropriate, parcels (land register data) where operations are carried out. 現場地點，如果適用，作業進行的土地區段(土地登記資料)。

1.1.3.3 Nature of operations and products. 作業與產品性質。

1.1.3.4 Undertaking by the operator to carry out the operation in accordance with the provision laid down in the Standard. 業者承諾依據本標準規定進行作業。

1.1.3.5 In the case of an agricultural holding, the date on which the producer ceased to apply products not authorized for organic production on the parcels concerned. 如果是農業租地時，生產者於該相關地段停止使用未核准有機生產用產品的日期。

1.1.4 The name(s) of any organic certifying agent(s) to which application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliance noted in the notification of noncompliance, including evidence of such correction. 以前申請過的驗證機構名稱、申請年度、申請結果，包括(如可取得)任

何驗證不符合通知或駁回驗證之文件複本；以及申請者對驗證不符合所做之矯正措施(證明)。

1.2 In addition to the above, the application for grower group operation must comply with the following requirements: 除上述規定外，欲申請栽培集團作業者應符合下列要求：

1.2.1 Prerequisites 條件

1.2.1.1 The grower group operation is composed of multiple production units, sites, and facilities. Their practice must be uniform and reflect a consistent process or methodology, using the same inputs/ processes. 栽培集團作業係由多個生產單位、場區及設施之作業，應採用統一作法、相同投料及程序，共同經營管理者。

1.2.1.2 Participation in the grower group operation is limited to those group members who market their organic production only through the group, unless the member is individually certified. 參與栽培集團作業的成員僅能透由集團來行銷其有機產品，除非該成員是以個人名義被驗證的。

1.2.1.3 Grower group operation must utilize centralized processing, distribution, marketing facilities and systems. 栽培集團作業必須使用集中式的加工、配送、行銷設施及系統。

1.2.1.4 Applicants apply for the grower group operation certification also need to complete “ Additional Requirements of Management Documents for Group Certification”. 申請栽培集團作業驗證須另填寫「集團驗證管理文件之額外要求」。

1.2.2 Grower group operation applicants who seek certification for their operations need to submit an Organic System Plan. It means a plan of management that includes written plans concerning all aspects of agricultural production or handling. 栽培集團作業申請者需對他們的作業提出一個有機系統計畫，包含農業生產或處理作業各環節的管理計畫。

1.2.3 The Organic System Plan has to be agreed by the applicants and TOC. 此有機系統計畫需經申請者及本公司同意。

1.2.4 The grower group operation must establish and implement an Internal Control System (ICS), with supervision and documentation of production practices and inputs used at each sub-unit, and collected at each production unit, site, or facility to insure compliance with the Standard and relevant EU regulation. 栽培集團作業必須建立和實施內部管理制度，用以監督其生產作業，確保每個子單位使用資材及匯集於每個生產單位、場區或設施的資材，符合本標準及歐盟相關法規。

1.2.5 The ICS must include the application of sanctions to individual members who do not comply with the organization’s OSP, the Standard and relevant EU regulation. It must inform TOC of the irregularities and minor non-compliances found. It must communicate

back to the source of the minor non-compliance the corrective actions imposed, with agreed time for completion. 此內部管理制度必須包括當個體成員不符合相關規定時之制裁措施，對於違規行為和次要不符合事項必須通知本公司，且須回覆本公司次要不符合的矯正措施及同意完成改善的時間。

- 1.2.6 The ICS must provide for the suspension or exclusion of members or subunits who are found to have major non-compliances, including a plan for corrective action that must be implemented before the member or subunit can be readmitted. It must inform TOC of all such actions, and a member who willfully or fraudulently violates the Standard should not be permitted to rejoin the group until TOC approves the measures taken to ensure that the violation is not repeated. 當發現有重要不符合情事時，此內部監控制度必須提出暫停或排除該成員或子單位之措施，包括在重新被認可前，需完成的矯正措施計劃。所有這些行動均須通知本公司，且對於蓄意欺騙違反本標準的成員，不允許其再加入該集團，直到本公司核可其所採取的措施，能確保違法行為不會再犯。
- 1.2.7 TOC will approve the designation of specific members or subunits as belonging to a single production unit according to the Attachment for Organic Plan (Crop) – Grower Group, Section 2: Grower Group Operation Criteria to ensure that the member or subunit complies with the regulations. 本公司將依據「集團驗證管理文件之額外要求」之第二節—栽培集團作業準則，來核可生產單位的特定成員或子單位是否符合資格，並用以判定其是否符合規定。
- 1.2.8 In order to mitigate the potential for non-compliances to go unreported, the ICS personnel must receive contractual (in-writing) assurances that under no circumstances are they to be admonished in any way because they have detected and reported a noncompliance. 為了減少潛在不符合事項被掩蓋，內部監控制度成員必須簽署書面契約書，確保不論其在任何情況下發現並報告不符合事項，均不會被以各種方式告誡。
- 1.3 Other information necessary to determine compliance with the Standard and relevant EU regulation. 其他研判是否符合本標準及歐盟相關法規規定的必要資料。

C. Review of application 書面審查

1. Upon acceptance of an application, TOC must review the application to ensure completeness pursuant to “B. Application for certification” of this section. 收到申請資料，本公司應先審查資料是否完整符合「B. 驗證申請」之要求。
2. Determine by an initial review of the application materials whether the applicant appears to comply or may be able to comply with the Standard. 由初步審查，判定該申請人是否符合或可能符合本標準規定。

2.1 If the review of application materials reveals that the operation is in compliance with the

requirements of the Standard, schedule and conduct an on-site inspection. 若審查資料顯示該作業符合本標準的規定，則安排並執行實地查驗。

3. Verify the applicant who previously applied to another certifying agent and received a notification of noncompliance or denial of certification, has submitted documentation to support the correction of any noncompliance identified in the notification of noncompliance or denial of certification. 若申請人以前曾向其他驗證機構申請，且收到不符合或駁回驗證通知單；確認該申請人應依不符合或駁回驗證通知上的不符合事項，提交相關補正文件。
4. The review of application materials and notification of its findings to the applicant shall be done within three months. 收到申請資料，應於三個月內執行書面審查，並將審查結果告知申請人。
5. The applicant may withdraw its application at any time. 申請人得隨時撤回其申請。
 - 5.1 An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. 申請人欲撤回申請時，必須繳付自提出申請至撤回期間所需之服務費用。
 - 5.2 An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. 在本公司發出不符合通知之前即自願撤回申請者，將不會被開出不符合通知。
 - 5.3 An applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial. 在本公司發出駁回驗證通知之前即自願撤回申請者，亦不會被開出駁回驗證通知。

D. Control Visit (The Standard Ref. 5.2.3) 查訪 (本標準第 5.2.3 條)

1. Preparation before inspection 查驗前準備作業

- 1.1 The initial on-site control visit must be conducted within three months following a determination that the applicant appears to comply with the Standard and relevant EU regulation. Except, that, the inspection may be delayed for a proper time not exceeding 6 months to comply with the requirement that the inspection be conducted when the land, facilities and activities that demonstrate compliance or capacity to comply can be observed. 稽核員收到申請資料，審查申請資料符合本標準及歐盟相關法規規定後，應於三個月內進行初次實地查驗。除非該查驗之進行需待其土地、設施或活動完成後才能符合需求時，該實地查驗可延遲至適當時機，但不能超過六個月。
- 1.2 Upon the inspector schedule the inspection time with the applicant, the applicant shall be notified with “Organic Inspection Plan” and signed for confirmation. 稽核員與申請人確認查驗時間後，擬定「有機查驗計畫表」通知申請者並簽署確認。
- 1.3 “Organic Inspection Plan” includes: certification products, inspection schedule, number and

days of inspectors, members of inspector, inspection requirements, administrative assistance and necessary support, safety and the relevant regulations, etc. 查驗計畫包括：驗證產品範圍、查驗時程表、查驗人天數、稽核小組成員、查驗準則、必要之後勤支援與安全防護、及相關規定等。

2 Inspection procedure 查驗作業

2.1 Inspector must conduct an initial on-site inspection on production unit, site, and facility for each operation of organic production or handling. 稽核員必須對包括在有機產品生產或處理作業中的生產單位、設施及場地，進行實地查驗。

2.2 All on-site inspections must be conducted when an applicant or authorized representative is present and at a time when land, facilities, activities, labels, labeling, market information and record keeping that demonstrate the operation's compliance with or capability to comply with the applicable provisions Ref. 4~9 of the Standard; This requirement does not apply to unfixed surveillance. 實地查驗時申請人或授權代表必須在場，此時驗證之土地、設施、活動、標籤、標示、市場資訊及記錄保存已符合或將符合本標準第4~9條有機生產與處理的規定；這項規定不適用於非定期查驗。

2.3 Verify the operation's compliance or capability to comply with the Standard; 確認申請人及其驗證作業符合本標準規範的能力。

2.4 Verify that the information provided in accordance with "B. Application for certification" and "G. Continuation of certification", accurately reflects the practices used or to be used by the applicant for certification or by the certified operation. 確認依照「B、驗證申請」及「G. 驗證的持續有效」所提供的資料正確顯示出該申請者或已驗證者已使用或將使用為其作業方式。

2.5 Verify that the agricultural products sold by the applicant as organic are produced and handled without the use of substances or materials not authorized for organic production in the Standard. 確認申請者所販售之有機農產品的生產與加工未使用本標準所允用以外的物質或原料。

2.6 Verify that genetically modified organisms (GMOs), and products produced from or by GMOs shall not be used as food, processing aids, plant protection products, fertilizers, soil conditioners, seeds, vegetative propagating material, and micro-organisms, in organic production. (The Standard Ref. 5.3(a)) 確認基因改造生物及其生產之產品不得用於有機生產之食品、加工助劑、植物保護產品、肥料、土壤改良劑、種子、無性繁殖材料與微生物。(本標準第5.3(a)條)

2.7 Verify that ionizing radiation is not used for the treatment of organic food or of raw materials used in organic food. (The Standard Ref. 5.4) 確認未使用離子化輻射處理有機食品或有機食品所用的原料。(本標準第5.4條)

2.8 TOC shall take and analyses samples for testing of products not authorized for organic production or for checking production techniques not in conformity with the organic production rules. Samples shall also be taken and analyzed for detecting possible contamination by products not authorized for organic production. The number of samples to be taken and analysed by the certification body every year shall correspond to at least 5% of the number of operators under its control. The selection of the operators where samples have to be taken shall be based on the general evaluation of the risk of non-compliance with the organic production rules. This general evaluation shall take into account all stages of production, preparation and distribution. 本公司應當對於未核准用於有機生產的產品予以採樣檢測，以檢查不符合有機生產規定的產品或生產技術；對於可能受未核准用於有機生產的產品污染的產品亦應採樣分析檢測。每年採樣數至少為驗證戶數之百分之五。採樣檢測對象之選擇，應依據不符合有機生產規定的風險評估，此評估應包括生產、製備和經銷等各階段。

However, such analysis shall be carried out where the use of products not authorized for organic production is suspected. In such cases no minimum number of samples to be taken and analysed shall apply. (The Standard Ref. 5.2.3(b)) 然而，當懷疑有機生產使用未核准的產品時進行檢測，在此情況之下，對於採樣檢測並無最低戶數的限制。(本標準第5.2.3(b)條)

2.9 For grower group application, in addition to verification of the OSP, audit of the functioning of the ICS is also needed, accompanied by a physical examination of every production unit and a meaningful sample of subunits within any given production unit. 若為栽培集團，除完成有機系統計畫的核驗，需對內部監控制度之運作需做全面稽核，並對每一個生產單位進行實體查驗，且對特定生產單位之子單位做有意義的採樣。

3 Exit interview 結束訪談

3.1 The inspector must conduct an exit interview with an authorized representative of the operation to confirm the accuracy and completeness of inspection observation and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern. 稽核員必須和申請者/授權代表進行結束訪談，以確認在實地查驗所作的觀察和所獲得的資料的準確性和完整性。稽核員亦必須對所要求的其他資訊和任何關切的事件加以說明。

3.2 A control report shall be drawn up after each visit, countersigned by the operator of the unit or his representative. (The Standard Ref. 5.2.3(c)) 每次訪查後應撰寫總結報告，且由業者或其代表人會簽。(本標準第5.2.3(c)條)

4 TOC shall carry out at least once a year a physical inspection of all operators. (The Standard Ref. 5.2.3(a)) 本公司每年對所有業者至少應進行一次查驗。(本標準第5.2.3(a)條)

5 Moreover, TOC shall carry out random control visits, primarily unannounced, based on the

general evaluation of the risk of non-compliance with the organic production rules, taking into account at least the results of previous controls, the quantity of products concerned and the risk for exchange of products (the Standard Ref. 5.2.3(d)). The risk analysis procedure as follows: 此外，本公司應進行隨機管制訪查，依一般風險評估不符合有機生產規定結果，實施不定期查核，至少需考慮前次查驗成果、有疑慮產品數量及產品交換的風險(本標準第5.2.3(d)條)。風險評估程序如下：

5.1 The risk analysis procedure shall be designed in such a way that the following criteria are taken into account for the risk analysis: (The Standard Ref. 5.5) 風險評估程序的制定應考量以下各點：(本標準第5.5條)

- Structure and complexity of the operator: Number of organic suppliers 經營業者的結構和複雜性：有機供應商的數量
- Structure and complexity of the operator: Number of subcontractors 經營業者的結構和複雜性：轉包商的數量
- Changes in ownership or key facility personnel/ Quality manager 經營權或主要管理者/品管經理變更
- Internal Quality management systems 內部品質管理系統
- Results of previous controls: Sanctions with regard to TOC Organic Standard 前次查驗結果：根據TOC有機標準的判定
- Results of actual control decision: Actual sanctions with regard to TOC Organic Standard 前次驗證決議結果：依據TOC有機標準的實際決議
- Use of unallowed inputs (farm or processing level) 使用非允用投入資材(農場或加工端)
- Parallel production 平行生產
- Conventional unit(s) on farm/ ICS or processing level 在農場、內部管理中心或加工端的慣行生產單位
- Groups with ICS: Functioning of ICS 有內部管理系統的集團：內部管理系統的功能
- Type of product 產品的型態

5.2 Additionally, the quantities produced are taken into account. 此外，生產的數量也被考慮在內。

5.3 The scoring per each criterion is follows: 0 - no risk, 1 - low risk, 2 - medium risk, 3 - high risk. Each calendar year 60% of the high risk operators receive an unannounced spot check, 30% of the medium operators and 10% of the low risk operators. 每個標準的分數如下：0 - 無風險，1 - 低風險，2 - 中風險，3 - 高風險。每個日曆年，60%的高風險經營業者都接受無預警查驗，中風險的30%和低風險經營業者10%。

5.4 The result of the risk analysis provides the basis for determining the intensity of the

unannounced or announced annual inspections and visits. 以風險評估的結果，做為決定無預警或預先通知的年度查驗和訪查頻率的依據。

- 5.5 Additional random control visits carried out in accordance with the Standard Ref. 5.2.3(d) of the production standard of at least 10% of operators under contract in accordance with the risk category are performed in each region where TOC is active. 在本公司執行業務的各個地區，根據風險級別，按照本標準第5.2.3(d)條對至少10%的客戶執行額外的隨機監督訪查。
- 5.6 At least 10% of all inspections and visits carried out in accordance with the Standard Ref. 5.2.3(a), (d) are unannounced. 依據本標準第5.2.3(a), (d)條執行的所有查驗和訪查至少10%為無預警。
- 5.7 The selection of operators to be submitted to unannounced inspections and visits is determined on the basis of the risk analysis and that these are planned according to the level of risk. 基於風險評估選擇執行無預警查驗和訪查的經營業者，並依據風險級別安排。
- 5.8 Spot-check inspection plans are maintained and continuously updated. 維持無預警查驗計畫並持續更新。
- 6 In the context of the Standard the nature and frequency of the controls shall be determined on the basis of an assessment of the risk of occurrence of irregularities and infringements as regards compliance with the requirements laid down in the Standard. In any case, all operators with the exception of wholesalers dealing only with pre-packaged products, shall be subject to a verification of compliance at least once a year. (The Standard Ref. 5.2.3(e)) 於本標準中，管制之性質與頻率應視未達本標準所訂要求，而發生違規與侵權風險之評估結果而定。但在任何情況下，除只做預先包裝產品之批發商外，所有業者每年應至少接受一次符合性驗證。(本標準第5.2.3(e)條)

E. Granting certification 授予驗證

- 1 Within two months after completion of the initial on-site inspection, the review and evaluation personnel must review the on-site inspection report, the results of analysis for substances conducted (if applicable), and any additional information requested from or supplied by the applicant. 在完成初次實地查驗後二個月內，審定人員必須審查實地查驗報告，檢測分析結果(如適用)及任何向申請人要求或申請人提供的資料。
- 2 If the review committee determines that “Organic System Plan” and all operation procedures and activities are in compliance with the requirements the Standard and that the applicant is able to conduct operations in accordance with “Organic System Plan”, TOC shall grant certification. 審定人員判斷申請人之「有機驗證申請書」及作業程序和活動符合本標準之要求，而且申請人有能力依照「有機驗證申請書」操作，則本公司將授與驗證。
- 3 For the purpose of the application of Article 29(1) of Regulation (EC) No 834/2007, TOC

shall use the model of the documentary evidence set out in Annex VII to the Standard. 為適用歐盟條例834/2007第29(1)條，本公司應使用本標準附件7所列的文件證明模式。

In case of electronic certification as referred to in Article 29(3) of Regulation (EC) No 834/2007, the signature in box 8 of the documentary evidence shall not be required if the authenticity of the documentary evidence is otherwise shown by a tamper-proof electronic method. 如果為歐盟條例834/2007第29(3)條所述的電子認證，若文件的真實性以防篡改方式另外顯示，則證明文件欄位8不需要簽字。

4 If an operator subject to TOC's control as referred to in point paragraph 3 of this section so requests within a time period to be indicated by those control authorities and control bodies, TOC shall provide complementary documentary evidence confirming the specific characteristics of the production method used by means of the model set out in Annex VIIa to the Standard. 如本節第3條所述，經本公司驗證的經營者在一段時間內要求提供上述文件，則本公司應提供額外的文件，以書面證明其生產符合本標準附件7a所列的生產方法。

5 Surrender of certification 自願撤回驗證

5.1 The applicant may withdraw its application along with a written notice of surrender to TOC at any time. 申請者有權隨時以書面向本公司敘明理由，提出申請自願撤回驗證。

5.2 TOC shall make an approval of the applicant's withdrawal, and reply with surrender notice. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. 本公司應依申請者提出之申請，核准其撤回驗證，並回覆“自願撤回驗證通知書”。已繳交之費用概不退還，且應繳清相關費用。

5.3 Upon surrender of EU organic certificate, the applicant may not produce, process, sell, market or represent as organic, products previously under certification, the applicant must complete a new application for certification if the applicant wish to obtain organic certification in the future. 提出撤銷驗證後，該申請者不得以歐盟有機名義生產、加工、販售，或在文宣等中廣告之前驗證之產品，未來該申請者必須完成一個新的驗證申請，以取得有機驗證。

5.4 An applicant that surrender its certificate prior to the issuance of a notice of suspension or revocation will not be issued a notice of suspension or revocation. 在本公司發出暫時中止或撤銷驗證之前即自願撤回驗證者，不會被開出暫時中止或撤銷驗證通知。

5.5 If the applicant wants to reapply after surrender, a time interval evaluation by TOC is required, but no more than six months from surrender. 自願撤回驗證資格者不得立即重新申請，其間隔時間由本公司評估，但最長不超過六個月。

F. Denial of certification 駁回驗證

1 When TOC has reason to believe, based on a review of the information specified in “C.

Review of Application” or “E. Granting certification” that an applicant for certification is not able to comply or is not in compliance with the Standard, TOC shall provide a written notification of noncompliance. 經依「C、書面審查」或「E、授予驗證」指定，對資料的審查，如本公司有理由認為驗證申請者無法或不符合本標準的規定；則本公司應寄發申請人一份不符合通知書。

- 2 Upon receipt of such notification of noncompliance, the applicant may: 接到不符合通知時，申請人可以：
 - 2.1 Correct noncompliance and submit a description of the corrective actions taken with supporting documentation to TOC. 矯正不符合事項，並提出矯正措施說明及證明文件予本公司。
 - 2.2 Correct noncompliance and submit a new application to another certifying agent; the applicant must include a complete application, the notification of noncompliance received from TOC, and a description of the corrective actions taken with supporting documentation; or 矯正不符合事項，並向其他驗證機構提出新申請；但申請人必須檢附完整之申請書、本公司所發的不符合通知及矯正說明和證明文件；或
 - 2.3 Submit written information to the TOC to rebut the noncompliance described in the notification of noncompliance. 對於本公司所陳述之不符合事項，可以書面資料提出反駁。
- 3 After receive the corrective actions of noncompliance, TOC must: 業者提出矯正措施後，本公司必須：
 - 3.1 Evaluate the applicant's corrective actions taken and supporting documentation or the written rebuttal, conduct an on-site inspection if necessary. 評估申請人所採取的矯正說明和證明文件，或其書面反駁資料，必要時再進行一次實地查驗。
 - 3.1.1 When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to “E. Granting certification”. 當申請人的矯正措施或反駁足以顯示合於驗證規定，則依據「E、授予驗證」核准申請人之驗證。
 - 3.1.2 When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification. 當申請人的矯正措施或反駁不符合驗證規定，則核發申請人一份書面的駁回驗證通知。
 - 3.2 Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance. 對沒有回覆不符合通知的申請人，發出一份書面的駁回驗證通知。
- 4 A notice of denial of certification must state the reason(s) for denial and the applicant's right

to: 駁回驗證通知書必需陳述駁回理由並述明申請人的權益如下：

- 4.1 Request mediation from TOC. 可向本公司要求調解。
 - 4.2 File an appeal of the denial of certification to TOC. 可向本公司提出駁回驗證的申訴。
 - 5 An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent. When such applicant submits a new application to a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification, and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliances. 驗證申請者收到書面不符合通知或駁回驗證通知，得隨時向其他驗證機構提出驗證申請。當申請人向其他驗證機構提出申請時，必須檢附不符合通知或是駁回驗證通知影本，以及不符合事項的矯正說明與證明文件。
 - 6 When TOC receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to “B. Application for certification”, “C. Review of application”, “D. On-site inspections” and “E. Granting certification”. 本公司收到一份包含不符合通知或駁回驗證通知的新申請時，必須將該申請視為一件新的申請案，並且從「B、驗證申請」、「C、書面審查」、「D、實地查驗」、「E、授予驗證」等程序開始審查。
 - 7 If TOC has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant’s operation or its compliance with the certification requirements pursuant to the Standard, TOC may denial certification without first issuing a notification of noncompliance. 如果本公司有充分理由認定申請人故意做不實的敘述，或故意虛構其作業，或該作業不符本標準之驗證規定，則本公司將直接駁回該驗證，不須先發出不符合通知。
- G. Continuation of certification 驗證的持續有效
- 1 To continue certification, a certified operation must annually pay the certification fees and submit the following information: 為驗證持續有效，已驗證者需每年繳交驗證管理費，並提供下列資料：
 - 1.1 An “Organic System Plan” which includes: 「有機驗證申請書」包括：
 - 1.1.1 A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic operation during the previous year. 前一年之有機作業所做的變更與修正，及簡要描述之證明文件。

