

(EU) 2018/848 Certification Procedure



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第一部分、(EU)2018/848 驗證標準



Based on

Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

- Commission Implementing Regulation (EU) 2020/464 of 26 March 2020 laying down certain rules for the application of Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the documents needed for the retroactive recognition of periods for the purpose of conversion, the production of organic products and information to be provided by Member States
- Commission Delegated Regulation (EU) 2020/1794 of 16 September 2020 amending Part I of Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the use of in-conversion and non-organic plant reproductive material
- Commission Delegated Regulation (EU) 2020/2146 of 24 September 2020 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards exceptional production rules in organic production
- Commission Delegated Regulation (EU) 2021/642 of 30 October 2020 amending Annex III to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards certain information to be provided on the labelling of organic products
- Commission Delegated Regulation (EU) 2021/715 of 20 January 2021 amending Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the requirements for groups of operators
- Commission Delegated Regulation (EU) 2021/771 of 21 January 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council by laying down specific criteria and conditions for the checks of documentary accounts in the framework of official controls in organic production and the official controls of groups of operators
- Commission Delegated Regulation (EU) 2021/716 of 9 February 2021 amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards organic production rules on sprouted seeds and chicory heads, on feed for certain aquaculture animals and on aquaculture parasite treatments
- Commission Implementing Regulation (EU) 2021/279 of 22 February 2021 laying down detailed rules for the implementation of Regulation (EU) 2018/848 of the European Parliament and of the Council on controls and other measures ensuring traceability and compliance in organic production and the labelling of organic products
- Commission Delegated Regulation (EU) 2021/1006 of 12 April 2021 amending Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the model of the certificate attesting compliance with the rules on organic production
- Commission Delegated Regulation (EU) 2021/1342 of 27 May 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the information to be sent by third countries and by control authorities and control bodies for the purpose of supervision of their recognition under Article 33(2) and (3) of Council Regulation (EC) No 834/2007 for imported organic products and the measures to be taken in the exercise of that supervision
- Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists
- Commission Implementing Regulation (EU) 2021/1378 of 19 August 2021 laying down certain rules concerning the certificate issued to operators, groups of operators and exporters in third countries involved in the imports of organic and in-conversion products into the Union and establishing the list of recognised control authorities and control bodies in accordance with Regulation (EU) 2018/848 of the European Parliament and of the Council
- Commission Delegated Regulation (EU) 2021/1691 of 12 July 2021 amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the requirements for record-keeping for operators in organic production
- Commission Delegated Regulation (EU) 2021/1697 of 13 July 2021 amending Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the criteria for the recognition of control authorities and control bodies that are competent to carry out controls on organic products in third countries, and for the withdrawal of their recognition
- Commission Delegated Regulation (EU) 2021/1698 of 13 July 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with procedural requirements for the recognition of control authorities and control bodies that are competent to carry out controls on operators and groups of operators certified organic and on organic products in third countries and with rules on their supervision and the controls and other actions to be performed by those control authorities and control bodies

Chapter I. SUBJECT MATTER, SCOPE AND DEFINITIONS 主旨、範圍及定義

Article 1 Subject matter 主旨

Regulation (EU) 2018/848 establishes the principles of organic production and lays down the rules concerning organic production, related certification and the use of indications referring to organic production in labelling and advertising, as well as rules on controls additional to those laid down in Regulation (EU) 2017/625. 為建立有機生產之原則，制定有機生產、驗證及使用標示及廣告所指有機生產標示之相關規則，以及制定不在(EU) 2017/625 號規章內之管制規則，特訂定(EU) 2018/848 號規章。

Article 2 Scope 範圍

1. Regulation (EU) 2018/848 applies to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union:

(EU) 2018/848 號規章適用於《歐洲聯盟運作條約(TFEU)》附件 1 所列以下源自農業之產品，包括水產和養蜂業，以及源自上述產品之產品，若正在或擬生產、調製、貼標示、流通(配銷)、投放市場、進口到歐盟或從歐盟出口之該等產品：

- (a) unprocessed agricultural products, including seeds and other plant reproductive material; 活體或未加工農產品，包括種子和其他植物繁殖材料；
- (b) processed agricultural products for use as food; 用作食品之加工農產品；
- (c) feed. *conserved*

This Regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

本法亦適用於本法附件 1 中所列與農業密切相關之某些其他產品，但以正在或擬生產、調製、貼標示、流通(配銷)、投放市場、進口到歐盟或從歐盟出口之該等產品為限。

2. This Regulation applies to any operator involved, at any stage of production, preparation and distribution, in activities relating to the products referred to in paragraph 1.
本法適用於參與生產、調製及流通(配銷)任何階段之任何農產品經營者，惟參與各階段之活動係以與第 1 項所指產品相關者。
3. Mass catering operations carried out by a mass caterer as defined in point (d) of Article 2(2) of Regulation (EU) No 1169/2011 are not subject to Regulation (EU) 2018/848 except as set out in this paragraph.
由(EU) 1169/2011 號規章第 2(2) (d)條所定義之大眾餐飲農產品經營者，進行之大眾餐飲業務不受(EU) 2018/848 號規章約束，但本項另有規定者，不在此限。

The organic production logo of the European Union shall not be used in the labelling, the presentation or the advertising of such products, and shall not be used to advertise the mass caterer. 該等產品之標示、展示或廣告，不得使用歐盟有機生產標章，大眾餐飲業投放廣告亦不得使用歐盟有機生產標章。

4. Except where otherwise provided, this Regulation applies without prejudice to related Union legislation, in particular, legislation in the fields of safety of the food chain, animal health and welfare, plant health and plant reproductive material.
除另有規定外，本法在適用上，不得妨礙歐盟之相關立法，特別是食品鏈安全、動物健康和福祉、植物健康和植物繁殖材料領域之立法。
5. This Regulation applies without prejudice to other specific Union law relating to the placing of products on the market and, in particular, to Regulation (EU) No 1308/2013 of the European Parliament and of the Council (32) and to Regulation (EU) No 1169/2011.
本法在適用上，不得妨礙與產品投放市場相關之其他特定歐盟法律，特別是歐洲議會及歐盟理事會(EU) 1308/2013 號規章及(EU) 1169/2011 號規章。
6. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending the list of products set out in Annex I by adding further products to the list, or by amending those added entries. Only products which are closely linked to agricultural products shall be eligible for inclusion in that list.
歐盟執委會有權依第 54 條規定通過授權法，修訂附件 1 所列產品清單，據以進一步增加附件 1 所列產品清單之產品，或據以修訂該等新增產品。僅與農產品密切相關之產品才有資格列入該清單。

Article 3 Definitions 定義

For the purposes of this Regulation, the following definitions apply:

就本法而這，採用以下名詞定義：

- (1) ‘organic production’ means the use, including during the conversion period referred to in Article 10, of production methods that comply with this Regulation at all stages of production, preparation and distribution;
「有機生產」指在生產、調製及流通(配銷)所有階段，包括第 10 條所指有機轉型期內，使用符合本法規定之生產方法；
- (2) ‘organic product’ means a product resulting from organic production, other than a product produced during the conversion period referred to in Article 10. The products of hunting or fishing of wild animals are not considered as organic products;
「有機產品」指有機生產所得到之產品，但在第 10 條所指有機轉型期內生產之產品除外。狩獵或捕撈野生動物之產品不視為有機產品；
- (3) ‘agricultural raw material’ means an agricultural product that has not been subjected to any operation of preservation or processing;
「農業原材料」指未經保存或加工操作之農產品；