- 1.1.2 Any additions or deletions to the previous year's organic operation, scope, item, which is intended to be undertaken in the coming year, detailed pursuant to the Standard requirements. 未來一年擬增加或刪除之有機作業、範圍、項目等依「本標準」的規定。
- 1.2 Other information as deemed necessary by TOC to determine compliance with the Standard. 本公司認定符合本標準規範所需資料；
- 1.3 The certification for grower groups also need to complete “Attachment for Organic Plan (Crop) - Grower Group” 栽培集團驗證須另填寫「集團驗證管理文件之額外要求」。
- 1.4 Any additions to or deletions from the original “Organic System Plan”. 原「有機驗證申請書」中任何項目的增加或刪減。
- 1.5 An update on the correction of minor noncompliances previously identified by TOC as requiring correction for continued certification. 上次查驗次要不符合之改善情況。
- 2 Following the receipt of the “Organic System Plan”, TOC shall arrange and conduct an on-site inspection of the certified operation within six months. 收到「有機驗證申請書」後，本公司應在六個月內安排實地查驗作業。
- 3 When TOC is impossible to conduct the annual regular surveillance within three months following receipt of the “Organic System Plan”, TOC may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: Provided, That, the annual on-site inspection, required to conduct within the first 6 months following the certified operation's scheduled date of annual update. 若本公司於收到「有機驗證申請書」後，三個月內無法執行年度追查，本公司得以前十二個月內最後的實地查驗資料核發更新驗證證書；但在年度更新日後六個月內必須完成實地查驗。
- 4 Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor noncompliance. 每一實地查驗前，提供稽核員前一次的實地查驗報告及驗證決定，和任何次要不符合事項的矯正要求。
- 5 If TOC has reason to believe, based on the annual regular surveillance, that a certified operation is not in compliance with the Standard, TOC shall provide a written notification of noncompliance to the operation in accordance with “XI. C. Noncompliance procedure for certified operations”. 如果於年度追查時，本公司發現申請者有不符合本標準之規定，則依「XI. C. 驗證作業之不符合程序」，將不符合事項以書面通知申請者。
- 6 If TOC determines that the certified operation is complying with the Standard and that any of the information specified on the certificate of organic operation has changed, TOC must

issue an updated certificate of organic operation. The applicant shall pay for the certificate fee. 如果該驗證作業符合本標準的規定，且其有機作業驗證證書上的資料有異動時，本公司應重新發證，申請者需繳交證書費。

H. Recordkeeping by certified operations (The Standard Ref. 9) 驗證作業的紀錄保存 (本標準第9條)

1 A certified operation must maintain records concerning the stock and financial, production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as “Organic,” or “Organic in conversion”. 以「有機」、「有機轉型期」販售、標示或展示的農產品，必須保存其庫存和財務、生產、收穫和處理的作業紀錄。

2 Such records must: 此紀錄必須：

2.1 Be adapted to the particular business that the certified operation is conducting. 適用於驗證作業的特定業務。

2.2 Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited. 提供驗證作業所有活動和交易，可充分了解、稽查的詳細資料。

2.3 Be maintained for not less than 5 years beyond their creation. 紀錄必須至少保持5年。

2.4 Be sufficient to demonstrate compliance with the Standard regulations. 足以顯示符合本標準的規範。

TOC

III. Documentation and records 文件化及紀錄

A. Documentation 文件化

- 1 To make organic certification operations follow the correct and effective implementation and the latest version of documents, the editing, review, approval, issuance, amendment and storage of the document shall be subjected to the following rules: 為使有機驗證之各項作業，均能依循正確、有效且最新版本之文件執行，文件之編訂、審查、核准、發行、修訂及保管等管制規定如下：
 - 1.1 The document shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to issuing any document following initial development being made. 文件編訂後，須經權責人員及主管審查核准方能發行。
 - 1.2 The document shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to issuing any document following any subsequent amendment or change being made. 文件修訂後，須經權責人員及主管審查核准才可發行。
 - 1.3 The regulations of organic certification shall be reviewed, renewed, and recorded regularly within three months. 有機驗證相關法規應於三個月內被定期地審視、更新及記錄。
- 2 To prevent from using of invalid/outdated documents by certification personnel, the distribution of all documents shall be controlled effectively to ensure that the appropriate and updated documentation is made available to personnel of the certification body. 為防止驗證作業人員使用無效/過期之文件，行政人員應有效管制以確保使用人持有效文件。

B. Records 紀錄

1 Recordkeeping 保存期限

- 1.1 Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt. 由驗證申請者及驗證作業所得之紀錄，必須保存至少5年。
- 1.2 Records created by TOC regarding applicants for certification and certified operations must be maintained for not less than 5 years beyond their creation. 由本公司所產生有關驗證申請者和驗證作業的紀錄必須保存至少5年。
- 2 All records shall be stored in cabinets kept by the administrative staff. 各項紀錄存放於專櫃，由行政人員負責保管。

C. Undertaking to comply with the provisions of Article 2 of Regulation (EU) 2021/1342: 承諾遵守歐盟條例 2021/1342 第 2 條的規定：

1. On the basis of annual reports and in the light of any other information received, the Commission shall ensure appropriate supervision of the control authorities and control bodies referred to in Article 57(1) of Regulation (EU) 2018/848 and included in the list established by an Implementing Regulation to be adopted pursuant to Article 57(2) of Regulation (EU) 2018/848 ('control authorities and control bodies') by regularly reviewing their recognition. For this purpose, the Commission may request the assistance of Member States. The nature of the supervision of the control authorities and control bodies shall be determined on the basis of a risk based approach of non-compliance, taking into account in particular the volume of certified products and their exports to the Union and the results of the regular on-the-spot evaluation, surveillance and multiannual re-assessment of their activities by an accreditation body or, as appropriate, by a competent authority. 根據年度報告並考慮收到的其他訊息，歐盟執委會將確保對《歐盟法規2018/848》第57(1)條所提及的控制機構和監管機構（以下簡稱'控制機構和監管機構'）進行適當的監督，並將其納入根據《歐盟法規2018/848》第57(2)條要採納的實施法規所建立的名單。為此，歐盟執委會可能請求成員國的協助。對於控制機構和監管機構的監督性質將基於風險管理的非合規性方法來確定，特別考慮到認證產品的數量以及其對歐盟的出口，以及由認證機構或必要時由主管機關進行的定期現場評估、監控和多年再評估的活動結果。
2. By 28 February of each year, TOC shall send the Commission an annual report. The annual report shall update the information of the technical dossier included in the initial application for the recognition, as last modified. It shall at least include: 每年的2月28日之前，慈心應向歐盟執委會提交年度報告。年度報告應更新最後修改的初次申請中包含的技術文件的訊息。它應至少包括以下內容：
 - (a) an overview of the activities of TOC in the third country or third countries for which it has been recognised, including the number of operators and groups of operators involved and the nature of agricultural products and foodstuffs, sorted by categories and grouped by tariff codes; 慈心在其獲得承認的第三國或第三國的活動概述，包括參與的經營者和集團經營者的數量，以及按類別和關稅代碼分類的農產品和食品類別；
 - (b) any updates on the production standards applied in the third country or third countries for which TOC has been recognised, including an assessment of the equivalence of those standards to the production rules referred to in Titles III and IV of Regulation (EC) No 834/2007; 慈心已獲得承認的第三國或第三國所應用的生產標準的任何更新，包括評估這些標準與 (EC) 834/2007 第III章和第IV章所提到的生產規則等同性；
 - (c) any updates on the control measures applied in the third country or third countries for which TOC has been recognised, including an assessment of the equivalence to those referred to in Title V of Regulation (EC) No 834/2007, and confirmation that such control measures have been permanently and effectively applied; 慈心已獲得承認的第三國或

第三國所應用的控制措施的任何更新，包括對 (EC) 834/2007 第V章所提到的控制措施等同性的評估，以及確認這些控制措施已經永久且有效地應用；

- (d) a description of the control activities carried out by TOC in the previous year in the third country or third countries for which it has been recognised, the results obtained, the irregularities and infringements observed and the corrective measures taken; 慈心在前一年在其獲得承認的第三國或第三國進行的控制活動描述，所獲得的結果，觀察到的不規則和違規行為，以及採取的修正措施；
- (e) any other updates on the information of the technical dossier that was sent with the initial application for the recognition and its further updates; 初次申請承認時隨附的技術文件訊息以及進一步的更新訊息；
- (f) a copy of the latest assessment report issued by the accreditation body or, where appropriate, by a competent authority, which shall contain the results of the regular on-the-spot evaluation, surveillance and multiannual re-assessment of the activities of TOC in the third country or third countries for which it has been recognised. That assessment report shall confirm that the control authority or control body has been satisfactorily assessed on its ability to meet the conditions applicable to its recognition by the Commission and that it has effectively implemented its activities according to those conditions. Furthermore, the assessment report shall demonstrate and confirm the equivalence of the production standards and control measures referred to in points (b) and (c); 認證機構或必要時主管機關發布的最新評估報告副本，該報告應包含對慈心在其獲得承認的第三國或第三國活動的定期現場評估、監控和多年再評估結果的評估。該評估報告應確認慈心已得到滿意評估，符合歐盟執委會認可條件，並根據這些條件有效地實施其活動。此外，評估報告應證實和確認點(b)和(c)中提到的生產標準和控制措施的等同性；
- (g) the internet website where the list of operators subject to the control system can be found in an official language of the Union, as well as a contact point where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products; 可以在聯盟的官方語言中找到控制系統的經營者名單的互聯網網站，以及可提供有關其認證狀態、相關產品類別以及暫停和取消認證經營者和產品的聯繫點；
- (h) any other information deemed relevant by TOC. 慈心認為相關的任何其他訊息。

The annual report and any additional information requested by the Commission concerning the annual report shall be provided via OFIS. 年度報告和歐盟執委會要求的有關年度報告的任何附加訊息應通過OFIS提供。

3. The Commission may request any additional information concerning the annual report. That additional information shall be provided in electronic form. 歐盟執委會可以要求有
-

關年度報告的任何附加訊息。該附加訊息應以電子形式提供。



IV. Confidentiality 保密性

TOC shall maintain strict confidentiality with respect to its client under the applicable organic certification program and not disclose to third parties (with the exception of the Commission authorized representatives) any business-related information concerning any client obtained in the course of its certification activities at all levels of its organization, including administrative staff, inspectors, and committees and external bodies or individuals acting on its behalf. 客戶申請有機驗證資料，所有驗證人員(包含行政人員、稽核人員及審定人員)應予絕對保密，不應對第三者(除歐盟執委會授權代表外)洩露驗證過程中所獲之任何業務資訊。

V. Information 資訊

- A. The website of TOC provides information on certification for enquiry and reference on: 本公司網站提供驗證作業相關資訊，以供外界查詢及參考，內容包括 (Regulation (EC) 1235/2008 Art. 11(3)) :
1. The Standard and relevant EU regulations. 本標準和歐盟相關法規。
 2. The basis and standards of certification, certification procedures and fees schedule for all services of certification. 驗證依據及標準、驗證作業流程、驗證服務費用表。
 3. The list of operators, as well as a contact point where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products. 已驗證者名錄，內容包含：驗證狀態、驗證產品、終止和取消驗證的驗證者和產品...等資料。
 4. Other matters 其他事項
- B. In case of changes on requirements or procedures of certification, TOC shall notify the applicant or the certified operator 15 days prior to the implementation of changes through written notification, electronic media, e-mail, facsimile or other means. 驗證相關要求及作業程序若有變更時，應於正式實施前 15 天將變更部分，以書面通知或電子媒體公佈或電子郵件或傳真等方式知會已申請者或已驗證者。
- C. Exchange of information (The Standard Ref. 5.2.7) 訊息交換 (本標準第 5.2.7 條)
1. Where the operator and/or the subcontractors of that operator are checked by different control bodies, TOC shall exchange the relevant information on the operations under their control. 如果業者和/或其轉包商接受不同驗證機構的驗證，機構間應交換相關資訊。
 2. Where operators and/or their subcontractors change their control body, the change shall be notified without delay to other control bodies by the control bodies concerned. 如果業者和/或其轉包商更換他們的驗證機構，相關驗證機構應立即通知其它驗證機構。

The previous control body shall hand over the relevant elements of the control file of the operator concerned and the reports referred to the Standard Ref. 5.2.1(b)(ii) to the subsequent control body. The new control body shall ensure that non-conformities noted in the report of the previous control body have been or are being addressed by the operator. 並將其驗證相關文件及本標準第5.2.1(b)(ii)條所提文件轉交予後續的驗證機構。新的驗證機構應確認業者對前驗證機構報告中所提之不符合事項均已矯正。

3. Where the operator withdraws from the control system, TOC shall, without delay, inform other control bodies. 當業者退出驗證，本公司應立即通知其它驗證機構。
4. Where a control body finds irregularities or infringements affecting the organic status of products, it shall without delay inform other control bodies. That control body may require, on its own initiative, also any other information on irregularities or infringements. In case of any irregularities or infringements found with regard to products under the control of other control bodies, it shall also inform those control bodies without delay. 當發現影響產品有機資格的違規或侵權行為時，立即通知其他驗證機構。該驗證機構得同時主動要求，其他關於侵權或不符合行為的任何資訊。如所發現侵權或不符合行為的產品與其他驗證機構有關，應當立即通知該驗證機構。
5. Upon a request duly justified by the necessity to guarantee that a product has been produced in accordance with this production standard, TOC shall exchange relevant information on the results of their controls with other competent authorities, control authorities and control bodies. They may also exchange such information on their own initiative. 如被合理要求需保證產品符合本生產標準，本公司得根據其要求，將其驗證結果與其他主管部門，主管機關和驗證機構交換相關訊息。該等機構也可以主動交換這些訊息。

TOC

VI. Inspection and Testing, Reporting, and Exclusion from Sale 查驗與檢測、報告、及禁止銷售

- A. Sampling inspection and testing of agricultural product to be sold or labeled “Organic”, “Organic in conversion” 以「有機」、「有機轉型期」名義販售或標示之農產品的採樣查驗和檢測
- 1 All agricultural products that are to be sold, labeled, or represented as “Organic,” or “Organic in conversion” must be made accessible by certified organic production or handling operations for examination by TOC. 所有以「有機」或「有機轉型期」之名銷售、標示或展示的農產品，都必須讓本公司得以隨時檢查其有機生產或處理作業。
 - 2 TOC may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as “organic,” or “Organic in conversion” when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. 當本公司有理由認為所使用的農業資材或產品，可能與禁用物質接觸或曾使用GMO等排除方法時，得要求對以「有機」或「有機轉型期」之名銷售、標示或展示的農產品，於收穫前或收穫後進行所使用的農業資材或農產品的檢測。
 - 3 The preharvest or postharvest tissue test sample collection pursuant to paragraph 2 of this section must be performed by an inspector representing TOC. Sample integrity must be maintained throughout the chain of custody (see Appendix II for sampling procedures). 本節第2段之收穫前或收穫後之檢測樣品，必須由本公司指派的稽核員採樣；樣品保管過程中應保持其完整性(採樣流程詳附錄2)。
 - 4 The residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the Official Methods of Analysis of the AOAC International or other current applicable validated methodology determining the presence of contaminants in agricultural products. 殘留檢測應由經認證之實驗室執行，化學分析必須依最新版的國際AOAC之法定分析方法，或其他現行已驗證之農產品污染物檢出方法。

VII. Prevent Conflicts of Interest 避免利益衝突

- A. TOC does not certify a production or handling operation if TOC or a responsibly connected party of the organization has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. 申請者在提出驗證申請前12個月內，如果本公司中之相關單位對該生產或處理作業有商業利益(包括直接親屬利益或提供諮詢服務)，則本公司不得驗證其生產或處理作業。
- B. TOC excludes any person in the organization (including contractors) with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operation for all applicants in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. 申請者在提出驗證申請前12個月內，如果本公司之任何人在該實體中有商業利益(包括直接親屬利益或提供顧問服務)；則本公司須排除此等人在該驗證過程中參與工作、討論和決策，以及監督該驗證生產或處理之作業。
- C. TOC does not permit any employees, inspector, review and evaluation personnel or other personnel of the organization to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected. 本公司不允許任何員工、稽核員、審定人員或其他人員，接受任何受查業務明定費用外的付款、禮物或任何型式的餽贈。
- D. TOC does not give advice or provide consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification. 本公司對驗證申請者或驗證作業已被確認之驗證障礙，不得提供解決之建議或諮詢服務。
- E. TOC requires all persons who review applications for certification, perform on-site inspections, review Organic System Plan, evaluate qualifications for certification, making recommendations concerning certification, or make certification decisions and all parties responsibly connected to TOC to complete an annual conflict of interest disclosure report. 本公司會要求所有參與驗證作業的人，每年完成利益衝突聲明書。此等人為：審查驗證申請書，執行實地查驗，審查驗證文件，評估驗證資格，撰寫驗證建議或做驗證決策的人以及與本公司有責任相關的所有實體。
- F. TOC ensures that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection. 本公司會確保做驗證作業的決策人不是審查文件的人以及實地查驗的人。
- G. TOC must reconsider a certified operation's application for certification and, if necessary, perform a new on-site inspection when it is determined, within 12 months of certifying the

operation, that any person participating in the certification process and covered under section B of this chapter has or had a conflict of interest involving the applicant. All costs associated with a reconsideration of application, including on-site inspection costs, shall be borne by TOC. 當有參與驗證過程之任何人以及本章B節所述之曾有或現有涉及某申請人之利害衝突發生時，本公司在發給驗證作業的12個月內，必須再重新考慮該驗證作業的申請，必要時進行一次新的實地查驗，所有重新考慮驗證申請所發生的成本，包括實地查驗的成本，將都由本公司負責。

- H. TOC shall refer a certified operation to a different accredited certifying agent for recertification and reimburse the operation for the cost of the recertification when it is determined that any person covered under section A of this chapter at the time of certification of the applicant had a conflict of interest involving the applicant. 當有任何人如本章A節述及，於申請驗證時涉及該申請人之利害衝突，本公司應將該驗證作業之再驗證委交另一個不同的驗證機構，並償付該作業再驗證的費用。



VIII. Compliance 符合性

A. General 總則

1. The accreditation body may inspect and review certified production and handling operations and TOC for compliance with The Standard and ISO/IEC 17065:2012. 認證機構可查驗及審查已驗證之生產和處理作業以及本公司是否符合本標準和ISO/IEC 17065:2012之規範。
2. Each notification of noncompliance, noncompliance resolution etc. issued pursuant to items B and C of this section, and such notification must be sent to the recipient's place of business via a delivery services by TOC. 本公司對所核發之不符合事項、不符合事項決議書等通知，都必須以郵件遞送到收件人之處所。

B. Measures in case of suspicion of infringements and irregularities (The Standard Ref. 5.2.6) 侵權與違規疑慮之處置 (本標準第 5.2.6 條)

- 1 Where an operator considers or suspects that a product which he has produced, prepared or that he has received from another operator, is not in compliance with organic production rules, he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. He may only put it into processing or packaging or on the market after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method. 當業者認為或懷疑他們所生產、調製、進口或接收來自其他業者的產品不符合有機生產規定，他應採取行動回收任何與此有機生產方法相關的產品或區分識別這些產品。他僅能在消除疑慮以後再進行繼續加工、包裝或上市，除非這些產品流入市場並未標示有機方法生產。

In case of such doubt, the operator shall immediately inform TOC. TOC may require that the product cannot be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated. 若有此懷疑時，業者應立即通知本公司。本公司得要求該相關產品不應以有機名義販售，直到接獲來自業者或其他來源確定疑慮已消除。

- 2 Where TOC has a substantiated suspicion that an operator intends to place on the market a product not in compliance with the organic production rules but bearing a reference to the organic production method, TOC can require that the operator may provisionally not market the product with this reference for a time period to be set by that certification body. Before taking such a decision, TOC shall allow the operator to comment. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the certification body is sure that the product does not fulfil the requirements of organic production. 本公司具體懷疑業者有意將不符合有機生產準則的產品標示為有機生產上市時，本公司可以要求業者這些有問題的產品於其規定期間內暫時不應銷

售。未採取這項決定之前，本公司應當允許業者表達意見。若本公司確認產品不符合有機生產準則，上述決定可以附帶強制業者收回任何標示為有機生產的相關產品。

However, if the suspicion is not confirmed within the said time period, the decision referred to in the paragraph 1 of this section shall be cancelled not later than the expiry of that time period. The operator shall cooperate fully with TOC in resolving the suspicion. 但是，如果於上述期限內未能證實這些懷疑，最遲應於該期限過期前撤銷本節第1項有關決定。業者應與本公司充分配合解決這些疑慮事項。

- 3 Where an irregularity is found as regards compliance with the requirements laid down in the Standard, TOC shall ensure that no reference to the organic production method is made in the labelling and advertising of the entire lot or production run affected by this irregularity, where this would be proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the irregular activities. 若發現有不合本標準所訂定之要求，且該不符合活動的性質與特殊情況已相對應的違反本標準的規定，本公司應確保涉及該違規事項之整批產品或生產行為不得以有機名義標示與廣告。

Where a severe infringement or an infringement with prolonged effect is found, TOC shall prohibit the operator concerned from marketing products which refer to the organic production method in the labelling and advertising for a defined period of time. 若發現有嚴重侵權或長期侵權，本公司應暫時中止其產品以有機名義販售及廣告。

- 4 Information on cases of irregularities or infringements affecting the organic status of a products shall be immediately communicated between the certification bodies and competent authorities. The level of communication shall depend on the severity and the extent of the irregularity or infringement found. 有關影響產品有機資格之違規或侵權資訊應立即通報於相關之驗證機構與主管單位。通報層級應依所發現的違規或侵權程度。
- 5 Notification: when an inspection, review, or investigation of a certified operation by TOC reveals any noncompliance with the Standard, a written notification of noncompliance shall be sent to the certified operation by TOC. Such notification shall provide: 通知書：對已驗證作業之查驗、審查或調查中發現任何與本標準規定不符合時，必須發給已驗證者一份書面的不符合通知。通知書中須載明：

5.1 A description of each noncompliance issued by TOC. 敘述不符合事項。

5.2 The facts upon which the notification of noncompliance is based. 該不符合事事實的根據。

5.3 The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. 對不符合事項提出反駁或矯正與提供證明文件的期限。

- 6 Resolution: when a certified operation demonstrates that each noncompliance has been

resolved, TOC shall send the certified operation a written notification. 決議書：當已驗證者矯正完成不符合事項，本公司需發送書面的決議通知給該驗證者。

7 Suspension or revocation: when rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, TOC shall send the certified operation a written notification of suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. The notification of suspension or revocation of certification shall state: 暫時中止或撤銷：於限期內，對不符合事項未提出反駁，或未完成不符合事項之矯正，本公司應發給該已驗證者一份全部或部份驗證範圍的暫時中止或撤銷書面通知書。暫時中止或撤銷之通知須載明：

7.1 The reasons for the proposed suspension or revocation. 暫時中止或撤銷的原因。

7.2 The effective date of such suspension or revocation. 暫時中止或撤銷的有效期限。

7.3 The right to file an appeal. 可提出申訴之權利。

8 Willful violation: If TOC has reason to believe that a certified operation has willfully violated the Standard, TOC shall send the certified operation a notification of suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. 蓄意違反：若本公司有理由認定已驗證者蓄意違反本標準規定，則可對該已驗證者直接給予暫時中止或撤銷驗證之通知書。

9 A certified operation or a person responsibly connected with an operation whose certification has been revoked by TOC or any other certifying agent will be ineligible to receive certification for a period of 6 months following the date of such revocation. 被撤銷驗證的驗證作業或負責人，6個月內不得再申請驗證。

TOC

IX. Compliant and Appeal process 申訴抱怨程序

A. General 總則

1. The applicants of certification who believe they are adversely affected by a noncompliance decision may compliant or appeal such decision to TOC. 驗證申請者認為本公司所做不符合之決定使其受不利影響時，得向本公司提出抱怨或申訴。
2. All written communication between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service. 所有涉及申訴程序的雙方書面來往信件，皆須以郵件遞送至收件人處所。
3. All appeals shall be reviewed, heard, and decided by persons not involved with the decision being appealed. 所有申訴將由不涉及該申訴決策的人士審查、公聽和決定。