- (4) ‘preventive measures’ means measures that are to be taken by operators at every stage of production, preparation and distribution in order to ensure the preservation of biodiversity and soil quality, measures for the prevention and control of pests and diseases and measures that are to be taken to avoid negative effects on the environment, animal health and plant health;
「預防措施」指農產品經營者在生產、調製及流通(配銷)每個階段，為確實保護生物多樣性和土壤品質所採取之措施，預防及防治病蟲害所採取之措施，以及為避免對環境、動物健康、植物健康產生負面影響所採取之措施；
- (5) ‘precautionary measures’ means measures that are to be taken by operators at every stage of production, preparation, and distribution to avoid contamination with products or substances that are not authorised for use in organic production in accordance with this Regulation, and to avoid the commingling of organic products with non-organic products;
「防護措施」指農產品經營者在生產、調製及流通(配銷)每個階段，為避免被未經本法授權用於有機生產之產品或物質污染，並避免有機產品與非有機產品混雜，所採取之措施；
- (6) ‘conversion’ means the transition from non-organic to organic production within a given period, during which the provisions of this Regulation concerning organic production apply;
「轉型」指在一定時期內，從非有機生產至有機生產之過渡，在此期間適用本法有機生產之相關規定；
- (7) ‘in-conversion product’ means a product that is produced during the conversion period referred to in Article 10;
「有機轉型期產品」指第 10 條所指在有機轉型期內生產之產品；
- (8) ‘holding’ means all the production units operated under single management for the purpose of producing live or unprocessed agricultural products originating from aquaculture and beekeeping, referred to in point (a) of Article 2(1) or products listed in Annex I other than essential oils and yeast;
「經營主體」指在單一管理下經營之所有生產單位，以生產活體或未加工農產品為目的，產品包括源自第 2(1)條第(a)點或附件 1 所列的水產及養蜂產品，但精油和酵母除外；
- (9) ‘production unit’ means all assets of a holding, such as primary production premises, land parcels, pasturages, open air areas, livestock buildings or parts thereof, hives, fish ponds, containment systems and sites for algae or aquaculture animals, rearing units, shore or seabed concessions, and premises for the storage of crops, of crop products, of algae products, of animal products, of raw materials and of any other relevant inputs managed as described in point (10), point (11) or point (12); 「生產單位」指經營主體之所有資產，例如初級生產場所、地塊、牧場、露天區域、家畜建築物或其部分、蜂巢、魚塘、圍容系統及藻類或水產動物之地點、飼養單位、海岸或海底特許權、及用於管理儲存作物、作物產品、藻類產品、動物產品、原材料及任何其他相關投入之場所，如第(10)點、第(11)點或第(12)點所述；
- (10) ‘organic production unit’ means a production unit, excluding during the conversion period referred to in Article 10, which is managed in compliance with the requirements applicable to organic production;

「有機生產單位」指生產單位在管理上遵守適用於有機生產要求者，但不包括第 10 條所指有機轉型期內之這類生產單位；

- (11) ‘in-conversion production unit’ means a production unit, during the conversion period referred to in Article 10, which is managed in compliance with the requirements applicable to organic production; it may be constituted of land parcels or other assets for which the conversion period referred to in Article 10 starts at different moments in time;

「有機轉型期生產單位」指第 10 條所指有機轉型期內，生產單位在管理上遵守適用於有機生產要求者；有機轉型期生產單位得由第 10 條所指有機轉型期，在不同時刻開始之地塊或其他資產構成；

- (12) ‘non-organic production unit’ means a production unit which is not managed in compliance with the requirements applicable to organic production;

「非有機生產單位」指未依照有機生產要求進行管理的生產單位；

- (13) ‘operator’ means the natural or legal person responsible for ensuring that Regulation (EU) 2018/848 is complied with at every stage of production, preparation and distribution that are under that person’s control;

「農產品經營者」指負責管制生產、調製及流通(配銷)每個階段，確保每個階段均符合 (EU) 2018/848 號規章相關規定之自然人或法人；

- (14) ‘farmer’ means a natural or legal person, or a group of natural or legal persons, regardless of the legal status of that group and its members under national law, who exercises an agricultural activity;

「農民」指從事農業活動之自然人或法人，或自然人或法人集團，無論該集團及其成員在國家法律下之法律地位如何；

- (15) ‘agricultural area’ means agricultural area as defined in point (e) of Article 4(1) of Regulation (EU) No 1307/2013;

「農業區」指(EU) 1307/2013 號規章第 4(1)條第(e)點所定義之農業區；

- (16) ‘plants’ means plants as defined in point (5) of Article 3 of Regulation (EC) No 1107/2009;

「植物」係指(EC) 1107/2009 號規章第 3 條第(5)點所定義之植物；

- (17) ‘plant reproductive material’ means plants and all parts of plants, including seeds, at any stage of growth that are capable of, and intended for, producing entire plants;

「植物繁殖材料」指植物及植物之所有部分，包括種子，處於任何生長階段，能夠並擬用於生產整株植物；

- (18) ‘organic heterogeneous material’ means a plant grouping within a single botanical taxon of the lowest known rank which:

「有機異質材料」指在一個最低已知分類階層級的植物分類群，其：

(a) presents common phenotypic characteristics; 呈現共同之外表型特徵；

(b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that that plant grouping is represented by the material as a whole, and not by a small number of units; 以個體繁殖單位之間的高度遺傳和外表型多樣性為特徵，因此該植物群以整體而非少部分特徵為代表；

- (c) is not a variety within the meaning of Article 5(2) of Council Regulation (EC) No 2100/94;
不是歐盟理事會(EC) 2100/94 號規章第 5(2)條含義內之品種；
- (d) is not a mixture of varieties; and 不是多個品種混合物；及
- (e) has been produced in accordance with Regulation (EU) 2018/848; 業已依(EU) 2018/848 號規章生產；
- (19) ‘organic variety suitable for organic production’ means a variety as defined in Article 5(2) of Regulation (EC) No 2100/94 which:
「適合有機生產之有機品種」指(EC) 2100/94 號規章第 5(2)條所定義之品種：
(a) is characterised by a high level of genetic and phenotypical diversity between individual reproductive units; and 以個別繁殖單位之間的高度遺傳和表型多樣性為特徵；及
(b) results from organic breeding activities referred to in point 1.8.4 of Part I of Annex II to Regulation (EU) 2018/848; 來自(EU) 2018/848 號規章附件 2 第 1 部分第 1.8.4 點所指有機育種活動之結果；
- (20) ‘mother plant’ means an identified plant from which plant reproductive material is taken for the reproduction of new plants;
「母本植物」指一種已確定之植物，從該植物中取得植物繁殖材料以繁殖新植物；
- (21) ‘generation’ means a group of plants constituting a single step in the line of descent of plants;
「世代」指構成植物世系中一個單一步驟之一組植物；
- (22) ‘plant production’ means production of agricultural crop products including harvesting of wild plant products for commercial purposes;
「植物生產」指農作物產品之生產，包括為商業目的的而採收的野生植物產品；
- (23) ‘plant products’ means plant products as defined in point (6) of Article 3 of Regulation (EC) No 1107/2009;
「植物產品」指(EC) 1107/2009 號規章第 3 條第(6)點所定義之植物產品；
- (24) ‘pest’ means a pest as defined in Article 1(1) of Regulation (EU) 2016/2031 of the European Parliament and of the Council;
「有害生物(害蟲)」指歐洲議會及歐盟理事會(EU) 2016/2031 號規章第 1(1)條所定義之有害生物；
- (25) ‘biodynamic preparations’ means mixtures traditionally used in biodynamic farming;
「生物動力製劑」指傳統上用於生物動力農法之混合物；
- (26) ‘plant protection products’ means the products referred to in Article 2 of Regulation (EC) No 1107/2009;
「植物保護產品」指(EC) 1107/2009 號規章第 2 條所指產品；
- (27) ~ (34) ‘livestock production’ 「家畜生產」/‘veranda’ 「露臺或封閉舍外廊」/‘pullets’ 「新母雞」/‘laying hens’ 「蛋雞」/‘usable area’ 「可用區域」/‘aquaculture’ 「水產」/‘aquaculture products’ 「水產品」/‘closed recirculation aquaculture facility’ 「封閉式循環水產設施」
Conserved 保留

- (35) ‘energy from renewable sources’ means energy from renewable non-fossil sources such as wind, solar, geothermal, wave, tidal, hydropower, landfill gas, sewage treatment plant gas and biogases;
「再生來源之能源(再生能源)」指來自風能、太陽能、地熱能、波浪能、潮汐能、水力發電、掩埋沼氣、污水處理廠氣體、生質氣體等非化石來源之再生能源；
- (36) ~ (43) ‘hatchery’ 「孵化場」 / ‘nursery’ 「育苗場」 / ‘water pollution’ 「水污染」 / ‘polyculture’ 「混養」 / ‘production cycle’ 「生產週期」 / ‘locally grown species’ 「當地生長物種」 / ‘veterinary treatment’ 「獸醫治療」 / ‘veterinary medicinal product’ 「獸藥產品」 *Conserved* 保留
- (44) ‘preparation’ means the operations of preserving or processing of organic or in-conversion products, or any other operation that is carried out on an unprocessed product without altering the initial product, such as slaughtering, cutting, cleaning or milling, as well as packaging, labelling or alterations made to the labelling relating to organic production;
「調製」係指對有機產品或有機轉型期產品進行保存或加工之操作，或在不改變初始產品之情況下，對未加工產品進行之任何其他操作，如屠宰、切割、清潔或碾磨，以及與有機生產有關之包裝、標示或對標示所做之更改；
- (45) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council;
「食品」指歐洲議會及歐盟理事會(EC) 178/2002 號規章第 2 條所定義之食品；
- (46) ~ (47) ‘feed’ 「飼料」 / ‘feed materials’ 「飼料材料」 *Conserved*
- (48) ‘placing on the market’ means placing on the market as defined in point (8) of Article 3 of Regulation (EC) No 178/2002;
「投放市場」指依(EC) 178/2002 號規章第 3 條第(8)點所定義之投放市場；
- (49) ‘traceability’ means the ability to trace and follow food, feed or any product referred to in Article 2(1), and any substance intended or expected to be incorporated into food or any product referred to in Article 2(1), through all stages of production, preparation and distribution;
「可追溯性」指能夠追縱和跟蹤第 2(1)條所指食品、飼料或任何產品，以及擬或預期透過生產、調製及流通(配銷)所有階段，加入第 2(1)條中所指食品、飼料或任何產品中之任何物質；
- (50) ‘stage of production, preparation and distribution’ means any stage from the primary production of an organic product through its storage, processing, transport, and sale or supply to the final consumer, including, where relevant, labelling, advertising, import, export and subcontracting activities;
「生產、調製及流通(配銷)階段」，指從有機產品從最初的生產，到其儲存、加工、運輸、及販賣或供應給最終消費者之任何階段，包括相關之標示、廣告、進口、出口及委外活動；
- (51) ‘ingredient’ means an ingredient as defined in point (f) of Article 2(2) of Regulation (EU) No 1169/2011 or, for products other than food, any substance or product used in the manufacture or preparation of products that is still present in the finished product, even in altered form;

「原料」指(EU) 1169/2011 號規章第 2(2)條第(f)點所定義之原料，或就食品以外之產品而言，用於製造或調製產品之任何物質或產品，這些原料、物質或產品仍存在於成品中，即使存在之形式改變；

- (52) ‘labelling’ means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a product that are placed on any packaging, document, notice, label, ring or collar that accompanies or refers to that product;

「標示」指針對某個產品，在隨附於該產品或指名該產品之任何包裝、文件、通知、標示、圓環或圈扣上，所列與該產品相關之任何文字、細節、商標、品牌名稱、圖片素材或符號；

- (53) ‘advertising’ means any presentation of products to the public, by any means other than a label, that is intended or is likely to influence and shape attitudes, beliefs and behaviours in order to directly or indirectly promote the sale of products;

「廣告」指藉由標示以外之任何方式向公眾展示產品，旨在影響或可能影響及塑造態度、信念及行為，以直接或間接促進產品販賣；

- (54) ‘competent authorities’ means competent authorities as defined in point (3) of Article 3 of Regulation (EU) 2017/625;

「主管機關」指(EU) 2017/625 號規章第 3(3)條所定義之主管機關；

- (55) ‘control authority’ means an organic control authority as defined in point (4) of Article 3 of Regulation (EU) 2017/625, or an authority recognised by the Commission or by a third country recognised by the Commission for the purposes of carrying out controls in third countries for the import of organic and in-conversion products into the Union;

「管制機關」指(EU) 2017/625 號規章第 3(4)條所定義之有機管制機關，或歐盟執委會認可之機關，或歐盟執委會認可之第三國所認可之機關，目的為在第三國執行管制，俾便將有機產品及有機轉型期產品進口至歐盟；

- (56) ‘control body’ means a delegated body as defined in point (5) of Article 3 of Regulation (EU) 2017/625, or a body recognised by the Commission or by a third country recognised by the Commission for the purposes of carrying out controls in third countries for the import of organic and in-conversion products into the Union;

「管制機構」指(EU) 2017/625 號規章第 3(5)條所定義之受委託機構，或歐盟執委會認可之機構，或歐盟執委會認可之第三國所認可之機構，目的為在第三國執行管制，俾便將有機產品及有機轉型期產品進口至歐盟；

- (57) ‘non-compliance’ means non-compliance with Regulation (EU) 2018/848 or non-compliance with the delegated or implementing acts adopted in accordance with Regulation (EU) 2018/848;