B. Complaint 抱怨

- 1 Any applicant for certification who has opinion to TOC or TOC's customer, may complain to TOC. 對本公司或客戶之行為有意見時，得向本公司提出抱怨。
- 2 Complaints can be made by e-mail or in writing, and the following should be stated. 抱怨可以電子郵件或書面方式提出，並敘明下列事項。
 - 2.1 Definitely indicate the object of complaint. 明確指出抱怨對象。
 - 2.2 Provide a sufficient explanation of the cause of the complaint (e.g, a statement that violates the provisions of TOC organic code) and its claims. 對抱怨的原因提出充分的解釋(例如：具體說明違反本公司有機規範中那一項規定)及其訴求。
 - 2.3 Relevant supporting documents (if applicable). 相關佐證文件(如有)。
 - 2.4 The basic information of the complainant (name/company name, address, telephone or other contact information). 抱怨者的基本資料(姓名/公司名稱、地址、電話或其他聯絡方式)。
- 3 If the complaint is not made as point paragraph 2 of this section stated or the information is not complete or the complaint is not relevant to the verification activity of TOC, TOC may not respond. 如未以本節第2條方式提出、提出資料不齊全或提出之抱怨與本公司負責的驗證活無關，本公司得視情況不予回覆。
- 4 TOC will decide to accept the complaint or not will be decided, depends on whether the relevant evidence provided by customer is sufficient within 1 month after the complaint is received. 本公司收到抱怨案件一個月內視客戶提出之證據決定是否受理。
- 5 After the complaint is accepted, in principle, the handling of complaints will be complete within 1 month. However, if necessary, the processing period might be extended with the

agreement of the complainers. 本公司受理抱怨案後，原則上於一個月內完成抱怨事件之處理，必要時得徵詢抱怨者同意後延長處理期限。

- 6 If an investigation is no need to the complaint, TOC may reply by telephone, e-mail or written, as appropriate; if necessary, it will be proceeded as follows: 如抱怨案無需調查，本公司得視情況以電話、電子郵件或書面回覆；如需調查，則依下列原則進行：
 - 6.1 TOC may investigate the object of complaint (including TOC's customers) without notice. 本公司得在無預告情況下，對受抱怨對象(含本公司客戶)展開調查。
 - 6.2 Contents of investigation including consult with the review committee, experts/ scholars, on-site inspection or other method that TOC deemed necessary. 調查項目：包括諮詢審查委員或專家學者、實地查驗及其他本公司認定之必要資訊。
 - 6.3 Any person who may affect the justice of the investigation, shall not be the investigator of the case. 任何可能影響調查公正性的關係者，不得擔任該案件之調查工作。
- 7 If the complaint is withdrawn before the investigation is completed, the investigation will be terminated unless TOC finds that the complaint has sufficient facts and is of great significance. 如未完成調查前，抱怨案即撤回，除非本公司認定抱怨案有足夠事實，且具有重大意義外，否則將終止調查。
- 8 The investigation of the case may be terminated, if it has been involved in criminal investigation. 所調查的抱怨案，若已涉及刑事偵查者，得停止調查。
- 9 The complaints should be reviewed or decided by persons who are not involved in the relevant certification activities. To whom have consulted or been hired by the client, he/she will not be allowed to participate in the review or decision of the complaint within two years after the consultation or employment. 抱怨案應由未參與相關驗證活動之人員審查或決定。如曾為客戶提出顧問諮詢或曾受客戶雇用之人員，在顧問諮詢或雇用結束後兩年內亦不得參與抱怨案之審查或決定。
- 10 TOC may disclose or not disclosed, as the case may, the information obtained during the investigation in whole or in part. 除法令規定或本公司保密政策所認定的機密資訊外，本公司得視情況公開或不公開調查所得的全部或部分資料。

C. Appeals 申訴

- 1 An applicant for certification who has objection to TOC's notice of certification, may file an appeal to TOC. 驗證申請者對本公司之驗證決定有異議，得對本公司提出申訴。
- 2 An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. the appeal would not be accepted if not filed in a timely manner. 必須在通知書註明

之期限內或收到通知書30天內(以二者之中較晚者為準)提出對不符合決定的申訴。申訴應於收到抱怨裁決、驗證裁決通知之日起一個月內以書面為之，並以一次為限。逾期申訴者，本公司不予受理。

- 3 The appeal should specify the reason and demand in writing. 申訴人應以書面方式明確說明申訴原因及其訴求。
- 4 The fee for each appeal is NT\$2,500, and which amount will be returned once the appeal is established, no matter if the decision will be changed or not. 單一案件申訴費用為每件新台幣2,500元，若該申訴案成立，則不論裁決是否有異動，申訴費一律退回。
- 5 Upon receipt of the appeal, TOC shall make a preliminary decision on the documents received immediately, and the appeal shall not be accepted if it is unrelated to the control activities. In addition, the applicant must submit other information different from what previous found as the reason for appeal, otherwise the appeal will not be accepted. 本公司收到申訴案件，應立即對所提文件作初步裁決，申訴內容如與驗證活動無關，本公司不予受理。此外，申訴人必須提出有別以往所提資訊，以新資訊做為提出申訴的理由，否則本公司不予受理。
- 6 Investigation and an review committee should be held within 1 months after the appeal is accepted. 本公司受理申訴案後，一個月內應進行案件調查並舉行審查會議。
- 7 TOC Personnel who handle the appeal shall be different from those who handle the inspection and determination of certification. 處理申訴過程的人員需不同於執行稽核與驗證決定的人員。

The investigation of appeals: 申訴案件調查：

Contents of investigation including consult with the review committee, experts/ scholars, on-site inspection or other method that TOC deemed necessary. 調查內容：諮詢審查委員或專家學者、實地查驗及其他本公司認定必要之資訊。

During the period of investigation, the effect of original decision would not be affected; Provided, if necessary, the implementation of relevant decision may suspend. 期間，原驗證決定之效力不受申訴提出之影響；惟必要時，得暫停該案驗證決定之執行。

Any fees derived from the appeals process, such as sample inspection fees or inspection fees, are on the cost by the applicant. 在申訴程序中所衍生的其他費用，如樣品檢驗費或查驗費等，由申訴人支付。

- 8 Conduct the review meeting: After the investigation has been completed, TOC shall notice the applicant and the review team to attend the review committee. If the applicant fails to attend without reason, the appeal shall be deemed to have withdrawn. 召開申訴審查會議：申訴案件於調查完畢後，由本公司通知申訴人及審查小組出席審查會議，申訴人無正當理由未出席者，得視為撤回申訴案件。

X. Labels, Labeling, and Market Information 標籤、標示及市場資訊

A. Use of terms referring to organic production (The Standard Ref. 8.1) 有機生產用語之使用 (本標準第 8.1 條)

1. A product shall be eligible for bearing terms referring to the organic production method where, in the labelling, advertising material, or commercial documents, such a product, its ingredients have been obtained in accordance with the rules laid down in the Standard. 若產品之成分依據本標準所訂規則取得，則此產品在其標示、廣告材料或商業文件中能合格使用有關有機生產方法的用語。

In the labelling and advertising of unprocessed agricultural products, terms referring to the organic production method may be used only where all the ingredients of that product have also been produced in accordance with the requirements laid down in the Standard. 未加工農產品之標示與廣告，宣稱為有機方法生產之用語，只能在該產品之所有成分也都是依據本標準規定生產時，才可使用。

2. Labelling as referred to in paragraph 1 of this section shall not be used for a product for which it has to be indicated in the labelling or advertising that it contains GMOs, consists of GMOs, or is produced from GMOs. 本節第1條提及之標示不得用於在標示或廣告中註明其含有基因改造生物、以基因改造生物組成或從基因改造生物生產之產品。
3. As regards processed food, the labelling referred to in paragraph 1 of this section may be used: 關於加工食品，本節第1條所指的標示可用於：

3.1 In the sales description, provided that: 銷售說明，但：

- 3.1.1 The processed food complies with the Standard Ref. 7.1 and 7.4. 該加工食品符合本標準第7.1及7.4條規定。

- 3.1.2 At least 95 % by weight, of its ingredients of agricultural origin are organic. 其農業來源的成分，按重量計算，至少95%為有機。

3.2 Only in the list of ingredients, provided that the food complies with the Standard Ref. 7.4. 限於成分表中，但該食品須符合本標準第7.4條規定。

3.3 In the list of ingredients and in the same visual field as the sales description, provided that: 成分表及在相同視野的銷售說明，但：

- 3.3.1 The main ingredient is a product of hunting or fishing. 主成份為狩獵或漁獲的產品。

- 3.3.2 It contains other ingredients of agricultural origin that are all organic. 所含之其他農業來源成分必須全為有機

- 3.3.3 The food complies with the Standard Ref. 7.1 (a) and 7.4 (a),(b),(d) 該食品符合本標準7.1

(a)和7.4(a),(b),(d)。

The list of ingredients shall indicate which ingredients are organic. 成分表必須指明何者為有機成分。

In the case where paragraph 3.2 and 3.3 of this section apply, the references to the organic production method may only appear in relation to the organic ingredients and the list of ingredients shall include an indication of the total percentage of organic ingredients in proportion to the total quantity of ingredients of agricultural origin. The terms and the indication of percentage referred to in paragraph 3 of this section shall appear in the same color, identical size and style of lettering as the other indications in the list of ingredients. 若適用本節第3.2、3.3條，則有機方法生產之引述必須只與有機成分有關，而成分表亦應註明有機成分佔農業來源成分總量的比例。第3條提及之用語與百分比註明，應與成分表中的其他註明使用相同顏色、同樣大小與字體。

B. Product composition (The Standard Ref. 7.4) 產品組成 (本標準第7.4條)

The following conditions shall apply to the composition of organic processed food: 有機加工食品之組成應符合以下條件：

1. The product shall be produced mainly from ingredients of agricultural origin; in order to determine whether a product is produced mainly from ingredients of agricultural origin, added water and cooking salt shall not be taken into account. 產品之生產，其成分應以農業來源為主；在認定某一產品之成分是否以農業來源為主時，不得將所添加的水與鹽列入考慮。
2. Only additives, processing aids, flavorings, water, salt, preparations of micro-organisms and enzymes, minerals, trace elements, vitamins, as well as amino acids and other micronutrients in foodstuffs for particular nutritional uses may be used, and only in so far as they have been authorized for use in organic production in accordance with Annex III to the Standard. 僅可使用於特定營養用途之食品添加物、加工助劑、調味料、水、鹽、微生物與酶的製劑、礦物質、微量元素、維他命、以及胺基酸與其他微量營養元素，且只有依據本標準附件3所列允用於有機生產之產品。
3. Non-organic agricultural ingredients may be used only if they have been listed in Annex IV to the Standard. 非有機農業原料之使用，僅限於本標準附件4中所列。
4. An organic ingredient shall not be present together with the same ingredient in non-organic form or an ingredient in conversion. 有機原料不得與非有機形式的相同原料或轉型期原料混合。
5. Food produced from in-conversion crops shall contain only one crop ingredient of agricultural origin. 轉型期作物生產之食品只能含有一種農業來源的作物原料。

- C. Use of certain products and substances in processing of food (The Standard Ref. 7.4.1) 使用於食品加工/製造的產品與物質(本標準第7.4.1條)
1. Only the following substances can be used in the processing of organic food. 只有下列物質可用於有機食品的加工/製造。
 - 1.1 Substances listed in Annex III to the Standard. 本標準附件3所列的物質。
 - 1.2 Preparations of micro-organisms and enzymes normally used in food processing; however, enzymes to be used as food additives have to be listed in Annex III to the Standard. 一般用於食品加工的微生物與酶的製劑；但，用於食品添加物的酶必須為本標準附件3所列。
 - 1.3 Substances, and products labelled as natural flavoring substances or natural flavoring preparations. 標示為天然香料或天然香料製劑的物質和產品。
 - 1.4 Drinking water and salt (with sodium chloride or potassium chloride as basic components) generally used in food processing. 一般用於食品加工的飲用水與食鹽(以氯化鈉或氯化鉀為基本成分)。
 - 1.5 Minerals (trace elements included), vitamins, amino acids, and micronutrients, only authorized as far their use is legally required in the foodstuffs in which they are incorporated. 礦物質(包含微量元素)、維生素、胺基酸與微量營養素，且僅在它們被納入食品可合法使用時授權。
 2. For the purpose of the calculation, referred to the Standard Ref. 8.1. 計算時，參照本標準第8.1條的規定。
 - 1.1 Food additives listed in Annex III to the Standard and marked with an asterisk in the column of the additive code number, shall be calculated as ingredients of agricultural origin. 本標準附件3所列的食品添加劑，如果其添加物編號欄位標註“星號”，應以農產品的成分計算；
 - 1.2 Preparations and substances referred to in paragraph 1.2, 1.3, 1.4, and 1.5 of this section and substances not marked with an asterisk in the column of the additive code number shall not be calculated as ingredients of agricultural origin. 本節第1.2~1.5條所指製劑與物質，如果其添加物編號欄位未標註“星號”，不應以農糧產品的成分計算；
- D. Use of certain non-organic ingredients of agricultural origin in processing food (The Standard Ref. 7.4.2) 使用非有機農產品的成分於加工/製造食品 (本標準第7.4.2條)
- An ingredient of agricultural origin may only be used in non-organic form if it has been listed in Annex IV to the Standard. 非有機農產品的使用僅限於本標準附件4所列。
- E. Organic production logos (The Standard Ref. 8.4) 有機生產標章 (本標準第8.4條)
- The Organic Logo of the European may be used in the labelling, presentation and

advertising of products which satisfy the requirements set out under the Standard. The Organic Logo of the European Union shall not be used in the case of in-conversion products and food as referred to in the Standard Ref. 8.1 (c)(ii),(iii). 歐盟有機標章得用於符合本標準所訂要求之產品之標示、說明與廣告。歐盟標章不得用於本標準第8.1(c)(ii),(iii)條提及之轉型期產品與食品。

National and private logos may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under the Standard. 政府與品牌標章得使用於符合本標準要求產品之標示、說明與廣告。

The Commission shall lay down specific criteria as regards presentation, composition, size and design of the Organic Logo of the European Union. 委員會應就歐盟有機標章有關的陳列、構圖、大小與設計制定具體標準。



PART B. Equivalent Standard for Operators in Non-EU Countries

TOC

Based on

- Council Regulation (EC) No 834/2007 of 28 June 2007
- Commission Regulation (EC) No 889/2008 of 5 September 2008

Amended by

- Commission Regulation (EC) No 967/2008 of 29 September 2008
- Commission Regulation (EC) No 1254/2008 of 15 December 2008
- Commission Regulation (EC) No 710/2009 of 5 August 2009
- Commission Regulation (EU) No 271/2010 of 24 March 2010
- Commission Implementing Regulation (EU) No 344/2011 of 8 April 2011
- Commission Implementing Regulation (EU) No 1030/2013 of 24 October 2013
- Commission Implementing Regulation (EU) No 1364/2013 of 17 December 2013
- Commission Implementing Regulation (EU) No 354/2014 of 9 April 2014
- Commission Implementing Regulation (EU) No 1358/2014 of 18 December 2014
- Commission Implementing Regulation (EU) No 2016/673 of 29 April 2016
- Commission Implementing Regulation (EU) No 2016/1842 of 14 October 2016
- Commission Implementing Regulation (EU) No 2017/838 of 17 May 2017
- Commission Implementing Regulation (EU) No 2017/2273 of 8 December 2017
- Commission Implementing Regulation (EU) No 2018/1584 of 22 October 2018
- Commission Implementing Regulation (EU) No 2019/2164 of 17 December 2019
- Commission Implementing Regulation (EU) 2021/181 of 15 February 2021
- Commission Delegated Regulation (EU) 2021/1342 of 27 May 2021
- Commission Delegated Regulation (EU) 2021/2306 of 21 October 2021
- Commission Implementing Regulation (EU) 2021/2307 of 21 October 2021

INTRODUCTION

The Tse-Xin Organic Certification Corporation (hereinafter referred to as “TOC”) is currently in operation of organic crops, aquatic plants and handling operations certification in Taiwan, R.O.C., TOC also was accredited by USDA to perform certification operation for the scope of organic crops, wild crops and handling operations in Taiwan or other countries under approval of the government.

This TOC Organic Equivalent Standard for Operators in Non-EU Countries (TOC Organic Standard) has been adapted from Regulation (EC) N° 834/2007 and Regulation (EC) N° 889/2008. It is a standard for organic operators who work outside the European Union and who wish to be certified as meeting requirements that are equivalent to the requirements of the Regulations of the European Union.

The TOC Organic Standard combines the propositions and provisions of the said EU Regulations for certification of organic products and it adapts them for application in non-EU countries. The Standard establishes rules for organic production and its certification which is equivalent to the rules set by the Regulations of the European Union for operators within the European Union.

The Regulations of the European Union include requirements with respect to the control system, which are based on the presence of certain administrative structures in the Member States and on the level of the institutions of the European Union which are not present in non-EU countries. Where specific clauses of the Regulations of the European Union make reference to authorities in the Member States, this competence is entrusted to the certification body acting in Third Countries and hereby considered as compliant; where reference is made to institutions, services or technical requirements which are not available, not relevant or inappropriate in non-EU countries these are replaced by equivalent measures.

The language of the TOC Organic Standard follows closely the language of the Regulations of the European Union. It deviates only where organic production in non-EU countries is based on equivalent conditions to meet the requirements of the European Union.

Section A: TOC Organic Standard (Production Standard)

Ref.		EU ref. ¹	C/E ²
1 Objectives			
	<p>The Standard provides the basis for the sustainable development of organic production while ensuring the effective functioning of the market, guaranteeing fair competition, ensuring consumer confidence and protecting consumer interests.</p> <p>It establishes common objectives and principles to support the rules set out under the Standard concerning:</p> <p>(a) All stages of production, preparation and distribution of organic products and their control;</p> <p>(b) The use of indications referring to organic production in labeling and advertising.</p>	834-Art. 1	C
2 Scope			
2.1 Agricultural products for the EU market			
	<p>The Standard shall apply to the following products originating from agriculture where such products are placed on the EU market or are intended to be placed on the EU market:</p> <p>(a) Unprocessed agricultural products;</p> <p>(b) Processed agricultural products for use as food.</p>	834-Art.1	C
2.2 Operators			
	<p>The Standard shall apply to any operator involved in activities, at any stage of production, preparation and distribution, relating to the products set out in Ref. 2.1.</p> <p>However, mass catering operations shall not be subject to the Standard.</p>	834-Art.1	C
2.3 Framework of relevant law			
	<p>The Standard shall apply without prejudice within the framework of relevant national or international law concerning products specified in Ref. 2.1, such as provisions governing the production, preparation, marketing, labeling and control, including legislation on foodstuffs.</p>	834-Art.1	C

1. 834 = EU Regulation (EC) No 834/2007; 889 = EU Regulation (EC) No 889/2008
2. C = compliant; E = equivalent to EU Regulations

Ref.		EU ref. ¹	C/E ²
3 Objectives for organic production			
	<p>The following objectives and principles in Ref. 3 and 4 shall set the framework for the application of all subsequent requirements and shall be used as points of reference when questions of interpretation arise. Organic production shall pursue the following general objectives:</p> <p>(a) Establish a sustainable management system for agriculture that:</p> <p>i respects nature's systems and cycles and sustains and enhances the health of soil, water, plants and animals and the balance between them;</p> <p>ii contributes to a high level of biological diversity;</p> <p>iii makes responsible use of energy and the natural resources, such as water, soil, organic matter and air.</p> <p>(b) Aim at producing products of high quality;</p> <p>(c) Aim at producing a wide variety of foods and other agricultural products that respond to consumers' demand for goods produced by the use of processes that do not harm the environment, human health, plant health or animal health and welfare.</p>	834-Art. 3	C
4 Principles of organic production			
4.1 Overall principles			
	<p>Organic production shall be based on the following principles:</p> <p>(a) The appropriate design and management of biological processes based on ecological systems using natural resources which are internal to the system by methods that:</p> <p>i use living organisms and mechanical production methods;</p> <p>ii practice land-related crop cultivation and production or practice aquacultural seaweeds production;</p> <p>iii exclude the use of GMOs and products produced from or by GMOs;</p> <p>iv are based on risk assessment, and the use of precautionary and preventive measures, when appropriate.</p> <p>(b) The restriction of the use of external inputs. Where external inputs are required or the appropriate management practices and methods referred to in paragraph (a) of this Ref. do not exist, these shall be limited to:</p> <p>i inputs from organic production;</p> <p>ii natural or naturally-derived substances;</p> <p>iii low solubility mineral fertilizers.</p> <p>(c) the strict limitation of the use of chemically synthesized inputs to exceptional cases these being:</p>	834-Art. 4	C

Ref.		EU ref. ¹	C/E ²
i ii iii (d)	where the appropriate management practices do not exist; the external inputs referred to in paragraph (b) of this Ref. are not available on the market; where the use of external inputs referred to in paragraph (b) of this Ref. contributes to unacceptable environmental impacts; The adaptation, where necessary, and within the framework of the Standard, of the rules of organic production taking account of sanitary status, regional differences in climate and local conditions, stages of development.		
4.2 Specific principles applicable to farming			
(a) (b) (c) (d) (e) (f)	In addition to the overall principles set out in Ref. 4.1, organic farming shall be based on the following specific principles: The maintenance and enhancement of soil life and natural soil fertility, soil stability and soil biodiversity preventing and combating soil compaction and soil erosion, and the nourishing of plants primarily through the soil ecosystem; The minimization of the use of non-renewable resources and off- farm inputs; The recycling of wastes and by-products of plant and animal origin as inputs in plant production; Taking account of the local or regional ecological balance when taking production decisions; The maintenance of plant health by preventative measures, such as the choice of appropriate species and varieties resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and the protection of natural enemies of pests; The maintenance of the biodiversity of natural aquatic ecosystems, the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems.	834-Art. 5	C
4.3 Specific principles applicable to processing of organic food			
(a)	In addition to the overall principles set out in Ref. 4.1, the production of processed organic food shall be based on the following specific principles: The production of organic food from organic agricultural ingredients, except where an ingredient is not available on the market in organic form;	834-Art. 6	C

Ref.		EU ref. ¹	C/E ²
(b)	The restriction of the use of food additives, of non organic ingredients with mainly technological and sensory functions and of micronutrients and processing aids, so that they are used to a minimum extent and only in case of essential technological need or for particular nutritional purposes;		
(c)	The exclusion of substances and processing methods that might be misleading regarding the true nature of the product;		
(d)	The processing of food with care, preferably with the use of biological, mechanical and physical methods.		
5 General Production Rules			
5.1 Compliance with standards			
	Operators shall comply with the production rules set out in the relevant Ref. 5~8. In order to demonstrate compliance, they are obliged to maintain the relevant records described in Ref. 9.	834-Art. 8	C
5.2 Adherence to the control system			
(a)	Any operator who produces, prepares, stores, or exports from a third country organic products or who places such products on the market shall, prior to placing on the market of any products as organic or in conversion to organic shall notify his activity and submit his undertaking to an authorized certification body.	834-Art. 28.1	C
(b)	Where an operator contracts out any of the activities to a third party, that operator shall nonetheless be subject to the requirements referred to in paragraph (a) of this Ref., and the subcontracted activities shall be subject to the control system.	834-Art. 28.2	C
(c)	Where an operator runs several production units in the same area, the units producing non-organic crops, together with storage premises for farm input products shall also be subject to these Standards and the control system.	889-Art. 73	C
(d)	TOC shall keep an updated list containing the names and addresses of operators under their control. This list shall be made available to the interested parties.	834-Art. 28	C
5.2.1 Minimum control requirements			
(a)	When the control arrangements are first implemented, the operator shall draw up and subsequently maintain:	889-Art. 63.1	C
i	a full description of the unit and/or premises and/or activity;		

Ref.		EU ref. ¹	C/E ²
ii	all the practical measures to be taken at the level of the unit and/or premises and/or activity to ensure compliance with the organic production rules;		
iii	the precautionary measures to be taken in order to reduce the risk of contamination by unauthorized products or substances and the cleaning measures to be taken in storage places and throughout the operator's production chain.		
iv	Where appropriate, the description and measures provided for in paragraph (a) of this Ref. may be part of a quality system as set up by the operator.		
(b)	The description and the measures referred to in paragraph (a) of this Ref. shall be contained in a declaration, signed by the responsible operator. In addition, this declaration shall include an undertaking by the operator:	889-Art. 63.2	C
i	to perform the operations in accordance with the organic production rules;		
ii	to accept, in the event of infringement or irregularities, the enforcement of the measures of the organic production rules;		
iii	to undertake to inform in writing the buyers of the product in order to ensure that the indications referring to the organic production method are removed from this production;		
iv	to accept, in cases where the operator and/or the subcontractors of that operator are checked by different control authorities or control bodies, the exchange of information between those authorities or bodies;		
v	to accept, in cases where the operator and/or the subcontractors of that operator change their control authority or control body, the transmission of their control files to the subsequent control authority or control body;		
vi	to accept, in cases where the operator withdraws from the control system, to inform without delay the relevant competent authority and control authority or control body;		
vii	to accept, in cases where the operator withdraws from the control system, that the control file is kept for a period of at least five years;		
viii	to accept to inform the relevant control authority or authorities or control body or bodies without delay of any irregularity or infringement affecting the organic status of their product or organic products received from other operators or subcontractors.		