「不符合」指不符合(EU) 2018/848 號規章，或不符合依(EU) 2018/848 號規章通過之授權法或施行法；

- (58) ‘genetically modified organism’ or ‘GMO’ means a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council (42)

which is not obtained through the techniques of genetic modification listed in Annex I.B to that Directive;

「基因改造生物」指歐洲議會及歐盟理事會 2001/18/EC 號指令第 2(2)條所定義之基因改造生物(基改生物)，其並非透過該指令附件 1.B 所列基因改造技術而取得者；

(59) 'produced from GMOs' means derived in whole or in part from GMOs but not containing or consisting of GMOs;

「生產自基因改造生物」指全部或部分衍生自基因改造生物，但不包含基因改造生物，亦非由基因改造生物組成；

(60) '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;

「由基因改造生物生產」指在生產過程中，使用基因改造生物作為最後生物體而衍生者，但不包含基因改造生物，亦非由基因改造生物組成，亦非生產自基因改造生物；

(61) 'food additive' means a food additive as defined in point (a) of Article 3(2) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council;

「食品添加物」指歐洲議會及歐盟理事會(EC) 1333/2008 號規章第 3(2) (a)條所定義之食品添加物；

(62) 'feed additive' 「飼料添加物」 *Conserved* 保留

(63) 'engineered nanomaterial' means an engineered nanomaterial as defined in point (f) of Article 3(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council;

「工程奈米材料」指歐洲議會及歐盟理事會(EU) 2015/2283 號規章第 3(2) (f)條所定義之工程奈米材料；

(64) 'equivalence' means meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity;

「同等性」指經由應用相同水準的符合性保證的規則，滿足相同目標和原則；

(65) 'processing aid' means a processing aid as defined in point (b) of Article 3(2) of Regulation (EC) No 1333/2008 for food and in point (h) of Article 2(2) of Regulation (EC) No 1831/2003 for feed;

「加工助劑」指(EC) 1333/2008 號規章第 3(2) (b)條，為食品所定義之加工助劑，及指(EC) 1831/2003 號規章第 2(2) (h)條，為飼料所定義之加工助劑；

(66) 'food enzyme' means a food enzyme as defined in point (a) of Article 3(2) of Regulation (EC) No 1332/2008 of the European Parliament and of the Council;

「食品酵素」指歐洲議會及歐盟理事會(EC) 1332/2008 號規章第 3(2) (a)條所定義之食品酵素；

(67) 'ionising radiation' means ionising radiation as defined in point (46) of Article 4 of Council Directive 2013/59/Euratom;

「游離輻射」指歐盟理事會 2013/59/Euratom 號指令第 4(46)條所定義之游離輻射；

(68) 'prepacked food' means prepacked food as defined in point (e) of Article 2(2) of Regulation (EU) No 1169/2011;

「預包裝食品」指(EU) 1169/2011 號規章第 2(2)(e)條所定義之預包裝食品；

- (69) 'poultry house' 「家禽舍」 *Conserved*
- (70) 'soil-related crop cultivation' means production in living soil or in soil that is mixed or fertilised with materials and products that are allowed in organic production in connection with the subsoil and bedrock;
「土壤相關作物栽培」指在活土或在以有機生產允用的材料及產品混合或施肥之底土及基岩相關的土壤中；
- (71) 'unprocessed products' means unprocessed products as defined in point (n) of Article 2(1) of Regulation (EC) No 852/2004 of the European Parliament and of the Council, irrespective of packaging or labelling operations;
「未加工產品」指歐洲議會及歐盟理事會(EC) 852/2004 號規章第 2(1)(n)條點所定義之未加工產品，無涉包裝或標示作業；
- (72) 'processed products' means processed products as defined in point (o) of Article 2(1) of Regulation (EC) No 852/2004, irrespective of packaging or labelling operations;
「加工產品」指(EC) 852/2004 號規章第 2(1)(o)條所定義之加工產品，無涉包裝或標示作業；
- (73) 'processing' means processing as defined in point (m) of Article 2(1) of Regulation (EC) No 852/2004; this includes the use of substances referred to in Articles 24 and 25 of Regulation (EU) 2018/848 but does not include packaging or labelling operations;
「加工」指(EC) 852/2004 號規章第 2(1)(m)條所定義之加工，這包括使用(EU) 2018/848 號規章第 24 條和第 25 條所指物質，但不包括包裝或標示作業；
- (74) 'integrity of organic or in-conversion products' means the fact that the product does not exhibit non-compliance which:
「有機產品或有機轉型期產品之完整性」指產品不存在以下不符合之事實：
(a) in any stage of production, preparation and distribution affects the organic or in-conversion characteristics of the product; or
在生產、調製及流通(配銷)之任何階段，影響產品之有機或有機轉型期特徵；
(b) is repetitive or intentional;
重複或有意；
- (75) 'pen' 「圍欄」 *Conserved*