Ref.		EU ref. ¹	C/E ²
(c)	<p>The declaration provided for in paragraph (b) of this Ref. shall be verified by the certification body that issues a report identifying the possible deficiencies and non-compliances with the organic production rules. The operator shall countersign this report and take the necessary corrective measures.</p> <p>For the application of Ref. 5.2.1 of the Standard the operator shall notify the following information to the certification body:</p> <ul style="list-style-type: none"> i name and address of operator; ii location of premises and, where appropriate, parcels (land register data) where operations are carried out; iii nature of operations and products; iv undertaking by the operator to carry out the operation in accordance with the provision laid down in the Standard; v in the case of an agricultural holding, the date on which the producer ceased to apply products not authorized for organic production on the parcels concerned. 	889-Art. 63.3	C
5.2.2 Modification of control arrangements			
	<p>The operator responsible shall notify any change in the description or of the measures referred to in Ref. 5.2.1 and in the initial control arrangements set out in Ref. 5.2.5.1, 5.2.5.2, 5.2.5.3, to the certification body in due time.</p>	889-Art. 64	C
5.2.3 Control visits			
(a)	<p>The certification body shall carry out at least once a year a physical inspection of all operators.</p>	889-Art. 65.1	C
(b)	<p>The certification body shall take and analyze samples for testing of products not authorized for organic production, for checking production techniques not in conformity with the organic production rules. Samples shall also be taken and analyzed for detecting possible contamination by products not authorized for organic production. The number of samples to be taken and analyzed by the certification body every year shall correspond to at least 5% of the number of operators under its control. The selection of the operators where samples have to be taken shall be based on the general evaluation of the risk of non-compliance with the organic production rules. This general evaluation shall take into account all stages of production, preparation and distribution.</p>	889-Art. 65.2	C

Ref.		EU ref. ¹	C/E ²
	However, such analysis shall be carried out where the use of products not authorized for organic production is suspected. In such cases no minimum number of samples to be taken and analyzed shall apply.		
(c)	A control report shall be drawn up after each visit, countersigned by the operator of the unit or his representative.	889-Art. 65.3	C
(d)	Moreover, certification body shall carry out random control visits, primarily unannounced, based on the general evaluation of the risk of non-compliance with the organic production rules, taking into account at least the results of previous controls, the quantity of products concerned and the risk for exchange of products.	889-Art. 65.4	C
(e)	In the context of the Standard the nature and frequency of the controls shall be determined on the basis of an assessment of the risk of occurrence of irregularities and infringements as regards compliance with the requirements laid down in the Standard. In any case, all operators with the exception of wholesalers dealing only with pre-packaged products, shall be subject to a verification of compliance at least once a year.	834-Art. 27.3	C
5.2.4 Access to facilities			
	The operator shall:	889-Art. 67.1	C
(a)	Give the certification body, for control purposes, access to all parts of the unit and all premises, as well as to the accounts and relevant supporting documents;		
(b)	Provide the certification body with any information reasonably necessary for the purposes of the control		
(c)	Submit, when requested by the certification body, the results of its own quality assurance programs.		
5.2.5 Control requirements			
5.2.5.0 Communications			
	Each year, before the date indicated by the control authority or control body, the operator shall notify the control authority or control body of its schedule of production of crop products, giving a breakdown by parcel.	889-Art. 71	C
5.2.5.1 Specific Control requirements for plants and plant products from farm production or collection			
(a)	The full description of the unit referred to in Ref. 5.2.1 (a) (i) shall:	889-Art. 70.1	C
i	be drawn up even where the operator limits his activity to the collection of wild plants;		

Ref.		EU ref. ¹	C/E ²
ii	indicate the storage and production premises and land parcels and/or collection areas and, where applicable, premises where certain processing and/or packaging operations take place; and		
iii	specify the date of the last application on the parcels and/or collection areas concerned of products, the use of which is not compatible with the organic production rules.		
(b)	In case of collection of wild plants, the practical measures referred to in Ref. 5.2.1 (a)(ii) shall include any guarantees given by third parties which the operator can provide to ensure that the provisions of Ref. 6.6 (b) of the Standard are complied with.	889-Art. 70.2	C
5.2.5.2 Control requirements for units for preparation of plant products and food stuffs composed of plant products			
	In the case of a unit involved in the preparation for its own account or for account of a third party, and including in particular units involved in packaging and/or re-packaging of such products or units involved in labelling and/or re-labelling of such products, the full description of the unit referred to in Ref. 5.2.1 (a)(i) shall show the facilities used for the reception, the processing, packaging, labelling and storage of agricultural products before and after the operations concerning them, as well as the procedures for the transport of the products.	889-Art. 80	C
5.2.5.3 Control requirements for units involved in the production, preparation of organic products and which have contracted out to third parties in part or in total the actual operations concerned			
	With regard to the operations, which are contracted out to third parties, the full description of the unit referred to in Ref. 5.2.1 (a)(i) shall include:	889-Art. 86	C
(a)	A list of the subcontractors with a description of their activities and an indication of the certification bodies to which they are subject;		
(b)	Written agreement by the subcontractors that their holding will be subject to inspection and certification.		
(c)	All the practical measures, including inter alia an appropriate system of documentary accounts, to be taken at the level of the unit to ensure that the products the operator places on the market can be traced to, as appropriate, their suppliers, sellers, consignees and buyers.		

Ref.		EU ref. ¹	C/E ²
5.2.6 Measures in case of suspicion of infringements and irregularities			
(a)	<p>Where an operator considers or suspects that a product which he has produced, prepared or that he has received from another operator, is not in compliance with organic production rules, he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. He may only put it into processing or packaging or on the market after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method.</p> <p>In case of such doubt, the operator shall immediately inform the certification body. The certification body may require that the product cannot be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated.</p>	889-Art. 91.1	C
(b)	<p>Where TOC has a substantiated suspicion that an operator intends to place on the market a product not in compliance with the organic production rules but bearing a reference to the organic production method, the certification body can require that the operator may provisionally not market the product with this reference for a time period to be set by TOC. Before taking such a decision, TOC shall allow the operator to comment. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if TOC is sure that the product does not fulfil the requirements of organic production.</p> <p>However, if the suspicion is not confirmed within the said time period, the decision referred to in the first subparagraph shall be cancelled not later than the expiry of that time period. The operator shall cooperate fully with TOC in resolving the suspicion.</p>	889-Art. 91.2	C
(c)	<p>Where an irregularity is found as regards compliance with the requirements laid down in the Standard, the certification body shall ensure that no reference to the organic production method is made in the labelling and advertising of the entire lot or production run affected by this irregularity, where this would be proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the irregular activities.</p>	834-Art. 30.1	C

Ref.		EU ref. ¹	C/E ²
(d)	<p>Where a severe infringement or an infringement with prolonged effect is found, the certification body shall prohibit the operator concerned from marketing products which refer to the organic production method in the labelling and advertising for a defined period of time.</p> <p>Information on cases of irregularities or infringements affecting the organic status of a product shall be immediately communicated between the certification bodies and competent authorities. The level of communication shall depend on the severity and the extent of the irregularity or infringement found.</p>	834-Art. 30.2	C
5.2.7 Exchange of information			
(a)	Where the operator and/or the subcontractors of that operator are checked by different control bodies, TOC shall exchange the relevant information on the operations under their control.	889-Art. 92.1	C
(b)	<p>Where operators and/or their subcontractors change their control body, the change shall be notified without delay to other control bodies by the control bodies concerned.</p> <p>The previous control body shall hand over the relevant elements of the control file of the operator concerned and the reports referred to in Ref. 5.2.1 (b) to the subsequent control body.</p> <p>The new control body shall ensure that non-conformities noted in the report of the previous control body have been or are being addressed by the operator.</p>	889-rt.92.2	C
(c)	Where the operator withdraws from the control system, TOC shall, without delay, inform other control bodies.	889-Art. 92.3	C
(d)	<p>Where a control body finds irregularities or infringements affecting the organic status of products, it shall without delay inform other control bodies.</p> <p>That control body may require, on its own initiative, also any other information on irregularities or infringements.</p> <p>In case of any irregularities or infringements found with regard to products under the control of other control bodies, it shall also inform those control bodies without delay.</p>	889-Art. 92.4	C

Ref.		EU ref. ¹	C/E ²
(e)	Upon a request duly justified by the necessity to guarantee that a product has been produced in accordance with this production standard, TOC shall exchange relevant information on the results of their controls with other competent authorities, control authorities and control bodies. They may also exchange such information on their own initiative.	834-Art. 31	C
(f)	TOC shall make available to the public, in an appropriate manner including publication on the internet, the updated lists referred to in Reference 5.2 (d) containing updated documentary evidence related to each operator, as provided for in Ref. 29(a) of that Standard and using the model set out in Annex VII to the Standard.	889-Art. 92b	C
5.3 Prohibition on the use of GMOs			
(a)	Genetically modified organisms (GMOs), and products produced from or by GMOs shall not be used as food, processing aids, plant protection products, fertilizers, soil conditioners, seeds, vegetative propagating material, and micro-organisms, in organic production.	834-Art. 9.1	C
(b)	For the purpose of the prohibition referred to in paragraph (a) of this Ref., operators using such non-organic products purchased from third parties shall require the vendor to confirm that the products supplied have not been produced from or by GMOs.	834-Art. 9.2	C
(c)	An optional model for such a vendor declaration is set out in Annex VIII to the Standard.	889-Art. 69	C
5.4 Prohibition on the use of ionizing radiation			
	The use of ionizing radiation for the treatment of organic food or of raw materials used in organic food is prohibited.	834-Art. 10	C
5.5 Supervisory activities relating to control bodies			
	Supervisory activities relating to control bodies for the ISO 17065 accreditation are as follows: every 5 years a re-accreditation needs to be done, each year an office audit needs to take place, witness audits on site/control visits are to be scheduled according to criteria defined in the latest version of quality manual and relevant operating procedures of TOC and TOC Organic Equivalent Standard for Operators in Non-EU Countries.	889-Art. 92c.1	E

Ref.		EU ref. ¹	C/E ²
	<p>The accreditation body of TOC provides on one hand the accreditation according to ISO 17065 as well as it is at the same time the assessment body of the control body. The assessment includes the internal procedures of TOC for the controls, the management and examination of control files in the light of the obligations established by the ISO and the verification of handling of non-conformities and the handling of appeals and complaints.</p> <p>TOC should submit the risk analysis procedure and to fulfil the following to the accreditation body:</p> <p>The risk analysis procedure shall be designed in such a way that the following criteria are taken into account for the risk analysis:</p> <ul style="list-style-type: none"> • Structure and complexity of the operator: Number of organic suppliers • Structure and complexity of the operator: Number of subcontractors • Changes in ownership or key facility personnel/ Quality manager • Internal Quality management systems • Results of previous controls: Sanctions with regard to TOC Organic Standard • Results of actual control decision: Actual sanctions with regard to TOC Organic Standard • Use of unallowed inputs (farm or processing level) • Parallel production • Conventional unit(s) on farm/ ICS or processing level • Groups with ICS: Functioning of ICS • Type of product <p>Additionally, the quantities produced are taken into account.</p> <p>The scoring per each criterion is follows: 0 - no risk, 1 - low risk, 2 - medium risk, 3 - high risk. Each calendar year 60% of the high risk operators receive an unannounced spot check, 30% of the medium operators and 10% of the low risk operators.</p> <p>The result of the risk analysis provides the basis for determining the intensity of the unannounced or announced annual inspections and visits;</p> <p>Additional random control visits carried out in accordance with Ref. 5.2.3(d) of this production standard of at least 10% of operators under contract in accordance with the risk category are performed in each region where TOC is active;</p>	<p>889-Art. 92c.2</p> <p>889-Art. 92c.2(a)</p> <p>889-Art. 92c.2(b)</p>	<p>E</p> <p>C</p> <p>C</p>

Ref.		EU ref. ¹	C/E ²
	At least 10% of all inspections and visits carried out in accordance with Ref. 5.2.3 (a),(d) are unannounced;	889-Art. 92c.2(c)	C
	The selection of operators to be submitted to unannounced inspections and visits is determined on the basis of the risk analysis and that these are planned according to the level of risk.	889-Art. 92c.2(d)	C
	Spot-check inspection plans are maintained and continuously updated.		
5.6 Catalogue of measures in case of irregularities and infringements			
	TOC shall adopt a catalogue listing infringements and irregularities affecting the organic status of products and corresponding measures to be applied in case of infringements or irregularities by operators under their control who are involved in organic production.	889-Art. 92d	C
6 Farm Production			
6.1 General farm production rules			
	The entire agricultural holding shall be managed in compliance with the requirements applicable to organic production. A holding may be split up into clearly separated units which are not all managed under organic production. As regards plants, different varieties that can be easily differentiated shall be involved. Where not all units of a holding are used for organic production, the operator shall keep the land, and products used for, or produced by, the organic units separate from those used for, or produced by, the non-organic units and keep adequate records to show the separation.	834-Art. 11	C
6.2 Conversion			
6.2.1 General requirements			
	The following rules shall apply to a farm on which organic production is started:	834-Art. 17.1	E
(a)	The conversion period shall start at the earliest when the operator has notified his/her activity to the control system;		
(b)	During the conversion period all rules established by the Standard shall apply;		
(c)	Conversion periods specific to the type of crop production shall be defined (see Ref. 6.2.2);		
(d)	On a holding or unit partly under organic production and partly in conversion to organic production, the operator shall keep the organically produced and in-conversion products separate or readily separable and keep adequate records to show the separation;		

Ref.		EU ref. ¹	C/E ²
(e)	In order to determine the conversion period referred to above, a period immediately preceding the date of the start of the conversion period may be taken into account, in so far as certain conditions concur;		
6.2.2 Conversion – Plants and plant products			
(a)	For plants and plant products to be considered organic, the production rules as referred to in Ref. 5.3, 5.4, 6.1, 6.4 of the Standard must have been applied on the parcels during a conversion period of at least two years before sowing, or, in the case of grassland or perennial forage, at least two years before its use as feed from organic farming, or, in the case of perennial crops other than forage, at least three years before the first harvest of organic products.	889-Art. 36.1	C
(b)	The certification body may decide to recognize retroactively as being part of the conversion period any previous period in which:	889-Art. 36.2	C
i	the land parcels were registered in an official environmental protection or similar program, provided that the measures concerned ensure that products not authorized for organic production have not been used on those parcels, or		
ii	the parcels were natural or agricultural areas which were not treated with products not authorized for organic production. The period referred to in paragraph (b)(ii) of this Ref. can be taken into consideration retroactively only where satisfactory proof has been furnished to the certification body allowing it to satisfy itself that the conditions were met for a period of at least three years.		
iii	The certification body may decide, in certain cases, where the land had been contaminated with products not authorized for organic production, to extend the conversion period beyond the period referred to in paragraph (a) of this Ref..	889-Art. 36.3	C
6.3 Parallel production			
6.3.1 Parallel production – Plant production			
	Where an operator's holding faces climatic, geographical or structural constraints, a producer may apply to the certification body to run organic and non-organic production units in the same area under the following provisions:	889-Art. 40.1	C
(a)	in the case of the production of perennial crops, which require a cultivation period of at least three years, where varieties cannot be easily differentiated, provided the following conditions are met:	889-Art. 40.1(a)	C

Ref.		EU ref. ¹	C/E ²
i	the production in question forms part of a conversion plan in respect of which the producer gives a firm undertaking and which provides for the beginning of the conversion of the last part of the area concerned to organic production in the shortest possible period which may not in any event exceed a maximum of five years;	889-Art. 40.1(a)(i)	C
ii	appropriate measures have been taken to ensure the permanent separation of the products obtained from each unit concerned;	889-Art.40.1(a)(ii)	C
iii	the certification body will inquire about the harvest of each of the products concerned in advance;	889-Art.40.1(a)(iii)	E
iv	upon completion of the harvest, the producer informs the certification body of the exact quantities harvested on the units concerned and of the measures applied to separate the products;	889-Art.40.1(a)(iv)	C
v	the conversion plan has been approved by the certification body; this approval shall be confirmed each year after the start of the conversion plan.	889-Art.40.1(a)(v)	C
(b)	in the case of areas intended for agricultural research or formal education agreed by TOC and provided the conditions set out in paragraph (a)(ii)(iii)(iv) and the relevant part of (v) of this Ref. are met;	889-Art. 40.1(b)	C
(c)	in the case of production of seed, vegetative propagating material and transplants and provided the conditions set out in paragraph (a)(ii)(iii)(iv) and the relevant part of (v) of this Ref. are met;	889-Art. 40.1(c)	C
(d)	in the case of grassland exclusively used for grazing.	889-Art. 40.1(d)	C
6.4 Plant production rules			
	In addition to the general farm production rules laid down in Ref. 6.1, the following rules shall apply to organic plant production:	834-Art. 12.1	C
6.4.1 Seeds			
	For the production of products other than seed and vegetative propagating material only organically produced seed and propagating material shall be used. To this end, the mother plant in the case of seeds and the parent plant in the case of vegetative propagating material shall have been produced in accordance with the rules laid down in the Standard for at least one generation, or, in the case of perennial crops, two growing seasons;	834-Art. 12.1(i)	C
6.4.1.1 Use of seed or vegetative propagating material not obtained by the organic production method			
(a)	Where organic seed or vegetative propagating material is not available on the market,	889-Art. 45.1	E

Ref.		EU ref. ¹	C/E ²
i	seed and vegetative propagating material from a production unit in conversion to organic farming may be used,		
ii	where paragraph (a) of this Ref. is not applicable, the certification body may authorize the use of non-organic seed or vegetative propagating material if not available from organic production. However, for the use of non-organic seed the following paragraphs (b) to (h) of this Ref. apply.		
(b)	Non-organic seed may be used, provided that the seed are not treated with plant protection products, other than those authorized for treatment of seed in accordance with Ref. 6.4.3.1 unless chemical treatment is prescribed in accordance with national requirements for phytosanitary purposes for all varieties of a given species in the area where the seed are to be used.	889-Art. 45.2	C
(c)	Species for which it is established that organically produced seed are available in sufficient quantities and for a significant number of varieties may not be subject of authorizations pursuant to paragraph a(ii) above, unless these are justified by one of the purposes referred to in paragraph e(iii) below.	889-Art. 45.3	E
(d)	The responsibility for granting the authorization referred to in paragraph a(ii) rests with the certification body.	889-Art. 45.4	E
(e)	Authorization to use seed not obtained by the organic production method may only be granted in the following cases:	889-Art. 45.5	E
i	where no supplier, meaning an operator who markets seed to other operators, is able to deliver the seed before sowing or planting in situations where the user has ordered the seed in reasonable time;	889-Art. 45.5(b)	C
ii	where the user is able to demonstrate that the desired variety and none of the registered alternatives of the same species are appropriate and that the authorization therefore is significant for her/his production;	889-Art. 45.5(c)	C
iii	where it is justified for use in research, test in small-scale field trials, or for variety of conservation purposes agreed by the certification body.	889-Art. 45.5(d)	C
iv	varieties or seeds that can best adapt to the environment and possess pest resistance properties and, in principle, biological and genetic diversification should be selected to render the production environment more ecologically diversified;		
v	seeds shall not be processed by synthetic chemical substance, or plant extract harmful to human body or mineral materials;		

Ref.		EU ref. ¹	C/E ²
vi	during the seedling breeding process, there shall be no synthetic chemical substance used;		
vii	use of any genetically modified seeds or seedling is prohibited;		
viii	use of synthetic chemical substance for sterilization at the site of seedling breeding facilities is prohibited, except these synthetic substances are permitted for use in accordance with the Standard.		
(f)	The authorization shall be granted before the sowing of the crop.	889-Art. 45.6	C
(g)	The authorization shall be granted only to individual users for one season at a time and the certification body responsible for the authorizations shall register the quantities of seed authorized.	889-Art. 45.7	C
(h)	By way of derogation from paragraph (g), the certification body may grant to all users a general authorization:	889-Art. 45.8	E
i	for a given variety when and in so far as the conditions laid down in paragraph e(ii) are fulfilled. The authorizations referred to in this paragraph shall be clearly indicated in records maintained by the certification body.	889-Art. 45.8(b)	C
(i)	All authorizations shall be documented with the <ul style="list-style-type: none"> • scientific name of species, variety, denominations, • justification for authorization, • quantity of seed authorized, • chemical treatment for phytosanitary purposes 	889-Art. 54.1	E
6.4.2 Soil management and amendments			
(a)	Organic plant production shall use tillage and cultivation practices that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion.	834-Art. 12.1(a)	C
(b)	The fertility and biological activity of the soil shall be maintained and increased by multi-annual crop rotation including legumes and other green manure crops, and by the application of livestock manure or organic material, both preferably composted, from organic production.	834-Art. 12.1(b)	C
(c)	The use of biodynamic preparations is allowed.	834-Art. 12.1(c)	C
(d)	In addition, fertilizers and soil conditioners may only be used if they have been authorized for use in organic production under Annex V to the Standard.	834-Art. 12.1(d)	C
(e)	Mineral nitrogen fertilizers shall not be used.	834-Art. 12.1(e)	C
6.4.2.1 Resort to fertilizers and soil conditioners			

Ref.		EU ref. ¹	C/E ²
(a)	Where the nutritional needs of plants cannot be met by cultivation practices, crop rotation and the application of organic material (Ref. 6.4.2(a), (b), (c)) only fertilizers and soil conditioners referred to in Annex I to the Standard may be used in organic production and only to the extent necessary. Operators shall keep documentary evidence of the need to use the product.	889-Art. 3.1	C
(b)	The total amount of livestock manure applied on the holding may not exceed 170 kg of nitrogen per year/hectare of agricultural area used. This limit shall only apply to the use of farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrements, including poultry manure, composted farmyard manure and liquid animal excrements	889-Art. 3.2	C
(c)	Organic production holdings may establish written cooperation agreements exclusively with other holdings and enterprises which comply with the organic production rules, with the intention of spreading surplus manure from organic production. The maximum limit as referred to in paragraph (b), shall be calculated on the basis of all of the organic-production units involved in such cooperation.	889-Art. 3.3	C
(d)	Appropriate preparations of micro-organisms may be used to improve the overall condition of the soil or the availability of nutrients in the soil or in the crops.	889-Art. 3.4	C
(e)	For compost activation appropriate plant-based preparations or preparations of micro-organisms may be used.	889-Art. 3.5	C
6.4.2.2 Hydroponic production			
	Hydroponic production is prohibited.	889-Art. 4	C
6.4.3 Pest prevention and treatment			
(a)	The prevention of damage caused by pests, diseases and weeds shall rely primarily on the protection by natural enemies, the choice of species and varieties, crop rotation, cultivation techniques and thermal processes;	834-Art. 12.1(g)	C
(b)	In the case of an established threat to a crop, plant protection products may only be used if they have been authorized for use in organic production under Annex V to the Standard.	834-Art. 12.1(h)	C
6.4.3.1 Resort to pest treatments			

Ref.		EU ref. ¹	C/E ²
(a)	Where plants cannot be adequately protected from pests and diseases by the measures provided for in Ref.6.4.2(a), (b), (c) and 6.4.3(a), only products referred to in Annex II & IIa to the Standard may be used in organic production. Operators shall keep documentary evidence of the need to use the product.	889-Art. 5.1	C
(b)	For products used in traps and dispensers, except pheromone dispensers, the traps and/or dispensers, shall prevent the substances from being released into the environment and prevent contact between the substances and the crops being cultivated. The traps shall be collected after use and disposed of safely.	889-Art. 5.2	C
6.4.4 Contamination			
	All plant production techniques used shall prevent or minimize any contribution to the contamination of the environment.	834-Art. 12.1(f)	C
6.4.5 Storage of input products			
	In case of organic plant and seaweed production units, storage of input products other than those authorized under the Standard is prohibited in the production unit.	889-Art. 35.2	C
6.4.6 Cleaning and disinfection			
	Products for cleaning and disinfection in plant production shall be authorized by the certification body according to the criteria defined in Annex V to the Standard.	834-Art. 12.1(j)	C
6.5 Mushroom production			
(a)	For production of mushrooms, substrates may be used, if they are composed only of the following components:	889-Art. 6	C
i	Farmyard manure and animal excrements:		
	<ul style="list-style-type: none"> i either from holdings producing according to the organic production method; ii or referred to in Annex I to the Standard, only when the product referred to in point (i) of this paragraph is not available; and when they do not exceed 25% of the weight of total components of the substrate, excluding the covering material and any added water, before composting; 		
(b)	Products of agricultural origin, other than those referred to in paragraph (a), from holdings producing according to organic production method;		
(c)	Peat not chemically treated;		
(d)	Wood, not treated with chemical products after felling;		

Ref.		EU ref. ¹	C/E ²
(e)	Mineral products referred to in Annex I to the Standard, water and soil.		
6.6 Wild plant collection			
	The collection of wild plants and parts thereof, growing naturally in natural areas, forests and agricultural areas is considered an organic production method provided that:	834-Art. 12.2	C
(a)	Those areas have not, for a period of at least three years before the collection, received treatment with products other than those authorized for use in organic production under Annex V to the Standard.		
(b)	The collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.		
7 Production of Processed Food			
7.1 General rules			
(a)	The preparation of processed organic food shall be kept separate in time or space from non-organic food.	834-Art. 19.1	C
(b)	Substances and techniques that reconstitute properties that are lost in the processing and storage of organic food, that correct the results of negligence in the processing of these products or that otherwise may be misleading as to the true nature of these products shall not be used.	834-Art. 19.3	C
7.2 Rules for the production of processed food			
(a)	Additives, processing aids and other substances and ingredients used for processing food and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice.	889-Art. 26.1	C
(b)	Operators producing processed food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.	889-Art. 26.2	C
(c)	The application of the procedures referred to in paragraph 2 shall guarantee at all times that the produced processed products comply with the organic production rules.	889-Art. 26.3	C
(d)	Operators shall comply with and implement the procedures referred to in paragraph (b). In particular, operators shall:	889-Art. 26.4	C
i	take precautionary measures to avoid the risk of contamination by unauthorized substances or products;		
ii	implement suitable cleaning measures, monitor their effectiveness and record these operations;		
iii	guarantee that non-organic products are not placed on the market with an indication referring to the organic production method.		

Ref.		EU ref. ¹	C/E ²
7.3 Split operations			
	<p>Further to the provisions laid down in Ref. 7.2, when non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:</p> <p>(a) Carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non-organic products;</p> <p>(b) Store organic products, before and after the operations, separate by place or time from non-organic products;</p> <p>(c) Inform the certification body thereof and keep available an updated register of all operations and quantities processed;</p> <p>(d) Take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;</p> <p>(e) Carry out operations on organic products only after suitable cleaning of the production equipment.</p>	889-Art. 26.5	C
7.4 Product composition			
	<p>The following conditions shall apply to the composition of organic processed food:</p> <p>(a) The product shall be produced mainly from ingredients of agricultural origin; in order to determine whether a product is produced mainly from ingredients of agricultural origin, added water and cooking salt shall not be taken into account;</p> <p>(b) Only additives, processing aids, flavorings, water, salt, preparations of micro-organisms and enzymes, minerals, trace elements, vitamins, as well as amino acids and other micronutrients in foodstuffs for particular nutritional uses may be used, and only in so far as they have been authorized for use in organic production in accordance with Annex III to the Standard;</p> <p>(c) Non-organic agricultural ingredients may be used only if they have been listed in Annex IV to the Standard;</p> <p>(d) An organic ingredient shall not be present together with the same ingredient in non-organic form or an ingredient in conversion;</p> <p>(e) Food produced from in-conversion crops shall contain only one crop ingredient of agricultural origin.</p>	834-Art. 19.2	C
7.4.1 Use of certain products and substances in processing of food			
(a)	Only the following substances can be used in the processing of organic food:	889-Art. 27.1	E

Ref.		EU ref. ¹	C/E ²
i	substances listed in Annex III to the Standard;		
ii	preparations of micro-organisms and enzymes normally used in food processing; however, enzymes to be used as food additives have to be listed in Annex III to the Standard;		
iii	substances, and products as defined in Articles 1(2)(b)(i) and 1(2)(c) of Council Directive 88/388/EEC (14) labelled as natural flavouring substances or natural flavouring preparations, according to Articles 9(1)(d) and (2) of that Directive;		
iv	drinking water and salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;		
v	minerals (trace elements included), vitamins, amino acids, and micronutrients, only authorized as far their use is legally required in the foodstuffs in which they are incorporated.		
(b)	For the purpose of the calculation, referred to Ref. 8.1,	889-Art. 27.2	C
i	food additives listed in Annex III to the Standard and marked with an asterisk in the column of the additive code number, shall be calculated as ingredients of agricultural origin;		
ii	preparations and substances referred to in paragraph (a)(ii), (iii), (iv), and (v) of this Ref. and substances not marked with an asterisk in the column of the additive code number shall not be calculated as ingredients of agricultural origin.		
7.4.2 Use of certain non-organic ingredients of agricultural origin in processing food			
	An ingredient of agricultural origin may only be used in non-organic form if it has been listed in Annex IV to the Standard.	889-Art. 28	C
7.4.3 Authorization of non-organic food ingredients of agricultural origin			
	An ingredient of agricultural origin may only be used in non-organic form under the following conditions:	889-Art. 29.1	E
(a)	The operator has notified TOC of all the requisite evidence showing that the ingredient concerned is not produced in sufficient quantity in the country in accordance with the organic production rules or cannot be imported from other countries;		
(b)	TOC has issued formal authorization which will be reviewed annually;		
(c)	The authorization may be withdrawn when evidence suggests that the supply situation has improved.		

Ref.		EU ref. ¹	C/E ²
7.5	Collection, packaging, transport and storage of products		
7.5.1	Collection of products and transport to preparation units		
	Operators may carry out simultaneous collection of organic and non-organic products, only where appropriate measures are taken to prevent any possible commingling or contact with non-organic products and to ensure the identification of the organic products. The operator shall keep the information relating to collection days, hours, circuit and date and time of reception of the products available to the certification body.	889-Art. 30	C
7.5.2	Packaging and transport of products to other operators or units		
(a)	Operators shall ensure that organic products are transported to other units, including wholesalers and retailers, only in appropriate packaging, containers or vehicles in such a manner that substitution of the content cannot be achieved without manipulation or damage of the seal and provided with a label stating, without prejudice to any other indications required by law:	889-Art. 31.1	C
i	the name and address of the operator and, where different, of the owner or seller of the product;		
ii	the name of the product or a description of the compound accompanied by a reference to the organic production method;		
iii	the name and/or the code number of the certification body to which the operator is subject; and		
iv	where relevant, the lot identification mark according to a marking system agreed with the certification body which permits to link the lot with the accounts referred to in Ref. 9. The information referred to in points (i) to (iv) of this paragraph may also be presented on an accompanying document, if such a document can be undeniably linked with the packaging, container or vehicular transport of the product. This accompanying document shall include information on the supplier and/or the transporter.		
(b)	The closing of packaging, containers or vehicles shall not be required where:	889-Art. 31.2	C
i	transportation is direct between an operator and another operator who are both subject to the organic control system;		
ii	the products are accompanied by a document giving the information required under paragraph (a) of this Ref.;		

Ref.		EU ref. ¹	C/E ²
iii	both the expediting and the receiving operators shall keep documentary records of such transport operations available for verification by the certification body of such transport operations.		
7.5.3 Reception of products from other units and other operators			
	On receipt of an organic product, the operator shall check the closing of the packaging or container where it is required and the presence of the indications provided to in Ref. 7.5.2.	889-Art. 33	C
(a)	The operator shall crosscheck the information on the label referred to in Ref. 7.5.2 with the information on the accompanying documents. The Result of these verifications shall be explicitly mentioned in the documentary accounts referred to in Ref. 9.		
(b)	The operator shall verify the documentary evidence of the suppliers.	834-Art. 29.2	C
(c)	The form of the documentary shall include all details shown in Annex VII to the Standard.	834-Art. 29.3	C
7.5.4 Storage of products			
(a)	For the storage of products, areas shall be managed in such a way as to ensure identification of lots and to avoid any mixing with or contamination by products and/or substances not in compliance with the organic production rules. Organic products shall be clearly identifiable at all times.	889-Art. 35.1	C
(b)	In case where operators handle both non-organic products and organic products and the latter are stored in storage facilities in which also other agricultural products or foodstuffs are stored:	889-Art. 35.4	C
i	the organic products shall be kept separate from the other agricultural products and/or foodstuffs;		
ii	every measure shall be taken to ensure identification of consignments and to avoid commingling or contact with non-organic products;		
iii	suitable cleaning measures, the effectiveness of which has been checked, have been carried out before the storage of organic products; operators shall record these operations.		

Ref.		EU ref. ¹	C/E ²
8	Labelling		
8.1	Use of terms referring to organic production		
(a)	<p>A product shall be eligible for bearing terms referring to the organic production method where, in the labelling, advertising material, or commercial documents, such a product, its ingredients have been obtained in accordance with the rules laid down in the Standard.</p> <p>In the labelling and advertising of unprocessed agricultural products, terms referring to the organic production method may be used only where all the ingredients of that product have also been produced in accordance with the requirements laid down in the Standard.</p>	834-Art. 23.1	C
(b)	<p>Labelling as referred to in paragraph (a) of this paragraph shall not be used for a product for which it has to be indicated in the labelling or advertising that it contains GMOs, consists of GMOs, or is produced from GMOs.</p>	834-Art. 23.2	C
(c)	<p>As regards processed food, the labelling referred to in paragraph (a) of this paragraph may be used:</p> <p>i in the sales description, provided that:</p> <ul style="list-style-type: none"> • the processed food complies with Ref. 7.1 and 7.4.; • at least 95 % by weight, of its ingredients of agricultural origin are organic; <p>ii only in the list of ingredients, provided that the food complies with Ref. 7.4;</p> <p>iii in the list of ingredients and in the same visual field as the sales description, provided that:</p> <ul style="list-style-type: none"> • the main ingredient is a product of hunting or fishing; • it contains other ingredients of agricultural origin that are all organic; • the food complies with Ref. 7.1 (a) and Ref. 7.4 (a),(b),(d). <p>The list of ingredients shall indicate which ingredients are organic.</p> <p>In the case where point (ii),(iii) of this paragraph apply, the references to the organic production method may only appear in relation to the organic ingredients and the list of ingredients shall include an indication of the total percentage of organic ingredients in proportion to the total quantity of ingredients of agricultural origin.</p> <p>The terms and the indication of percentage referred to in the paragraph (c) of this Ref. shall appear in the same color, identical size and style of lettering as the other indications in the list of ingredients</p>	834-Art. 23.3	C

Ref.		EU ref. ¹	C/E ²
8.2 Compulsory indications			
(a)	<p>Where terms in line with Ref. 8.1 are used:</p> <p>i the code number of the control authority or control body to which the operator who has carried out the most recent production or preparation operation is subject, shall also appear in the labelling;</p> <p>ii the Organic Logo of the European Union as regards pre-packaged food shall also appear on the packaging;</p> <p>iii where the Organic Logo of the European Union is used, an indication of the place where the agricultural raw materials of which the product is composed have been farmed shall also appear in the same visual field as the logo and shall take one of the following forms, as appropriate:</p> <ul style="list-style-type: none"> • “EU Agriculture”, where the agricultural raw material has been farmed in the EU; • “non-EU Agriculture”, where the agricultural raw material has been farmed in third countries; • “EU/non-EU Agriculture”, where part of the agricultural raw materials has been farmed in the Community and a part of it has been farmed in a third country. <p>The abovementioned indication “EU” or “non-EU” may be replaced or supplemented by a country in the case where all agricultural raw materials of which the product is composed have been farmed in that country.</p> <p>For the abovementioned “EU” or “non-EU” indication, small quantities by weight of ingredients may be disregarded provided that the total quantity of the disregarded ingredients does not exceed 2 % of the total quantity by weight of raw materials of agricultural origin.</p> <p>The abovementioned “EU” or “non-EU” indication shall not appear in a color, size and style of lettering more prominent than the sales description of the product. The use of the Organic logo of the European Union and the indication referred to in the first subparagraph shall be optional for products imported from third countries. However, where the Organic logo of the European Union appears in the labelling, the indication referred to in the first subparagraph shall also appear in the labelling.</p>	834-Art. 24.1	C
(b)	<p>The indications referred to in paragraph 1 shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.</p>	834-Art. 24.2	C

Ref.		EU ref. ¹	C/E ²
8.3 Organic production logos			
(a)	The Organic Logo of the European Union (hereinafter “the Organic Logo”) may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under the Standard. The Organic Logo of the European Union shall not be used in the case of in-conversion products and food as referred to in Ref. 8.1 (c)(ii),(iii).	834-Art. 25.1	C
(b)	National and private logos may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under the Standard.	834-Art. 25.2	C
(c)	The Commission shall lay down specific criteria as regards presentation, composition, size and design of the Organic Logo.	834-Art. 25.3	C
8.4 Organic logo of the European Union			
	In accordance with Ref. 8.3 (c), the Organic Logo shall follow the model set out in Annex VI to the Standard. For the purpose of labelling, the Organic Logo shall only be used if the product concerned is produced in accordance with the requirements of the Standard, by operators who comply with the requirements of the control system referred to in Ref. 5.2 of the Standard.	889-Art. 57	C
8.4.1 Conditions for the use of the code number and place of origin			
(a)	The indication of the code number of the control authority or control body referred to in Ref. 8.2 shall,	889-Art. 58.1	C
i	start with the acronym identifying the Member State or the third country, as referred to in the international standard for the two letter country codes under ISO 3166 (“TW” for Taiwan, Republic of China);		
ii	include a term which establishes a link with the organic production method, as referred to in Ref. 8.1;		
iii	include a reference number to be decided by the Commission or by the competent authority of the Member States;		
iv	be placed in the same visual field as the Organic Logo, where the Organic Logo is used in the labelling;		
(b)	The indication of the place where the agricultural raw materials of which the products is composed have been farmed, as referred to in Ref. 8.2 (a)(iii), shall be placed immediately below the code number referred to in paragraph (a) of this Ref..	889-Art. 58.2	C
8.5 In-conversion products of plant origin			
	In-conversion products of plant origin may bear the indication “product under conversion to organic farming” provided that:	889-Art. 62	C

Ref.		EU ref. ¹	C/E ²
(a)	A conversion period of at least 12 months before the harvest has been complied with;		
(b)	The indication shall appear in a color, size and style of lettering which is not more prominent than the sales description of the product, the entire indication shall have the same size of letters;		
(c)	The product contains only one crop ingredient of agricultural origin;		
(d)	The indication is linked to the code number of the certification body referred to at Ref. 8.2.		
9 Record keeping responsibilities of operators			
9.1 General			
(a)	Stock and financial records shall be kept in the unit or premises and shall enable the operator to identify and the certification body to verify: <ul style="list-style-type: none"> <li data-bbox="145 835 217 925">i the supplier and, where different, the seller, or the exporter of the products; <li data-bbox="145 925 217 1070">ii the nature and the quantities of organic products delivered to the unit and, where relevant, of all materials bought and the use of such materials; <li data-bbox="145 1070 217 1171">iii the nature and the quantities of organic products held in storage at the premises; <li data-bbox="145 1171 217 1317">iv the nature, the quantities and the consignees and, where different, the buyers, other than the final consumers, of any products which have left the unit or the first consignee's premises or storage facilities; <li data-bbox="145 1317 217 1503">v in case of operators who do not store or physically handle such organic products, the nature and the quantities of organic products bought and sold, and the suppliers, and where different, the sellers or the exporters and the buyers, and where different, the consignees. 	889-Art. 66.1	C
(b)	The documentary accounts shall also comprise the results of the verification at reception of organic products and any other information required by the certification body for the purpose of proper control. The data in the accounts shall be documented with appropriate justification documents. The accounts shall demonstrate the balance between the input and the output.	889-Art. 66.2	C
(c)	Where an operator runs several production units in the same area, the units for non-organic products, together with storage premises for input products must also be subject to the minimum control requirements.	889-Art. 66.3	C

Ref.		EU ref. ¹	C/E ²
9.2 Plant production records			
	<p>Plant production records shall be compiled in the form of a register and kept available to the certification body at all times at the premises of the holding. In addition to Ref. 9.1, such records shall provide at least the following information:</p> <p>(a) as regards the use of fertilizer: date of application, type and amount of fertilizer, parcels concerned;</p> <p>(b) as regards the use of plant protection products: reason and date of treatment, type of product, method of treatment;</p> <p>(c) as regards purchase of farm inputs: date, type and amount of purchased product;</p> <p>(d) as regards harvest: date, type and amount of organic or in conversion crop production.</p>	889-Art. 72	C
10 Documentary Evidence			
(a)	<p>For the purpose of the application of Article 29(1) of Regulation (EC) No 834/2007, TOC shall use the model of the documentary evidence set out in Annex VII to the Standard.</p> <p>In case of electronic certification as referred to in Article 29(3) of Regulation (EC) No 834/2007, the signature in box 8 of the documentary evidence shall not be required if the authenticity of the documentary evidence is otherwise shown by a tamper-proof electronic method.</p>	889-Art. 68.1	C
(b)	<p>If an operator subject to the control of TOC as referred to in paragraph (a) of this Ref. so requests within a time period to be indicated by TOC, the TOC shall provide complementary documentary evidence confirming the specific characteristics of the production method used by means of the model set out in Annex VII to the Standard.</p>	889-Art. 68.2	C
11 Import into the Union and the Certificate of Inspection		(EU) 2021/2306	C
11.1 Subject matter			
(a)	the verification in third countries of consignments of products intended to be placed on the market within the Union as organic products or in-conversion products and the issuance of the certificate of inspection;		
(b)	official controls on products entering the Union from third countries intended to be placed on the Union market as organic products or in-conversion products; and		

Ref.		EU ref. ¹	C/E ²
	action in cases of suspected or established non-compliance with Regulation (EU) 2018/848 to be taken by competent authorities, control authorities and control bodies in third countries.		
11.2 Verification in the third country			
(1)	The relevant control authority or control body recognised in accordance with Article 46 of Regulation (EU) 2018/848 shall verify the consignment in accordance with Article 16 of Commission Delegated Regulation (EU) 2021/1698.		
(2)	For the purposes of Articles 48 and 57 of Regulation (EU) 2018/848, the relevant control authority or control body shall verify the consignment with regard to compliance with the requirements laid down in Regulation (EC) No 834/2007 and production standards and control measures accepted as equivalent. That verification shall include systematic documentary checks and, as appropriate according to a risk assessment, physical checks, before the consignment leaves the third country of export or of origin.		
(3)	For the purposes of paragraphs 2 to 5, the relevant control authority or control body shall be:		
(a)	a control authority or control body as referred to in Article 57 of Regulation (EU) 2018/848 that has been recognised for the products concerned and for the third country in which the products have their origin, or, where applicable, in which the last operation for the purpose of preparation has been carried out; or		
(b)	a control authority or control body that has been designated by a competent authority of a recognised third country as referred to in Article 48 of Regulation (EU) 2018/848 in which the products have their origin, or, where applicable, in which the last operation for the purpose of preparation has been carried out.		
(4)	The verification referred to in paragraph 2 shall be carried out by:		
(a)	the control authority or control body of the producer or the processor of the product concerned; or		
(b)	where the operator or the group of operators carrying out the last operation for the purpose of preparation as defined in Article 3, point (44), of Regulation (EU) 2018/848 is different from the producer or processor of the product, the control authority or control body of the operator or the group of operators carrying out the last operation for the purpose of preparation.		

Ref.		EU ref. ¹	C/E ²
(5)	The documentary checks referred to in paragraph 2 shall verify:		
(a)	the traceability of the products and ingredients;		
(b)	that the volume of the products included in the consignment is in line with the mass balance checks of the respective operators according to the assessment carried out by the control authority or control body;		
(c)	the relevant transport documents and commercial documents (including invoices) of the products;		
(d)	<p>in case of processed products, that all organic ingredients of such products have been produced by operators or by groups of operators certified in a third country by a control authority or control body recognised in accordance with Article 46 or referred to in Article 57 of Regulation (EU) 2018/848 or by a third country recognised in accordance with Article 47 or 48 of Regulation (EU) 2018/848, or have been produced and certified in the Union in accordance with that Regulation.</p> <p>Those documentary checks shall be based on all relevant documents, including the certificate of operators referred to in Article 45(1), point (b)(i), of Regulation (EU) 2018/848, records of the inspections, the production plan for the product concerned and records kept by the operators or the groups of operators, available transport documents, commercial and financial documents and any other documents deemed relevant by the control authority or control body.</p>		
11.3 Issuance of the certificate of inspection			
(1)	The control authority or control body that has verified the consignment in accordance with Article 3 shall issue a certificate of inspection in accordance with Article 5 for every consignment before the consignment leaves the third country of export or of origin.		
(2)	Where the control authority or control body has been recognised in accordance with Article 46 of Regulation (EU) 2018/848, it shall issue the certificate of inspection for consignments containing high risk products as referred to in Article 8 of Delegated Regulation (EU) 2021/1698 only once it is in possession of the complete documentation of the traceability and it has received and assessed the results of the analyses of the samples taken on the consignment in accordance with Article 16(6) of that Delegated Regulation.		

Ref.		EU ref. ¹	C/E ²
11.4 Format of the certificate of inspection and use of TRACES			
(1)	The control authority or control body shall issue in the Trade Control and Expert System (TRACES) the certificate of inspection in accordance with the model and the notes set out in the Annex and shall complete boxes 1 to 18 of that certificate.		
(2)	When issuing the certificate of inspection, the control body or control authority shall upload into TRACES all the supporting documents, including the following:		
(a)	the results of analyses or tests carried out on the samples taken, where applicable;		
(b)	the commercial and transport documents such as the bill of lading, invoices and packaging list and, where the control authority or control body has been recognised in accordance with Article 46 of Regulation (EU) 2018/848, the travel plan as drawn up in accordance with Article 16(5) of Delegated Regulation (EU) 2021/1698.		
(3)	The certificate of inspection shall be issued in TRACES and shall bear a qualified electronic seal. If unavailable at the moment of the issuance, the information relating to the number of packages referred to in box 13 of the certificate of inspection and the information referred to in boxes 16 and 17 thereof, as well as the documents referred to in paragraph 2, shall be included or updated in the certificate of inspection within 10 days from its issuance and, in any case, before its verification and endorsement by the competent authority in accordance with Article 6.		
(4)	The certificate of inspection shall be drawn up:		
(a)	in the official language or in one of the official languages of the Member State of the border control post of entry into the Union, in the case of products subject to official controls at border control posts;		
(b)	in the official language or in one of the official languages of the Member State where the consignment is to be released for free circulation, in the case of products exempted from official controls at border control posts in accordance with Delegated Regulation (EU) 2021/2305.		
(5)	By way of derogation from paragraph 4, a Member State may consent to certificates being drawn up in another official language of the Union and accompanied, if necessary, by an authenticated translation.		