Chapter II. OBJECTIVES AND PRINCIPLES OF ORGANIC PRODUCTION 有機生產目標和原則

Article 4 Objectives 目標

Organic production shall pursue the following general objectives: 有機生產應追求以下一般目標：

- (a) contributing to protection of the environment and the climate; 有助於保護環境和氣候；
- (b) maintaining the long-term fertility of soils; 保持土壤長期肥培；
- (c) contributing to a high level of biodiversity; 有助於高水準生物多樣性；
- (d) substantially contributing to a non-toxic environment; 對無毒環境做出重大貢獻；
- (e) contributing to high animal welfare standards and, in particular, to meeting the species-specific behavioural needs of animals; *Conserved*
- (f) encouraging short distribution channels and local production in the various areas of the Union;—
Conserved
- (g) encouraging the preservation of rare and native breeds in danger of extinction; 鼓勵保育瀕臨滅絕之稀有在地品種；
- (h) contributing to the development of the supply of plant genetic material adapted to the specific needs and objectives of organic agriculture; 促進適應有機農業特定需要和目標的植物遺傳材料之供應的發展；
- (i) contributing to a high level of biodiversity, in particular by using diverse plant genetic material, such as organic heterogeneous material and organic varieties suitable for organic production; 促進高度生物多樣性，特別是藉由使用多種植物遺傳材料，例如有機異質材料和適合有機生產之有機品種；
- (j) fostering the development of organic plant breeding activities in order to contribute to favourable economic perspectives of the organic sector. 促進有機植物育種活動的發展，有助於有機部門邁向有利之經濟前景。

Article 5 General principles 總則

Organic production is a sustainable management system that is based on the following general principles: 有機生產是以下列一般原則為基礎之永續管理系統：

- (a) respect for nature's systems and cycles and the sustainment and enhancement of the state of the soil, the water and the air, of the health of plants and animals, and of the balance between them; 尊重自然系統和循環，維持和增強土壤、水和空氣狀態、植物和動物健康，以及、彼此之間的平衡；
- (b) the preservation of natural landscape elements, such as natural heritage sites; 保育自然景觀要素，例如自然遺產；
- (c) the responsible use of energy and natural resources, such as water, soil, organic matter and air; 負責任的使用能源和自然資源，例如水、土壤、有機物質及空氣；

- (d) the production of a wide variety of high-quality food and other agricultural and aquaculture products that respond to consumers' demand for goods that are produced by the use of processes that do not harm the environment, human health, plant health or animal health and welfare; 生產各種高品質食品、其他農產品及水產品以滿足消費者對使用不傷害環境、人類健康、植物健康或動物健康及福祉之生產過程的產品的需求；
- (e) ensuring the integrity of organic production at all stages of the production, processing and distribution of food; 食品和飼料在生產、加工及流通(配銷)之所有階段，確保有機生產完整性；
- (f) the appropriate design and management of biological processes, based on ecological systems and using natural resources which are internal to the management system, using methods that: 基於生態系統和使用管理系統內部之自然資源，使用以下方法對生物過程進行適當設計和管理：
 - (i) use living organisms and mechanical production methods; 使用生物體和機械生產方法；
 - (ii) practice soil-related crop cultivation and land-related livestock production, or practice aquaculture which complies with the principle of the sustainable exploitation of aquatic resources; 從事土壤相關作物栽培和土地相關家畜生產，或從事符合水產資源永續開發原則之水產業；
 - (iii) exclude the use of GMOs, products produced from GMOs, and products produced by GMOs, other than veterinary medicinal products; 排除使用基因改造生物、生產自基因改造生物之產品及由基因改造生物生產之產品，獸藥產品不在此限；
 - (iv) are based on risk assessment and the use of precautionary measures and preventive measures, where appropriate; 以風險評估為基礎及使用防護措施和預防措施(如適當)；
- (g) the restriction of the use of external inputs; where external inputs are required or the appropriate management practices and methods referred to in point (f) do not exist, the external inputs shall be limited to: 限制使用外來投入；若需要外來投入或第(f)點所指適當管理作業和方法不存在，則外來投入應限於：
 - (i) inputs from organic production; in the case of plant reproductive material, priority shall be given to varieties selected for their ability to meet the specific needs and objectives of organic agriculture; 來自有機生產之投入；就植物繁殖材料而言，應優先選擇能夠滿足有機農業特定需要和目標之品種；
 - (ii) natural or naturally-derived substances; 自然或自然衍生之物質；
 - (iii) low solubility mineral fertilisers; 低可溶性礦物肥料；
- (h) *Conserved*
 - (i) the exclusion from the whole organic food chain of ionising radiation; 從整個有機食物鏈中排除游離輻射；
- (j) *Conserved*