Ref.		EU ref. ¹	C/E ²
11.5 Official controls on consignments			
(1)	The competent authority at a border control post or at a point of release for free circulation, as appropriate, shall perform official controls on consignments for the verification of compliance with Regulation (EU) 2018/848 as follows:		
(a)	documentary checks on all consignments;		
(b)	identity checks carried out randomly; and		
(c)	<p>physical checks at a frequency depending on the likelihood of non-compliance with Regulation (EU) 2018/848.</p> <p>Documentary checks shall include an examination of the certificate of inspection, of all other supporting documents as provided in Article 5, and, where applicable, of the results of analyses or tests carried out on the samples taken.</p> <p>In case a certificate of inspection requires corrections of a purely clerical or editorial nature, the competent authority may accept that the control authority or control body that has issued the certificate of inspection updates the information in TRACES by replacing the document in accordance with the procedure available in TRACES without modifying the information in the initial certificate concerning the identification of the consignment, its traceability and the guarantees.</p>		
(2)	For consignments of high-risk products referred to in Article 8 of Delegated Regulation (EU) 2021/1698, the competent authority referred to in paragraph 1 of this Article shall carry out systematic identity and physical checks, take at least one representative sample of the consignments and check the documentation referred to in Article 16(6) of that Regulation. The competent authority shall establish a representative sampling procedure appropriate to the category, quantity and packaging of the product.		
(3)	After the verification as referred to in paragraph 1, and, where applicable, in paragraph 2, the competent authority shall take a decision on each consignment. The decision on the consignment shall be recorded in box 30 of the certificate of inspection in accordance with the model and the notes set out in the Annex and indicate one of the following:		
(a)	the consignment can be released for free circulation as organic;		
(b)	the consignment can be released for free circulation as in-conversion;		
(c)	the consignment can be released for free circulation as non-organic;		

Ref.		EU ref. ¹	C/E ²
(d)	the consignment cannot be released for free circulation;		
(e)	<p>part of the consignment can be released for free circulation with an extract of the certificate of inspection.</p> <p>The competent authority shall endorse the certificate of inspection in TRACES with a qualified electronic seal.</p>		
(4)	For products subject to official controls at border control posts, the following shall apply:		
(a)	paragraph 3 shall apply in addition to the rules regarding the use of the Common Health Entry Document (CHED) by the competent authorities at border control posts in accordance with Article 56(3), point (b)(i), of Regulation (EU) 2017/625 and at control points in accordance with Commission Delegated Regulation (EU) 2019/2123 (10) and with the rules on decisions on consignments laid down in Article 55 of Regulation (EU) 2017/625;		
(b)	documentary checks referred to in paragraph 1, point (a), may be performed at distance from border control posts in relation to certain organic products and in-conversion products in accordance with Articles 7 and 8 of Delegated Regulation (EU) 2019/2123;		
(c)	identity and physical checks referred to in paragraph 1, points (b) and (c), may be performed at control points in relation to certain organic products and in-conversion products in accordance with Articles 2 to 6 of Delegated Regulation (EU) 2019/2123.		
(5)	<p>The decision on consignments taken in accordance with Article 55 of Regulation (EU) 2017/625 shall refer to one of the indications referred to in paragraph 3, first subparagraph, of this Article. Where the importer has requested the placing under a special customs procedure in accordance with Article 7(1) of this Regulation, by completing box 23 of the certificate of inspection, the decision on consignments in accordance with Article 55 of Regulation (EU) 2017/625 shall indicate the applicable customs procedure.</p> <p>The decision recorded in the certificate of inspection indicating that the consignment or part thereof cannot be released for free circulation shall be notified without delay in TRACES to the relevant competent authority performing official controls in order to verify compliance with the rules referred to in Article 1(2), points (a) to (h) and (j), of Regulation (EU) 2017/625.</p>		

Ref.		EU ref. ¹	C/E ²
	<p>In case the decision taken in the CHED in accordance with Article 55 of Regulation (EU) 2017/625 indicates that the consignment does not comply with the rules referred to in Article 1(2) of that Regulation, the competent authority at the border control post shall inform in TRACES the competent authority that has taken the decision in accordance with paragraph 3 of this Article, in order to update the certificate of inspection. In addition, any competent authority performing official controls in order to verify compliance with the rules referred to in Article 1(2), points (a) to (h) and (j), of Regulation (EU) 2017/625 shall provide in TRACES any relevant information, such as laboratory analysis results, to the competent authority that has taken the decision in accordance with paragraph 3 of this Article in order to update, if relevant, the certificate of inspection.</p>		
(6)	<p>In case only part of a consignment is released for free circulation, the consignment shall be split into different batches before its release for free circulation. For each of the batches, the importer shall complete and submit in TRACES an extract of the certificate of inspection in accordance with Implementing Regulation (EU) 2021/2307. The competent authority of the Member State where the batch is intended to be released for free circulation shall perform the verification of the batch and shall endorse the extract of the certificate of inspection in TRACES with a qualified electronic seal.</p>		
(7)	<p>For consignments subject to official controls at border control posts referred to in paragraph 4, the customs authorities shall allow the release for free circulation of the consignment only upon presentation of a duly finalised CHED in accordance with Article 57(2), point (b), of Regulation (EU) 2017/625, and of a certificate of inspection endorsed in accordance with paragraph 6 of this Article indicating that the consignment can be released for free circulation.</p> <p>Where the consignment is split into different batches, the customs authorities shall require the presentation of a duly finalised CHED in accordance with Article 57(2), point (b), of Regulation (EU) 2017/625, and of an extract of the certificate of inspection in accordance with Implementing Regulation (EU) 2021/2307 indicating in box 12 that the batch can be released for free circulation.</p>		

Ref.		EU ref. ¹	C/E ²
11.6 Special customs procedures			
(1)	<p>Where a consignment is placed under a customs warehousing or inward processing procedure as referred to in Article 240(1) and Article 256(3), point (b), of Regulation (EU) No 952/2013 of the European Parliament and of the Council (11), and undergoes one or more preparations as referred to in the second subparagraph of this paragraph, the competent authority shall verify the consignment in accordance with Article 6 of this Regulation before the first preparation is carried out. The reference number of the customs declaration by which the goods have been declared for the customs warehousing or inward processing procedure shall be indicated by the importer in box 23 of the certificate of inspection.</p> <p>The preparations referred to in the first subparagraph shall be limited to the following types of operations:</p>		
(a)	packaging or change of packaging; or		
(b)	affixing, removal and altering of labels concerning the presentation of the organic production method.		
(2)	After the preparations referred to in paragraph 1, the competent authority shall verify the consignment and endorse the certificate of inspection in accordance with Article 6 prior to the release of the consignment for free circulation.		
(3)	Before the release for free circulation, a consignment may be split into different batches under custom supervision after the verification and the endorsement of the certificate of inspection in accordance with Article 6. The importer shall complete and submit in TRACES an extract of the certificate of inspection in accordance with Implementing Regulation (EU) 2021/2307 for each batch resulting from the split.		
(4)	The competent authority of the Member State where the batch is to be released for free circulation shall perform the verification of the batch in accordance with Article 6(1) and (2), and shall endorse the extract of the certificate of inspection in TRACES with a qualified electronic seal.		
(5)	The preparation and splitting operations referred to in paragraphs 1 and 3 shall be carried out in accordance with the relevant provisions set out in Chapters III and IV of Regulation (EU) 2018/848.		

Ref.		EU ref. ¹	C/E ²
11.7	Contingency arrangements for TRACES in case of unavailability and in case of force majeure		
(1)	Control authorities and control bodies issuing the certificate of inspection in accordance with Article 4 shall maintain available a fillable template of that certificate in accordance with the model set out in the Annex and of all documents required by Regulation (EU) 2018/848 that may be uploaded in TRACES.		
(2)	<p>Where TRACES or one of its functionalities is continuously unavailable for more than 24 hours, its users may use a fillable printed or electronic template, as referred to in paragraph 1, to record and exchange information.</p> <p>The control authority or control body referred to in paragraph 1 shall give a reference to each issued certificate and keep a register of the issued certificates in chronological order to ensure the correspondence with the alphanumeric reference given by TRACES once it becomes functional.</p> <p>In case paper certificates of inspection are used, uncertified alterations or erasures shall invalidate it.</p>		
(3)	Once TRACES or its functionalities become available again, its users shall use the information recorded in accordance with paragraph 2 to produce electronically the certificate of inspection and upload the documents referred in paragraph 1.		
(4)	Certificates and documents produced in accordance with paragraph 2 shall bear the text 'produced during contingency'.		
(5)	In case of an event of force majeure, paragraphs 1 to 4 shall apply. In addition, the competent authorities, control authorities or control bodies shall inform the Commission without delay about such an event and control authorities or control bodies shall insert all the necessary details in TRACES within ten calendar days following the end of this event.		
(6)	Article 5(4) and (5) shall apply mutatis mutandis to certificates and documents produced in accordance with paragraph 2 of this Article.		

Ref.		EU ref. ¹	C/E ²
11.8	Use of the certificate of inspection and extract of the certificate of inspection by customs authorities		
	<p>For products subject to official controls at a point of release for free circulation in accordance with Article 4 of Delegated Regulation (EU) 2021/2305, the customs authorities shall allow the release for free circulation of a consignment only upon presentation of a certificate of inspection indicating in box 30 that the consignment can be released for free circulation.</p> <p>Where the consignment is split into different batches, the customs authorities shall require the presentation of an extract of the certificate of inspection in accordance with Implementing Regulation (EU) 2021/2307 indicating in box 12 that the batch can be released for free circulation.</p>		
11.9	Information to be provided by a competent authority, control authority or control body in a third country on suspected or established non-compliances on consignments		
(1)	<p>Where a competent authority, control authority or control body in a third country is notified by the Commission, after the Commission has received a notification from a Member State in accordance with Article 9 of Implementing Regulation (EU) 2021/2307 as regards suspected or established non-compliance affecting the integrity of the organic products or in-conversion products in a consignment, it shall carry out an investigation. The competent authority, control authority or control body shall reply to the Commission and the Member State that sent the initial notification (notifying Member State) within 30 calendar days from the date of receiving that notification and shall inform about the actions and measures taken, including the results of the investigation and provide any other available information and/or required by the notifying Member State, using the template set out in Section X of Annex II to Commission Implementing Regulation (EU) 2021/279 (12).</p>		
(2)	<p>The competent authority, control authority or control body shall provide any further information requested by a Member State as regards additional actions or measures taken.</p>		

Ref.		EU ref. ¹	C/E ²
	The Commission or a Member State may request the competent authority, control authority or control body to make available, without delay, the list of all operators or groups of operators in the organic production chain of which the consignment is part, and of their control authorities or control bodies.		
(3)	Where the control authority or control body has been recognised in accordance with Article 46 of Regulation (EU) 2018/848, Article 21(2) and (3) of Delegated Regulation (EU) 2021/1698 shall apply.		
12	Documents and notifications required for import into the Union	(EU) 2021/2307	C
12.1	Subject matter		
(1)	the declarations and communications by importers, operators responsible for the consignments, first consignees and consignees for the import of products from third countries for the purpose of placing those products on the market within the Union as organic products or in-conversion products; and		
(2)	the notification by the competent authorities of the Member States of suspected or established non-compliance of consignments.		
12.2	Prior notification of arrival		
(1)	For each consignment, the importer or, where appropriate, the operator responsible for the consignment, shall give prior notification of the arrival of the consignment at the border control post or the point of release for free circulation by completing and submitting in the Trade Control and Expert System (TRACES) referred to in Article 2, point (36), of Commission Implementing Regulation (EU) 2019/1715 (6) the relevant part of the certificate of inspection in accordance with the model and the notes set out in the Annex to Delegated Regulation (EU) 2021/2306 to the following entities:		
(a)	the competent authority referred to in Article 6 of Delegated Regulation (EU) 2021/2306;		
(b)	the control authority or control body of the importer.		
(2)	For each consignment subject to official controls at border control posts, paragraph 1 shall apply in addition to the requirements on prior notification to the competent authorities at the border control posts of arrival of consignments pursuant to Article 56(3), point (a), of Regulation (EU) 2017/625.		

Ref.		EU ref. ¹	C/E ²
(3)	Prior notifications pursuant to paragraph 1 shall be given in accordance with the minimum time requirements laid down in Commission Implementing Regulation (EU) 2019/1013 (7).		
12.3 Certificate of inspection and extract of the certificate of inspection			
(1)	The importer and the first consignee shall complete the certificate of inspection in TRACES as follows:		
(a)	in box 23 on special customs procedures, the importer shall complete in TRACES all the information, except the information on the verification carried out by the relevant competent authority;		
(b)	in box 24 on the first consignee, the importer shall complete in TRACES the information if the information has not been filled in by the control authority or control body in the third country before the verification of the consignment and the endorsement of the certificate of inspection by the competent authority; and		
(c)	box 31 on the declaration of the first consignee shall be completed in TRACES by the first consignee at the reception of the consignment after its release for free circulation.		
(2)	If the decision taken on the consignment in accordance with Article 6(3) of Delegated Regulation (EU) 2021/2306 indicates that the consignment is to be released for free circulation, the importer shall report the number of the certificate of inspection in the customs declaration for release for free circulation as referred to in Article 158(1) of Regulation (EU) No 952/2013 of the European Parliament and of the Council (8).		
(3)	Where a consignment is split into different batches under customs supervision and before the release for free circulation in accordance with Article 6(6) of Delegated Regulation (EU) 2021/2306, the importer shall complete and submit an extract of the certificate of inspection through TRACES for each of the batches in accordance with the model and the notes set out in the Annex to this Regulation.		
	The same applies if a consignment is split into different batches in accordance with Article 7(3) of Delegated Regulation (EU) 2021/2306 after the verification and the endorsement of the certificate of inspection.		

Ref.		EU ref. ¹	C/E ²
	If the decision in relation to a batch recorded in the extract of the certificate of inspection in accordance with Articles 6(6) and 7(4) of Delegated Regulation (EU) 2021/2306 indicates that the batch is to be released for free circulation, the number of the extract of the certificate of inspection shall be reported in the customs declaration for release for free circulation as referred to in Article 158(1) of Regulation EU) No 952/2013.		
	The consignee shall, at the reception of a batch, complete in TRACES box 13 of the extract of the certificate of inspection, confirming whether, at the reception of the batch, the packaging or container and, where relevant, the certificate of inspection are in accordance with point 6 of Annex III to Regulation (EU) 2018/848.		
(4)	The extract of the certificate of inspection shall be drawn up in the official language or in one of the official languages of the Member State where the batch is to be released for free circulation. A Member State may consent to an extract of the certificates being drawn up in another official language of the Union and accompanied, if necessary, by an authenticated translation.		
12.4 Documentary accounts			
	Upon request by the relevant competent authority, control authority or control body, the importer, the first consignee or the consignee shall provide the certificate of inspection or, where relevant, the extract of the certificate of inspection in which they are mentioned.		
12.5 Description of the production units and activities			
	In the case of an importer declaring the consignment for the release for free circulation, the full description of the organic or in-conversion production unit and of the activities as referred to in Article 39(1), point (d)(i), of Regulation (EU) 2018/848 shall include:		
(a)	the premises;		
(b)	the activities, indicating the points of release for free circulation in the Union;		
(c)	any other facilities that the importer intends to use for the storage of the imported products pending their delivery to the first consignee; and		

Ref.		EU ref. ¹	C/E ²
(d)	an undertaking to ensure that any facilities that will be used for the storage of imported products are submitted to control, to be carried out either by the control authority or control body or, where these storage facilities are situated in another Member State or region, by a control authority or control body recognised for controls in that Member State or region.		
	In the case of the first consignee and the consignee, the description shall include the facilities used for the reception of consignments and their storage.		
12.6 Notification of suspected or established non-compliance			
	If during the verification of compliance of a consignment in accordance with Article 6 of Delegated Regulation (EU) 2021/2306 cases of suspected or established non-compliance are identified, the Member State concerned shall immediately notify the Commission and the other Member States using the Organic Farming Information System (OFIS) and the template set out in Section 4 of Annex II to Commission Implementing Regulation (EU) 2021/279. The Commission shall inform the competent authority, or where relevant, the control authority or control body of the third country concerned.		
12.7 Transitional provisions for paper certificates of inspection and extracts thereof			
(1)	The paper certificate of inspection endorsed with a hand signature in accordance with Article 11(2) of Delegated Regulation (EU) 2021/2306 and the paper extract of the certificate of inspection endorsed with a hand signature in accordance with Article 11(5) of that Regulation shall accompany the goods to the premises of the first consignee or of the consignee.		
(2)	Upon reception of the paper certificate of inspection referred to in paragraph 1, the first consignee shall verify whether the information reported in that certificate corresponds to the information completed in that certificate in TRACES.		
	In case the information relating to the number of packages referred to in box 13 of the certificate of inspection and the information in boxes 16 and 17 of that certificate is not completed in the paper certificate of inspection, or in case that information is different from the information completed in the certificate in TRACES, the first consignee shall consider the information completed in the certificate in TRACES.		

Ref.		EU ref. ¹	C/E ²
(3)	After the verification referred to in paragraph 2, the first consignee shall hand sign the paper certificate of inspection in box 31 and shall send that certificate to the importer mentioned in box 12 thereof.		
(4)	The importer shall keep the paper certificate of inspection referred in paragraph 3 at the disposal of the control authority or the control body for at least two years.		
(5)	In case of a paper extract of the certificate of inspection as referred to in paragraph 1, the consignee shall, at the reception of the batch, hand sign that paper extract in box 13.		
(6)	The consignee of the batch shall keep the paper extract of the certificate of inspection referred to in paragraph 5 at the disposal of the control authorities and/or control bodies for at least two years.		
(7)	The first consignee or, where relevant, the importer may make a copy of the paper certificate of inspection referred to in paragraph 3 for the purpose of informing the control authorities and control bodies in accordance with Article 5. Any such copy shall carry the indication 'COPY' printed or stamped thereon.		
(8)	The consignee or, where relevant, the importer may make a copy of the paper extract of the certificate of inspection referred to in paragraph 5 for the purpose of informing the control authorities and control bodies in accordance with Article 5. Any such copy shall carry the indication 'COPY' printed or stamped thereon.		

TOC

Section B: Annexes

Note: The following annexes will be continuously updated on basis of Amending Regulations to
(EC) No 889/2008



ANNEX I. Fertilizers and soil conditioners referred to in Article 3(1) of Regulation (EC) 889/2008

Note: A: authorized under Regulation (EEC) No 2092/91 and carried over by Article 16(3)(c) of Regulation (EC) No 834/2007

B: authorized under Regulation (EC) No 834/2007

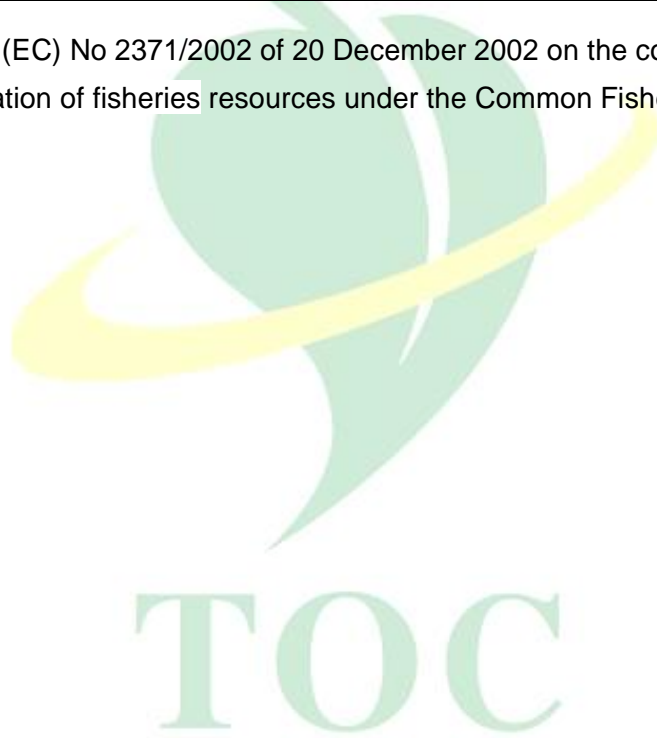
Authoriza- tion	Name Compound products or products containing only materials listed hereunder	Description, compositional requirements, conditions for use
A	Farmyard manure	Products comprising a mixture of animal excrements and vegetable matter (animal bedding) Factory farming origin forbidden
A	Dried farmyard manure and dehydrated poultry manure	Factory farming origin forbidden
A	Composted animal excrements, including poultry manure and composted farmyard manure included	Factory farming origin forbidden
B	Composted or fermented household waste	Product obtained from source separated household waste, which has been submitted to composting or to anaerobic fermentation for biogas production Only vegetable and animal household waste Only when produced in a closed and monitored collection system, accepted by TOC
A	Peat	Use limited to horticulture (market gardening, floriculture, arboriculture, nursery)
A	Mushroom culture wastes	The initial composition of the substrate shall be limited to products of this Annex
A	Dejecta of worms (vermi compost)	
A	Guano	
A	Composted or fermented mixture of vegetable matter	Product obtained from mixtures of vegetable matter, which have been submitted to composting or to anaerobic fermentation for biogas production
B	Products or by-products of animal origin as below: Bone meal or degelatinized	⁽¹⁾ Not to be applied to edible parts of the crop

Authoriza- tion	Name Compound products or products containing only materials listed hereunder	Description, compositional requirements, conditions for use
	bone meal Fish meal Dairy products Hydrolyzed proteins ⁽¹⁾	
A	Products and by-products of plant origin for fertilizers	Examples: oilseed cake meal, soybean meal, rice bran, cocoa husks, malt culms
B	Hydrolysed proteins of plant origin	
A	Seaweeds and seaweed products	As far as directly obtained by: (i) physical processes including dehydration, freezing and grinding (ii) extraction with water or aqueous acid and/or alkaline solution (iii) fermentation
A	Sawdust and wood chips	Wood not chemically treated after felling
A	Composted bark	Wood not chemically treated after fell in
A	Wood ash	From wood not chemically treated after felling
A	Soft ground rock phosphate	Product as specified in point 7 of Annex IA.2 to Regulation (EC) No 2003/2003 of the European Parliament and of the Council Cadmium content less than or equal to 90 mg/kg of P ₂ O ₅
A	Aluminium-calcium phosphate	Product as specified in point 6 of Annex IA.2. of Regulation (EC) 2003/2003, Cadmium content less than or equal to 90 mg/kg of P ₂ O ₅ Use limited to basic soils (pH > 7,5)
A	Basic slag	Products as specified in point 1 of Annex IA.2. of Regulation (EC) 2003/2003
A	Crude potassium salt or kainit	Products as specified in point 1 of Annex IA.3. of Regulation (EC) 2003/2003
A	Potassium sulphate, possibly containing magnesium salt	Product obtained from crude potassium salt by a physical extraction process, containing possibly also magnesium salts
A	Calcium carbonate, for instance (chalk, marl, ground limestone, ameliorant, phosphate chalk)	Only of natural origin
B	Mollusc waste	Only from sustainable fisheries, as defined in

Authoriza- tion	Name Compound products or products containing only materials listed hereunder	Description, compositional requirements, conditions for use
		Article 4 (1) (7) of Regulation (EU) No 1380/2013 or organic aquaculture
B	Egg shells	Factory farming origin forbidden
A	Magnesium and calcium carbonate	Only of natural origin e.g. magnesian chalk, ground magnesium, limestone
A	Magnesium sulphate (kieserite)	Only of natural origin
A	Calcium chloride solution	Foliar treatment of apple trees, after identification of deficit of calcium
A	Calcium sulphate (gypsum)	Products as specified in point 1 of Annex ID. of Regulation (EC) 2003/2003 Only of natural origin
A	Industrial lime from sugar production	By-product of sugar production from sugar beet
A	Industrial lime from vacuum salt production	By-product of the vacuum salt production from brine found in mountains
A	Elemental sulphur	Products as specified in Annex ID.3 of Regulation (EC) 2003/ 2003
A	Trace elements	Inorganic micronutrients listed in part E of Annex I to Regulation (EC) 2003/2003
A	Sodium chloride	
A	Stone meal and clays	
B	Leonardite (Raw organic sediment rich in humic acids)	Only if obtained as a by-product of mining activities
B	Humic and fulvic acids	Only if obtained by inorganic salts/solutions excluding ammonium salts; or obtained from drinking water purification
B	Xylite	Only if obtained as a by-product of mining activities (e.g. by- product of brown coal mining)
B	Chitin (Polysaccharide obtained from the shell of crustaceans)	Only if obtained from sustainable fisheries, as defined in Article 3(e) of Council Regulation (EC) No 2371/2002(*) or organic aquaculture
B	Organic rich sediment from fresh water bodies formed under exclusion of oxygen (e.g. sapropel)	Only organic sediments that are by-products of fresh water body management or extracted from former fresh water areas When applicable, extraction should be done in a way to cause minimal impact on the aquatic system

Authoriza- tion	Name Compound products or products containing only materials listed hereunder	Description, compositional requirements, conditions for use
		Only sediments derived from sources free from contaminations of pesticides, persistent organic pollutants and petrol like substances
B	Biochar — pyrolysis product made from a wide variety of organic materials of plant origin and applied as a soil conditioner	Only from plant materials, untreated or treated with products included in Annex II. Maximum value of 4 mg polycyclic aromatic hydro-carbons (PAHs) per kg dry matter (DM). This value shall be reviewed every second year, taking into account the risk of accumulation due to multiple applications'

- (*) Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy (OJ L 358, 31.12.2012, p. 59)



ANNEX II. Pesticides — plant protection products referred to in Article 5(1) of Regulation (EC) 889/2008

All the substances listed in this Annex have to comply at least with the conditions for use as specified in the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽¹⁾. More restrictive conditions for use for organic production are specified in the second column of each table.

1. Substances of plant or animal origin

Name	Description, compositional requirements, conditions for use
Allium sativum (Garlic extract)	
Azadirachtin extracted from <i>Azadir-achta indica</i> (Neem tree)	
Beeswax	Only as a pruning agent/wound protectant
COS-OGA	
Hydrolyzed proteins excluding gelatin	
Laminarin	Kelp shall be either grown organically in accordance with Article 6d or harvested in a sustainable way in accordance with Article 6c.
Maltodextrin	
Pheromones	Only in traps and dispensers
Plant oils	All uses allowed except herbicide
Pyrethrins	Only from plant origin
Quassia extracted from <i>Quassia amara</i>	Only as insecticide, repellent
Repellents by smell of animal or plant origin	Only on non-edible parts of the crop
Salix spp. Cortex (a.k.a. willow bark)	
Terpenes (eugenol, geraniol and thymol)	

2. Basic substances

Basic substances based on food (including: Lecithins, sucrose, fructose, vinegar, whey, chitosan hydrochloride ⁽²⁾ , and <i>Equisetum arvense</i> etc.)	Only those basic substances as defined by Article 23 of Regulation (EC) No 1107/2009 ⁽³⁾ which are food as defined in Article 2 of Regulation (EC) No 178/2002 and have plant or animal origin Substances not to be used as herbicides
--	--

3. Micro-organisms used for biological pest and disease control

Name	Description, compositional requirements, conditions for use
Micro-organisms	not from GMO origin
Spinosad	
Cerevisane	

4. Substances other than those mentioned in Sections 1, 2 and 3

Name	Description, compositional requirements, conditions or restrictions to use
Aluminium silicate (Kaolin)	
Calcium hydroxide	When used as fungicide, only in fruit trees, including nurseries, to control <i>Nectria galligena</i> .
Carbon dioxide	
Copper compounds in the form of: copper hydroxide, copper oxychloride, copper oxide, Bordeaux mixture, and tribasic copper sulphate	
Ethylene	
Fatty acid	all uses authorised, except herbicide.
Ferric phosphate (iron (III) orthophosphate)	Preparations to be surface-spread between cultivated plants.
Hydrogen peroxide	
Kieselgur (diatomaceous earth)	
Lime sulphur (calcium polysulphide)	
Paraffin oil	

Name	Description, compositional requirements, conditions or restrictions to use
Potassium and sodium hydrogen carbonate (aka potassium/sodium bicarbonate)	
Pyrethroids (only deltamethrin or lambda-cyhalothrin)	only in traps with specific attractants; only against <i>Bactrocera oleae</i> and <i>Ceratitis capitata</i> Wied.
Quartz sand	
Sodium chloride	All uses authorised, except herbicide
Sulphur	

- (1) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).
- (2) Obtained from sustainable fisheries or organic aquaculture.
- (3) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).



ANNEX II a. Pesticides — plant protection products equivalent to those listed in Annex II

1. Taking into account regional differences in climate and local conditions, the certification body may allow plant extracts/plant oils used as plant protection agents, where the following conditions apply:

- The plant extracts/plant oils are natural or naturally-derived substances in the understanding of Article 4.1
- The plant extracts/plant oils are used traditionally in organic farming in the respective country.

For assurance of compliance with EU regulations, the certification body will inform the Commission before the authorisation of the use of substances not listed on Annex II of (EU) No 889/2008.

For recognition the following criteria must be met:

- Specifications of plant extracts/plant oils have been provided
- The plant extracts/plant oils may not include tobacco (*Nicotiana tabacum*)
- Rotenone is not allowed.

2. The certification body may allow the use of post harvest treatment products for bananas such as organic acids and citric. For recognition the following criteria must be met:

- Specifications of all ingredients have been provided together with the vender's declaration regarding the absence of GMOs and their derivatives.
- The ingredients are allowed as processing aid in products of plant origin according to Annex III section A and B or obtained from natural or naturally-derived substances.

ANNEX III. Certain products and substances for use in production of processed organic food referred to in Article 27(1)(a) of Regulation (EC) 889/2008

SECTION A — FOOD ADDITIVES, INCLUDING CARRIERS

For the purpose of the calculation referred to in Article 23(4)(a)(ii) of Regulation (EC) No 834/2007, food additives marked with an asterisk in the column of the code number, shall be calculated as ingredients of agricultural origin.

Code	Name	Preparation of foodstuffs of		Specific conditions
		Plant origin	Animal origin	
E 153	Vegetable carbon		X	Ashy goat cheese Morbier cheese
E160b*	Annatto, Bixin, Norbixin		X	Red Leicester cheese Double Gloucester cheese Cheddar Mimolette cheese
E 170	Calcium carbonate	X	X	Shall not be used for colouring or calcium enrichment of products
E 270	Lactic acid	X	X	
E 290	Carbon dioxide	X	X	
E 296	Malic acid	X		
E 306*	Tocopherol-rich extract	X	X	Anti-oxidant
E 322*	Lecithins	X	X	With regard to foodstuffs of animal origin: Milk-based products Only when derived from organic production. Applicable as of 1 January 2022. Until that date, only when derived from organic raw material.
E 325	Sodium lactate		X	Milk-based products
E 330	Citric acid	X	X	
E 331	Sodium citrates	X	X	
E 333	Calcium citrates	X		

Code	Name	Preparation of foodstuffs of		Specific conditions
		Plant origin	Animal origin	
E 334	Tartaric acid (L(+)-)	X		
E 335	Sodium tartrates	X		
E 336	Potassium tartrates	X		
E 341(i)	Monocalcium-phosphate	X		Raising agent for self-raising flour
E 392*	Extracts of rosemary	X	X	Only when derived from organic production
E 400	Alginic acid	X	X	With regard to foodstuffs of animal origin: Milk-based products
E 401	Sodium alginate	X	X	With regard to foodstuffs of animal origin: Milk-based products and sausages based on meat
E 402	Potassium alginate	X	X	With regard to foodstuffs of animal origin: Milk-based products
E 406	Agar	X	X	With regard to foodstuffs of animal origin: Milk-based products
E 407	Carrageenan	X	X	With regard to foodstuffs of animal origin: Milk-based products
E 410*	Locust bean gum	X	X	Only when derived from organic production. Applicable as of 1 January 2022.
E 412*	Guar gum	X	X	Only when derived from organic production. Applicable as of 1 January 2022.
E 414*	Arabic gum	X	X	Only when derived from organic production. Applicable as of 1 January 2022.
E 415	Xanthan gum	X	X	
E 417	Tara gum powder	X	X	Thickener Only when derived from organic production. Applicable as of 1 January 2022.
E 418	Gellan gum	X	X	High-acyl form only Only when derived from organic production.

Code	Name	Preparation of foodstuffs of		Specific conditions
		Plant origin	Animal origin	
				Applicable as of 1 January 2022.
E 422	Glycerol	X		From plant origin Only when derived from organic production. Applicable as of 1 January 2022. For plant extracts and flavourings, humectant in gel capsules and as a surface coating of tablets
E 440(i)	Pectin	X	X	With regard to foodstuffs of animal origin: Milk-based products
E 464	Hydroxypropyl methyl cellulose	X	X	Encapsulation material for capsules
E 500	Sodium carbonates	X	X	
E 501	Potassium carbonates	X		
E 503	Ammonium carbonates	X		
E 504	Magnesium carbonates	X		
E 509	Calcium chloride		X	Milk coagulation
E 516	Calcium sulphate	X		Carrier
E 524	Sodium hydroxide	X		Surface treatment of 'Laugengebäck' and regulation of acidity in organic flavourings
E 551	Silicon dioxide	X	X	For herbs and spices in dried powdered form, flavourings and propolis
E 553b	Talc	X		
E 901	Beeswax	X		As a glazing agent for confectionary only. Beeswax from organic production
E 903	Carnauba wax	X		As a glazing agent for confectionary only. As a mitigating method for mandatory extreme cold treatment of fruit as a quarantine measure

Code	Name	Preparation of foodstuffs of		Specific conditions
		Plant origin	Animal origin	
				against harmful organisms (Commission Implementing Directive (EU) 2017/1279) ⁽¹⁾ Only when derived from organic production. Applicable as of 1 January 2022. Until that date, only when derived from organic raw material.
E 938	Argon	X	X	
E 939	Helium	X	X	
E 941	Nitrogen	X	X	
E 948	Oxygen	X	X	
E 968	Erythritol	X	X	Only when derived from organic production without using ion exchange technology

(1) Commission Implementing Directive (EU) 2017/1279 of 14 July 2017 amending Annexes I to V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 184, 15.7.2017, p. 33).

TOC

SECTION B — PROCESSING AIDS AND OTHER PRODUCTS, WHICH MAY BE USED FOR PROCESSING OF INGREDIENTS OF AGRICULTURAL ORIGIN FROM ORGANIC PRODUCTION

Name	Preparation of foodstuffs of		Specific conditions and restrictions in addition to Regulation (EU) No 1333/2008
	Plant origin	Animal origin	
Water	X	X	Drinking water within the meaning of Council Directive 98/83/EC
Calcium chloride	X	X	Coagulation agent with regard to foodstuffs of animal origin: sausages based on meat
Calcium carbonate	X		
Calcium hydroxide	X		
Calcium sulphate	X		Coagulation agent
Magnesium chloride (or nigari)	X		Coagulation agent
Potassium carbonate	X		With regard to foodstuffs of plant origin: drying of grapes
Sodium carbonate	X	X	
Lactic acid		X	With regard to foodstuffs of animal origin: for the regulation of the pH of the brine bath in cheese production
L(+)-lactic acid from fermentation	X		With regard to foodstuffs of plant origin: for the preparation of plant protein extracts
Citric acid	X	X	
Sodium hydroxide	X		With regard to foodstuffs of plant origin: for sugar(s) production; for oil production excluding olive oil production; for the preparation of plant protein extracts
Sulphuric acid	X	X	Gelatine production Sugar(s) production
Hop extract	X		With regard to foodstuffs of plant origin: only for antimicrobial purposes in production of sugar. When available from organic production
Pine rosin extract	X		With regard to foodstuffs of plant origin: only for

Name	Preparation of foodstuffs of		Specific conditions and restrictions in addition to Regulation (EU) No 1333/2008
	Plant origin	Animal origin	
			antimicrobial purposes in production of sugar. When available from organic production
Hydrochloric acid		X	With regard to foodstuffs of animal origin: Gelatine production; for the regulation of the pH of the brine bath in the processing of Gouda-, Edam and Maasdammer cheeses, Boerenkaas, Friese and Leidse Nagelkaas
Ammonium hydroxide		X	With regard to foodstuffs of animal origin: Gelatine production
Hydrogen peroxide		X	With regard to foodstuffs of animal origin: Gelatine production
Carbon dioxide	X	X	
Nitrogen	X	X	
Ethanol	X	X	Solvent
Tannic acid	X		Filtration aid
Egg white albumen	X		
Casein	X		
Gelatin	X		
Isinglass	X		
Vegetable oils	X	X	Greasing, releasing or anti-foaming agent Only when derived from organic production
Silicon dioxide gel or colloidal solution	X		
Activated carbon	X	X	
Talc	X		In compliance with the specific purity criteria for food additive E553b
Bentonite	X		
Cellulose	X	X	With regard to foodstuffs of animal origin: Gelatine production

Name	Preparation of foodstuffs of		Specific conditions and restrictions in addition to Regulation (EU) No 1333/2008
	Plant origin	Animal origin	
Diatomaceous earth	X	X	With regard to foodstuffs of animal origin: Gelatine production
Perlite	X	X	With regard to foodstuffs of animal origin: Gelatine production
Hazelnut shells	X		
Rice meal	X		
Beeswax	X		Releasing agent Beeswax from organic beekeeping
Carnauba wax	X		Releasing agent Only when derived from organic production. Applicable as of 1 January 2022. Until that date, only when derived from organic raw material
Wood fibre	X	X	The source of timber should be restricted to certified, sustainably harvested wood. Wood used must not contain toxic components (post-harvest treatment, naturally occurring toxins or toxins from micro-organisms)

TOC

SECTION C — PROCESSING AIDS FOR THE PRODUCTION OF YEAST AND YEAST PRODUCTS

Name	Primary yeast	Yeast confections/ formulations	Specific conditions
Calcium chloride	X		
Carbon dioxide	X	X	
Citric acid	X		For the regulation of the pH in yeast production
Lactic acid	X		For the regulation of the pH in yeast production
Nitrogen	X	X	
Oxygen	X	X	
Potato starch	X	X	For filtering Only when derived from organic production
Sodium carbonate	X	X	For the regulation of the pH
Vegetable oils	X	X	Greasing, releasing or anti-foaming agent Only when derived from organic production

ANNEX IV. Ingredients of agricultural origin which have not been produced organically referred to in Article 28 of Regulation (EC) 889/2008

1. UNPROCESSED VEGETABLE PRODUCTS AS WELL AS PRODUCTS DERIVED THEREFROM BY PROCESSES

1.1. Edible fruits, nuts and seeds:

- acorns *Quercus* spp.
- cola nuts *Cola acuminata*
- gooseberries *Ribes uva-crispa*
- maracujas (passion fruit) *Passiflora edulis*
- raspberries (dried) *Rubus idaeus*
- red currants (dried) *Ribes rubrum*

1.2. Edible spices and herbs:

- pepper (Peruvian) *Schinus molle* L.
- horseradish seeds *Armoracia rusticana*
- lesser galangal *Alpinia officinarum*
- safflower flowers *Carthamus tinctorius*
- watercress herb *Nasturtium officinale*

1.3. Miscellaneous:

Algae, including seaweed, permitted in non-organic foodstuffs preparation

2. VEGETABLE PRODUCTS

2.1. Fats and oils whether or not refined, but not chemically modified, derived from plants other than:

- cocoa *Theobroma cacao*
- coconut *Cocos nucifera*
- olive *Olea europaea*
- sunflower *Helianthus annuus*
- palm *Elaeis guineensis*
- rape *Brassica napus, rapa*
- safflower *Carthamus tinctorius*
- sesame *Sesamum indicum*
- soya *Glycine max*

2.2. The following sugars, starches and other products from cereals and tubers:

- fructose
- rice paper
- unleavened bread paper
- starch from rice and waxy maize, not chemically modified

2.3. Miscellaneous:

- pea protein *Pisum* spp.
- rum, only obtained from cane sugar juice
- kirsch prepared on the basis of fruits and flavorings as referred to Article 27(1)(c) of Regulation (EC) No 889/2008

ANNEX V. Products and substances used in farming and criteria for their authorization

- 1 For authorization of products and substances for use in organic production, the certification body refers to the Regulation (EC) 889/2008 and its relevant annexes. However, products and substances may only be authorized, if their use is permitted under national law.

- 2 a) By way of derogation from paragraph 1 the certification body may authorize for use in organic production and include in a restricted list the products and substances, which may be used in organic farming for the following purposes:
 - as plant protection products;
 - as fertilizers and soil conditioners;The authorization of such products for use in organic production and their inclusion in Annex IIa shall be subject to the criteria laid down in paragraph 3. Special consideration is given to products which are traditionally used in region concerned.
- b) Until the Commission has established a list of authorized products, the certification body may, by way of derogation from paragraph 1, authorize for use in organic production products and substances for cleaning and disinfection, provided they are classified for use in the food industry.

- 3 The authorization of the products and substances referred to in paragraph 1 is subject to the objectives and principles of organic farming and the following general and specific criteria which shall be evaluated as a whole:
 - a) Their use is necessary for sustained production and essential for its intended use.
 - b) All products and substances shall be of plant, animal, microbial or mineral origin except where products or substances from such sources are not available in sufficient quantities or qualities or if alternatives are not available.
 - c) For plant protection products, the following shall apply:
 - (i) Their use is essential for the control of a harmful organism or a particular disease for which other biological, physical or breeding alternatives or cultivation practices or other effective management practices are not available.
 - (ii) if products are not of plant, animal, microbial or mineral origin and are not identical to their natural form, they may be authorized only if their conditions for use preclude any direct contact with the edible parts of the crop;
 - d) For fertilizers and soil conditioners, the following shall apply: Their use is essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or specific soil-conditioning purposes;

- 4 The use of products and substances not covered under paragraph 1 shall only be authorized for use in organic farming if they are in line with the objectives and principles of organic farming and the general criteria in paragraph 3.

ANNEX VI. Logo and code number

A. Organic logo of the EU

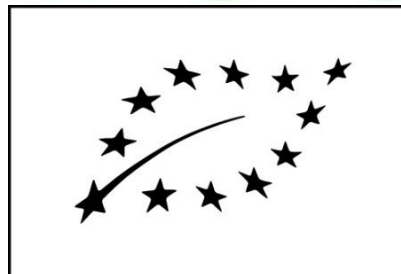
1. The Organic Logo of the EU shall comply with the model below:



2. The reference color in Pantone is Green Pantone No 376 and Green (50% Cyan + 100% Yellow), when a four- color process is used.
3. The Organic Logo of the EU can also be used in black and white as shown, only where it is not practicable to apply it in color:



4. If the background color of the packaging or label is dark, the symbols may be used in negative format, using the background color of the packaging or label.
5. If a symbol is used in color on a colored background, which makes it difficult to see, a delimiting outer line around the symbol can be used to improve contrast with the background colors.



6. In certain specific situations where there are indications in a single color on the packaging, the Organic Logo of the EU may be used in the same color.
7. The Organic Logo of the EU must have a height of at least 9 mm and a width of at least 13.5 mm; the proportion ratio height/width shall always be 1:1.5. Exceptionally the minimum size

may be reduced to a height of 6 mm for very small packages.

8. The Organic Logo of the EU may be associated with graphical or textual elements referring to organic farming, under the condition that they do not modify or change the nature of the Organic Logo of the EU, nor any of the indications mentioned at Article 58(1) of Regulation (EC) 889/2008. When associated to national or private logos using a green color different from the reference color mentioned in paragraph 2 of this section, the Organic Logo of the EU may be used in that non-reference color.
9. The use of the Organic Logo of the EU shall be in accordance with the rules accompanying its registration as Organic Farming Collective Mark in the Benelux Office for Intellectual Property and in the Community and International Trademark Registers.

B. Code numbers referred to in Article 58 of Regulation (EC) 889/2008.

The general format of the code numbers is as follows:

AB-CDE-999

Where:

1. “AB” is the ISO code as specified in Article 58(1)(a) for the country where the controls take place; and
2. “CDE” is a term, indicated in three letters to be decided by the Commission or each Member State, like “bio” or “öko” or “org” or “eko” establishing a link with the organic production method as specified in Article 58(1)(b); and
3. “999” is the reference number, indicated in maximum three digits, to be decided by the Commission or by the competent authority of the member states.

ANNEX VII. Model of documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007 referred to in Article 68 of Regulation (EC) No 889/2008

Documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007	
1. Document Number:	
2. Name and address of operator: Main activity (producer, processor, importer, etc.):	3. Name, address and code number of control body/authority
4. Product groups/Activity: <ul style="list-style-type: none"> ■ Plant and plant products: ■ Seaweed and seaweed products: ■ Livestock and livestock products: ■ Aquaculture animals and aquaculture animal products: ■ Processed products: 	5. Defined as: Organic production, in-conversion products; and also non-organic production where parallel production/processing pursuant to Article 11 of Regulation (EC) No 834/2007 occurs
6. Validity period: <ul style="list-style-type: none"> ■ Plant products from...to... ■ Seaweed products from...to ... ■ Livestock products from...to ■ Aquaculture animal products from...to... ■ Processed products from...to... 	7. Date of control(s):
8. This document has been issued on the basis of Article 29(1) of Regulation (EC) No 834/2007 and Regulation (EC) No 889/2008. The declared operator has submitted his activities under control, and meets the requirements laid down in the named Regulations.	
Date, place:	
Signature on behalf of the issuing control body/authority:	

ANNEX VII a. Model of complementary documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007 referred to in Article 68(2) of the Standard

Complementary documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007

- 1 1.1 Number of the document
1.2 Reference to the documentary evidence in accordance with the Article 29(1) of Regulation (EC) No 834/2007⁽¹⁾
2. Specific characteristics of the production method used by the operator, referred to in Article 68(2) of Regulation (EC) No 889/2008⁽²⁾

3. This document has been issued on the basis of Article 29(1) of Regulation (EC) No 834/2007 and Article 68(2) of Regulation (EC) No 889/2008. The declared operator has submitted his activities under control, and meet the requirements laid down in those Regulation.

Date, place:

Signature and stamp on behalf of the issuing control body/authority :

- (1) Insert number of documentary evidence provided in accordance with Article 68(1) of, and Annex VII to the Standard.
- (2) Insert the relevant entry set out in Annex XIIIb of this (EC) No 889/2008.

ANNEX VIII. Model of a vendor declaration referred to in Article 69 of Regulation (EC) 889/2008

Vendor declaration according to Article 9(3) of Regulation (EC) No 834/2007	
Name, address of vendor:	
Identification (e.g. lot or stock number):	Product name:
Components: (Specify all components existing in the product/used the last in the production process)	
<p> I declare that this product was manufactured neither 'from' nor 'by' GMOs as those terms are used in Articles 2 and 9 of Council Regulation (EC) No 834/2007. I do not have any information which could suggest that this statement is inaccurate. Thus, I declare that the above named product complies with Article 9 of Regulation (EC) No 834/2007 regarding the prohibition on the use of GMOs. I undertake to inform our customer and its control body/authority immediately if this declaration is withdrawn or modified, or if any information comes to light which would undermine its accuracy. I authorize the control body, which supervises our customer to examine the accuracy of this declaration and if necessary, to take samples for analytic proof. I also accept that this task may be carried out by an independent institution which has been appointed in writing by the control body. The undersigned takes responsibility for the accuracy of this declaration. </p>	
Country, place, date, signature of vendor:	Company stamp of vendor (if appropriate):

ANNEX IX. Definitions

For the purposes of the Standard, the following definitions shall apply:

- (a) “**organic production**” means the use of the production method compliant with the rules established in the Standard, at all stages of production, preparation and distribution;
- (b) “**stages of production, preparation and distribution**” means any stage from and including the primary production of an organic product up to and including its storage, processing, transport, sale or supply to the final consumer, and where relevant labelling, advertising, import, export and subcontracting activities;
- (c) “**organic**” means coming from or related to organic production;
- (d) “**operator**” means the natural or legal persons responsible for ensuring that the requirements of the Standard are met within the organic business under their control;
- (e) “**plant production**” means production of agricultural crop products including harvesting of wild plant products for commercial purposes;
- (f) the definition of “**aquaculture**” is that given in Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund;
- (g) “**conversion**” means the transition from non organic to organic farming within a given period of time, during which the provisions concerning the organic production have been applied;
- (h) “**preparation**” means the operations of preserving and/or processing of organic products, and also packaging, labelling and/or alterations made to the labelling concerning the organic production method;
- (i) the definitions of “**food**”, “**feed**” and “**placing on the market**” are those given 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;
- (j) “**labelling**” means any terms, words, particulars, trade marks, brand name, pictorial matter or symbol relating to and placed on any packaging, document, notice, label, board, ring or collar accompanying or referring to a product;
- (k) the definition of “**pre-packaged foodstuff**” is that given in Article 1 (3)(b) 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;
- (l) “**advertising**” means any representation to the public, by any means other than a label, that

is intended or is likely to influence and shape attitude, beliefs and behaviors in order to promote directly or indirectly the sale of organic products;

- (m) "**competent authority**" means the central authority of a Member State competent for the organization of official controls in the field of organic production in accordance with the provisions set out under the Standard, or any other authority on which that competence has been conferred to; it shall also include, where appropriate, the corresponding authority of a third country;
- (n) "**control authority**" means a public administrative organization of a Member State to which the competent authority has conferred, in whole or in part, its competence for the inspection and certification in the field of organic production in accordance with the provisions set out under the Standard; it shall also include, where appropriate, the corresponding authority of a third country or the corresponding authority operating in a third country;
- (o) "**control body**" means an independent private third party carrying out inspection and certification in the field of organic production in accordance with the provisions set out under the Standard; it shall also include, where appropriate, the corresponding body of a third country or the corresponding body operating in a third country;
- (p) "**mark of conformity**" means the assertion of conformity to a particular set of standards or other normative documents in the form of a mark;
- (q) the definition of "**ingredients**" is that given in Article 6 (4) of Directive 2000/13/EC;
- (r) the definition of "**plant protection products**" is that given in Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market;
- (s) the definition of "**Genetically modified organism (GMO)**" is that given in Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and which is not obtained through the techniques of genetic modifications listed in Annex I.B of that Directive;
- (t) "**produced from GMOs**" means derived in whole or in part from GMOs but not containing or consisting of GMOs;
- (u) "**produced by GMOs**" means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs;
- (v) "**equivalent**", in describing different systems or measures, means that they are capable of meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity;
- (w) "**processing aid**" means any substance not consumed as a food ingredient by itself,

intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product;

- (x) the definition of "**ionizing radiation**" is that given in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation and as restricted by Article 1 (2) of Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionizing radiation.
- (y) "**mass catering operations**" means the preparation of organic products in restaurants, hospitals, canteens and other similar food business at the point of sale or delivery to the final consumer.
- (z) 'importer' means a natural or legal person established in the Union and subject to the control system referred to in Regulation (EU) 2018/848, who presents the consignment for release for free circulation in the Union either on its own, or through a representative;
- (aa) 'border control post' means a border control post as defined in Article 3, point (38), of Regulation (EU) 2017/625;
- (bb) 'control point' means a control point other than a border control post as referred to in Article 53(1), point (a), of Regulation (EU) 2017/625;
- (cc) 'consignee' means a natural or legal person established in the Union and subject to the control system referred to in Regulation (EU) 2018/848 to whom the batch obtained from the splitting of a consignment is delivered by the importer after the release for free circulation and who receives it for further preparation and/or marketing;
- (dd) 'consignment' means a consignment, as defined in Article 3, point (37), of Regulation (EU) 2017/625, of products intended to be placed on the market within the Union as organic products or in-conversion products; however, in case of organic products and in-conversion products exempted from official controls at border control posts in accordance with Delegated Regulation (EU) 2021/2305, it means a quantity of products under one or more Combined Nomenclature codes, covered by a single certificate of inspection, conveyed by the same means of transport and imported from the same third country;
- (ee) 'documentary check' means a documentary check as defined in Article 3, point (41), of Regulation (EU) 2017/625;

- (ff) ‘first consignee’ means a natural or legal person established in the Union and subject to the control system referred to in Regulation (EU) 2018/848 to whom the consignment is delivered by the importer after the release for free circulation and who receives it for further preparation and/or marketing;
- (gg) ‘identity check’ means an identity check as defined in Article 3, point (42), of Regulation (EU) 2017/625;
- (hh) ‘operator responsible for the consignment’ means, for the purposes of Article 6(4) of Delegated Regulation (EU) 2021/2306 and Commission Delegated Regulation (EU) 2019/2123 (3), either the importer or a natural or legal person established in the Union who presents the consignment at the border control post on behalf of the importer;
- (ii) ‘physical check’ means a physical check as defined in Article 3, point (43) of Regulation (EU) 2017/625;
- (jj) ‘point of release for free circulation’ means a point of release for free circulation where official controls on organic and in-conversion products exempted from official controls at border control posts are carried out in accordance with Delegated Regulation (EU) 2021/2305;
- (kk) ‘qualified electronic seal’ means a qualified electronic seal as defined in Article 3, point (27), of Regulation (EU) No 910/2014 of the European Parliament and of the Council

TOC

PART C. Appendices 附錄



TOC

Appendix I. TOC Fee Schedule in Taiwan Dollars 本公司費用表(新台幣)

CERTIFICATION FEES 驗證費用表

PAYMENT 費用項目	FEES 費用 (NEW TAIWAN DOLLARS) (新台幣元)		DESCRIPTION 說明
NEW APPLICATION FEES 新申請費用			
Application Fees 申請費	NTD.30,000 / activity 30,000 元/件(生產線)		Document review, evaluation and report 文件審查、評估、報告
Inspection Fees 稽核費	NTD. 10,000/ person day/ site (transport days included) 10,000 元/人天/場次 (含移動日)		Review, evaluation, report 審查、評估、報告
Travel Fees 旅費	Taiwan 台灣	North of Taichung: NTD. 1,500/person day South of Taichung and Hualien/ Taitung: NTD. 3,000/person day & Actual Cost 台中以北 1,500 元/人天 台中以南及花東 3,000 元/人天 若超出以實際費用為準	Includes transportation, lodging, meals for overnight trips or other expenses necessary to perform your inspection 含交通、住宿、膳食等執 行現場稽核所需費用
	Area outside Taiwan 海外 地區	<ul style="list-style-type: none"> • Inland transportation fee NTD. 2,000 • Air tickets to be charged to the applicant • Fees of local transportation and accommodation to be charged to the applicant * <u>The accommodation period</u> start date: the prior day of the inspection end date: the posterior day of the inspection <ul style="list-style-type: none"> • 國內來回交通費 NTD. 2,000 • 機票由申請者負擔 • 當地交通、住宿(*)、膳食由申請者負擔 * <u>住宿期間</u> 起始日：查驗開始之前日 結束日：查驗結束之隔日	
Administrative Fees 管理費	NTD. 30,000 / activity 30,000 元/件(生產線)		Document review, evaluation, report, recordkeeping, unfixed intervals of surveillance. 文件審查、評估、報告、紀 錄保存、不定期追蹤查驗
REGULAR SURVEILLANCE FEES 定期追蹤查驗費用			
Document Review Fees 文件審查費	NTD. 10,000 / activity 10,000 元/件(生產線)		Check of application materials and related administrative matters 點檢驗證申請資料及相關 行政事項

PAYMENT 費用項目	FEES 費用 (NEW TAIWAN DOLLARS) (新台幣元)	DESCRIPTION 說明
Inspection Fees 稽核費	NTD. 10,000/ person/ day/ site 10,000 元/人天/場次	Review, evaluation, report 審查、評估、報告
Travel Fees 旅費	North of Taichung: NTD. 1,500/person day South of Taichung and Hualien/ Taitung: NTD. 3,000/person day & Actual Cost 台中以北 1,500 元/人天；台中以南及花東 3,000 元/人天 若超出以實際費用為準	Includes transportation, lodging, meals for overnight trips or other expenses necessary to perform your inspection 含交通、住宿、膳食等執行現場稽核所需費用
Administrative Fees 管理費	NTD. 30,000/ activity 30,000 元/件(生產線)	Document review, evaluation, report and recordkeeping 文件審查、評估、報告及紀錄保存
ADDING FIELDS/LINES/ITEMS FEES 增列費用		
Document Review Fees 文件審查費	NTD.20,000/ activity 20,000 元/件(生產線)	For new field or processing line 適用於增加田區或生產線
New Item Fees 增加品項費	NTD. 1,000/ item 1,000 元/項	For new items within one processing line and a maximum of five 適用於同一生產線增加品項 每次最多增五項

SEAL FEE SCHEDULE 標章費用表

Organic product sales amount / year (NTD) 有機產品銷售金額/年(新台幣)	Seal fee/year (NTD) 標章費/年(新台幣)
Below 5 millions (500 萬以下)	20 thousands (2 萬)
5 millions~10 millions (500~1,000 萬)	30 thousands (3 萬)
10 millions~30 millions (1,000~3,000 萬)	60 thousands (6 萬)
30 millions~50 millions (3,000~5,000 萬)	80 thousands (8 萬)
50 millions~80 millions (5,000~8,000 萬)	100 thousands (10 萬)
Above 80 millions (8,000 以上)	120 thousands (12 萬)

Transaction Certificate 交易證明: NTD. 1,000/copy 每份 1,000 元

Comment:

An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. After receiving the application and before assigning the inspector, the application fee is not refundable. After on-site inspection, the application, inspection and travel fee are not refundable. No refunds after review committee.

註：申請人欲撤回申請時，必須繳付自提出申請至撤回期間所需之服務費用；收件至派查前之階段不退申請費，實地查驗後不退申請費、稽核費及旅費，案件進入審定後，全數不退費。

Appendix II. Sampling Procedures for Residue Testing 殘留檢測採樣程序

1. Purpose 目的

This document outlines the sampling procedures recommended by the Tse-Xin Organic Company (TOC) for parties conducting residue testing of organically produced agricultural products under the requirements at § 205.670 of the NOP and EU relevant regulations. 為使有機農產品殘留檢測得以符合NOP§ 205.670及歐盟相關之規定，本公司特訂定本採樣程序導引。

2. Scope 適用範圍

This instruction applies to those samples which were collected by TOC representatives and entrust a subcontractor for conducting residue testing of organic agricultural products. 本指引適用於慈心派員採樣及委辦機構進行有機農產品殘留檢測。

3. Background & Policy 背景與法規依據

3.1 The regulations specifies the conditions under which responsible parties should conduct testing of agricultural products that will be sold, labeled, or represented as “100 percent organic,” “organic,” “organic in conversion” or “made with organic (specified ingredients or food group(s)).” To meet this regulatory requirement, TOC develops this instruction for sampling procedures. 以「100%有機」、「有機」、「有機轉型期」、或「使用有機(特定成分或食物群)」之名銷售、標示或展示的農產品，相關單位必須實施檢測。為符合本規定，本公司建立此採樣作業程序。

3.2 TOC will collect samples of organically produced agricultural products for testing to detect the presence of residues in violation of the NOP or EU regulations as specified under § 205.105 or other applicable laws as provided for at § 205.670(e) or EU relevant regulation. 本公司依據美國有機農業計畫或歐盟法規規定提供其它可適用的規定，負責收集有機農產樣品，以供檢測產品中違法使用物品的殘留。

3.3 Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. 保管流程中必須維持樣品的完整性，殘量檢測必須經由已認證的實驗室擔任。

3.4 Chemical analysis must be made in accordance with the methods described in the most current edition of the Official Methods of Analysis of the AOAC International or other current applicable validated methodology determining the presence of contaminants in agricultural products. 化學分析方法必須依據最新版的國際AOAC之法定分析方法，或其他現行適用經驗證的方法，以檢定農產品污染物。

3.5 To ensure consistency in the sampling approach used by parties conducting residue testing, TOC provide the following instructions for the collection, sample amounts, proper documentation, and chain of custody for samples collected as part of meeting the residue testing requirements under § 205.670 of the NOP or EU regulations. Furthermore, under § 205.504(b)(6), certifiers must have procedures for sampling and residue testing to ensure that

proper sampling is routinely followed. 為確保執行殘量檢測單位採樣方法的一致性，本公司依據美國有機農業計畫NOP§ 205. 670(e)或歐盟規定提供下列作業程序以供樣品的收集、數量規定、文件建立及保管流程符合殘量檢測的規範。

4 Procedure 程序

4.1 When to Collect Samples 採樣時機

Samples should be collected under the following conditions: 下列情況時需進行採樣：

- (1) When it is suspected that a prohibited substance has been applied. 有禁用物質被使用之疑慮時。
- (2) When it is suspected that contamination from genetically modified organisms, antibiotics, or prohibited substances may have occurred. 有被 GMO、抗生素或其他違禁品污染之疑慮時。
- (3) When pesticide drift may have occurred. 當有農藥漂移發生時。
- (4) To gather evidence as part of an investigation. 搜取證據以供調查時。
- (5) As part of a surveillance sampling program. 作為追蹤查驗取樣用。

4.2 Sample Selection 取樣

Sample collectors should collect a sample of a given organic agricultural product, selected from a single location in a field, bin, or pallet. A single sample analyzed for residues using sensitive test procedures should provide enough information to determine if residues are present. A sample of a crop could consist of the raw agricultural commodity (RAC) or processed commodity from the RAC (Table 1). Samples may also include the collection and testing of soil, water, waste, seeds, or plant tissue, if appropriate. Sample collectors may choose to select samples which attempt to detect contamination where it is most likely to occur due to risk factors present at a given operation or a location within an operation. A link to recommended methods of sampling for the determination of pesticide residues by The Codex Alimentarius Commission (Codex) is provided in the references section as additional guidance on sample collection. 取樣者須從田地、貯藏所或栽培床中選擇單一點處，收集指定的有機農產品樣品。如果使用較敏銳的檢驗程序分析單一樣品的殘留時，必須提供足夠的資訊以確定殘留是否存在。作物樣品可以是生鮮農產品(RAC)或其加工產品(表一)。適用時樣品得包括取樣檢測土壤、水、廢棄物、種子或植物組織。有些地區由於特定作業或位於作業範圍內之風險因素，易於產生污染。取樣者可選擇該等地區進行取樣，以便偵測到污染。此外，可參考所附文獻中有關所推薦Codex農藥殘量檢測的採樣方法。

4.3 Sample Amounts 取樣數量

Sample collectors should obtain sufficient sample to ensure the laboratories will have adequate amounts for processing and reanalysis if necessary (Table 1). The amounts shown are consistent with those instituted as part of the standard operating procedures (SOPs) for the USDA Agricultural Marketing Service (AMS) Pesticide Data Program. If collecting from multiple containers is needed to obtain the suggested amounts, sample collectors should confirm the products being sampled

are from the same lot.

取樣者必須取得足量的樣品，以確保實驗室有適度的量進行檢驗並在必要時重複分析(表一)。所提供採樣數量，係與美國農部農業產銷服務處之農藥資料計畫所訂定標準作業程序(SOP)之規定一致。如果樣品必須從多個容器收集，才能達到足量，則取樣者須對樣品是否來自同一批次加以確認。

Table 1: Suggested Sample Amounts by Commodity Type 依產品類型建議樣品數量

Commodity Type 產品類型	Recommended Sample Amount 建議樣品數量
Most fresh fruit and vegetables 大多數生鮮蔬果	1.5-2.5 kg (A single large melon or squash exceeding 2.5 kg is acceptable) 1.5-2.5公斤 (可接受單一冬甜瓜或南瓜達2.5公斤以上)
Blended commodities or those smaller than a strawberry: Berries, Cherries, Coffee beans, Dried Commodities, Flours, Grains, Herbs, Garlic, Legumes, Mushrooms (small), Nuts, Teas, Seeds, Small jars/packages (i.e. baby food sized), Spices 混合性或比草莓小之產品： 莓果、櫻桃、咖啡豆、乾物產品、麵粉、穀物類、草本類、蒜、豆類、小型菇類、核果類、茶、種子、小罐包裝(如：嬰兒食物)、香料	500 g 500克
All liquids and semisolid foods (e.g. juices, oils) Canned/jarred foods 液狀與半固狀食物(如：果汁、油類) 罐裝/瓶裝食物	500 mL to 1000 mL 500~1000 毫升

Table 1 Adapted from USDA AMS Pesticide Data Program SOPs and U.S. EPA Residue Chemistry Guidance

表一 參考USDA農藥資料計畫之標準作業程序及環保署殘量化學規範。

For raw commodities, the portion which should be sampled is generally the whole commodity. Adhering soil, decomposed outer leaves, and inedible root and tuber vegetable tops should be excluded from the sample. In addition to the U.S. EPA Residue Chemistry Guidance, Codex has guidance on which portion of the commodity should be sampled and provides recommended sample preparation methods for the determination of residues.

對生鮮產品，取樣的部分通常須為整個產品。樣品不應包括附著的土、腐壞的外葉及根莖作物無法食用的地上部分。除美國環境保護署之殘量化學規範外，Codex亦有關於殘留測定之產品採樣部位及樣品準備方法等規範。

4.4 Sample Documentation 樣品文件

Each sample should be identified by the following information: 每一樣品必需註明：

- (1) Certified operation name and mailing address. 經驗證作業者之名稱與通訊地址。
- (2) Identification of sampling site (may include site maps or field). 採樣地點之識別(可包括現場地圖或田區識別)。
- (3) Grower and handler information (both grower and handler should be included if the sample is not collected at the farm). 生產者與作業者之資料(如果樣品不是直接從生產地採樣，則二者均需包括)。
- (4) Sample identification, including commodity information, variety, brand name and lot number (if applicable), or other identification. 樣品識別：包括產品資訊、品種、品牌、批號(如果有)或其它證明資料。
- (5) Certifier name. 驗證者姓名及其簽字。
- (6) Collector's name & signature. 採樣者姓名及其簽字。
- (7) Date collected and date shipped. 採樣及運送日期。

Note: The certified operation must also receive documentation (i.e. a receipt) when a sample is obtained for analysis. 註：當取得樣品進行檢測時經驗證作業者必須同時收到相關文件(例. 收據)。

Upon arrival at the laboratory, the following information should be recorded by the laboratory and included with the sample results: 樣品抵達實驗室時，下列資料就必須由實驗室紀錄並列入樣品的檢測結果報告中：

- (1) Date received. 收到樣品的日期。
- (2) Name or initials of person receiving the sample. 簽收樣品人姓名。
- (3) Explanation for what happened to a sample that is not analyzed (e.g., chain of custody breached, rotten sample, sample miscoded). 樣品不能分析的說明(例如：違反保管流程、樣品腐壞，樣品誤標)。
- (4) Internal Sample ID: The laboratory should generate an internal Sample ID. 內部樣品識別：實驗室本身必須要有內部的樣品 ID 用以識別。

Table 2 below shows an example of a sample information collection worksheet that could be used or adopted for the purposes of proper sample documentation.

表二(如下)的樣品資料收集工作表範本，可引用為適當的採樣參考文件。

4.5 Maintaining Chain of Custody and Sample Integrity 保管流程之維護及樣品完整性

(1) Maintaining chain of custody 保管流程的維護

The chain of custody ensures the chronological possession of samples from the sample collector to the shipping carrier to the laboratory. 保管流程應確保樣品能按所屬時間順序從採樣者、運送者送至實驗室。

(2) Sample integrity 樣品完整性

- a) Each sample shall be packed by the sample collector using precautions to prevent sample contamination from commingling or contact with prohibited substances. Samples of fresh commodities must be taken using gloved hands (latex or clean rubber gloves) and removed from the plant or storage bins using a clean utensil. Sample collectors should avoid including excess dirt and foliage (as appropriate) from field samples. Samples should be placed into a clean plastic bag (or other receptacle required by a given laboratory) and sealed with tape to provide a tamper-proof seal. 每一樣品需由採樣者包裝，並採預防措施以免與禁用物質混雜或接觸而造成污染。生鮮產品之採樣應使用乳膠或乾淨橡膠手套，而且使用乾淨的器具將之從植物體或儲藏所取出。採樣者必須避免將多餘的灰塵及樹葉帶入樣品中。樣品必須置於一乾淨塑膠袋(或由實驗室指定之其它容器)，並以膠帶密封。
- b) Label 標示
Samples should be initialed and dated by the sample collector who has bagged the sample. A shipping label with time and date will be acceptable as evidence of transfer to the carrier and delivery to the laboratory. Sample collectors should ensure that the shipping container is properly sealed, labeled for perishable goods, and ship the container by the appropriate means of transportation. 採樣者包裝樣品時必須在樣品上註記其姓名縮寫與日期。具有時間與日期的運送標示可作為交付運送與交貨至實驗室的證據。採樣者必須確保易腐物的容器有適當的密封與標示，並以妥善方式運送。
- c) Shipping 運送
Sample collectors should avoid shipping samples that will arrive during a weekend or holiday when laboratories are not open to receive and process the samples for analysis. It is important to note that many samples will require refrigerated temperatures for shipping and should be placed in a pre-cooled, insulated shipping container with an adequate number of frozen cold packs. If samples are transported away from the collection site to be packed at a later time, then the samples must be maintained in a cooled container until they are packed for shipment. Sufficient packing materials (e.g. bubble wrap) should be used to prevent movement of the item during transit. Fresh and frozen samples should be shipped overnight. Processed foods that are normally stored at room temperature (e.g. canned vegetables, peanut butter, oils) can be shipped at ambient temperature by ground. There may be cases in which the shipping container will not change hands. In these instances, it is not necessary for the packing box to be sealed, but sample collectors must ensure that the product is placed in a pre-cooled insulated shipping container along with a sufficient number of frozen cold packs to ensure refrigerated temperatures during the time they are transporting the sample to the laboratory. 採樣者須避免使樣品在週末或假日送達實驗室，而致無人簽收及進行分析。多數樣品在運送時需低溫保存，應置放於經事先低溫處理，有足夠數目冷凍袋之絕緣保冰容器。如果樣品在運送離開採樣地點時並未馬上包裝，則該樣品在包裝運送前需保存在冷藏的容器中。為防止樣

品在運送時的移動，須以足夠的填充物包裝。生鮮與冷凍樣品必須連夜運送。通常貯存於室溫的加工食物(如：罐裝蔬菜)可以不需冷藏交由陸運。如果樣品將由採樣者直接送交實驗室，則樣品的包裝可以不必密封。但是採樣者應將之置放於經事先低溫處理，有足夠數目冷凍袋之絕緣保冰容器。確保其在運送至實驗室的過程處於冷藏的環境。

5. References 文獻參考

■ NOP Regulations (as amended to date) 美國國家有機計畫規範 (最新修訂版)

7 CFR § 205.105	Allowed and prohibited substances, methods, and ingredients in organic production and handling 有機生產中允用與禁用之物質、方法與成分
7 CFR § 205.504 (b)(6)	A copy of the procedures to be used for sampling and residue testing pursuant to § 205.670. 提供依據205.670取樣與殘量檢測程序的影本
7 CFR §§205.600~ 205.606	The National List of Allowed and Prohibited Substances. 國家允許和禁止物質清單
7 CFR § 205.670	Inspection and testing of agricultural product to be sold or labeled “organic.” 待售或貼“有機”標籤的農產品之檢驗測試

■ Other Laws and Regulations 其它法令規章

Recommended methods of sampling for the determination of pesticide residues by The Codex Alimentarius Commission. Web.25 Jan.2011

www.codexalimentarius.net/download/standards/361/CXG_033e.pdf

Codex Alimentarius Commission guidance on which portion of the commodity to be sampled and recommended methods of sample preparation for the determination of residues.Web.25 Jan.2011

www.codexalimentarius.net/download/standards/43/CXG_041e.pdf

United States. Department of Agriculture. Agricultural Marketing Service. AMS Pesticide Data program Standard Operating Procedures: SOP No: PDP SAMP PROC-02. Revision 7.

Washington, DC: United States Department of Agriculture, 2009. Print.

United States. Environmental Protection Agency. OCSPH Harmonized Test Guidelines Series 860 - Residue Chemistry Test Guidelines. United States Environmental Protection Agency, Aug. 1996. Web. 21 Dec. 2010.

http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series860.htm

Table 2 Sample Information Worksheet 表二 樣品資訊工作表

■ Sample ID Number 樣品編號

Certifying agent 驗證機關	Country 國別	Year 年	Month 月	Day 日	Commodity 商品名	Lab Code 實驗室代號

■ Commodity Information 商品資訊

Origin 來源: Domestic 國產/ Imported 進口/ Unknown 不明

If imported, country of origin: 若為進口, 進口國別:

Commodity: 商品

Claim 宣稱: 100% Organic/ Organic/ Made with Organic/ Other

■ Collection site Information 採樣地點資訊

Operation name and location 作業名稱及位址

Facility type 設施類別: Producer 生產者/ Distribution Center 配銷中心/ Warehouse 倉庫/

Packing Shed Field 包裝棚區/ Other 其他

Grower Name 種植者名稱:

Packing Company 包裝廠商:

Distributor/ Other 配銷商/其他:

Lot number or any other identification number on packaging 批號或包裝編號:

■ Shipping Information 運輸資訊

Date received 收件日期:

Received by (initials) 簽收人(縮寫)

Based on condition upon arrival, will sample be analyzed? (Y/N)

基於樣品抵達情況, 樣品是否要分析? (是/否)

If not analyzed, why? Rotten/Misidentified/other (describe)

如未分析, 為何? 腐壞/誤標/其他 (請說明)