Article 6 Specific principles applicable to agricultural activities 適用於農業活動之特定原則

As regards agricultural activities and aquaculture, organic production shall, in particular, be based on the following specific principles: 關於農業活動，有機生產尤其應以下列特定原則為基礎：

- (a) the maintenance and enhancement of soil life and natural soil fertility, soil stability, soil water retention and soil biodiversity, preventing and combating loss of soil organic matter, soil compaction and soil erosion, and the nourishing of plants primarily through the soil ecosystem; 維持和增強土壤生命和自然土壤肥力、土壤穩定性、水土保持及土壤生物多樣性，預防和防止土壤有機質流失、土壤壓實及土壤侵蝕，並主要透過土壤生態系統滋養植物；
- (b) the limitation of the use of non-renewable resources and external inputs to a minimum; 將不可再生資源和外來投入的使用限制在最低限度；
- (c) the recycling of waste and by-products of plant and animal origin as input in plant production; 將來自動植物的廢物和副產品作為植物生產的投入加以回收；
- (d) the maintenance of plant health by preventive measures, in particular the choice of appropriate species, varieties or heterogeneous material resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and protection of the natural enemies of pests; 藉由預防措施維護植物健康，特別是選擇適當物種、品種或對病蟲害有抵抗力之異質材料、適當輪作、機械和物理方法及保護害蟲之天敵；
- (e) the use of seeds with a high degree of genetic diversity and disease resistance; 使用具有高度遺傳多樣性及抗病性種子；
- (f) in the choosing of plant varieties, having regard to the particularities of the specific organic production systems, focusing on agronomic performance, disease resistance, adaptation to diverse local soil and climate conditions and respect for the natural crossing barriers; 在選擇植物品種時，考慮特定有機生產系統之特殊性，聚焦農藝性能、抗病性、對不同地方的土壤和氣候條件之適應性、及尊重天然雜交屏障；
- (g) the use of organic plant reproductive material, such as plant reproductive material of organic heterogeneous material and of organic varieties suitable for organic production; 使用有機植物繁殖材料，例如有機異質材料，及適合有機生產之有機品種的植物繁殖材料；
- (h) the production of organic varieties through natural reproductive ability and focusing on containment within natural crossing barriers; 透過自然繁殖能力生產有機品種，側重在天然雜交屏障內之抑制；
- (i) without prejudice to Article 14 of Regulation (EC) No 2100/94 and to the national plant variety rights granted under Member States' national law, the possibility for farmers to use plant reproductive material obtained from their own farms in order to foster genetic resources adapted to the special conditions of organic production; 在不妨礙(EC) 2100/94 號規章第 14 條，及不妨礙會員國國家法律授予國家植物品種權之情況下，農民有可能使用從其自家農場獲得之植物繁殖材料，來培育適應有機生產特定條件之遺傳資源；
- (j) *Conserved*
- (k) *Conserved*
- (l) *Conserved*

- (m) *Conserved*
- (n) *Conserved*
- (o) *Conserved*
- (p) *Conserved*
- (q) avoiding any endangerment of species of conservation interest that might arise from organic production. 避免有機生產可能對具有保育意義之物種造成任何危害。

Article 7 Specific principles applicable to the processing of organic food 適用於有機食品加工之特定原則

The production of processed organic food shall be based, in particular, on the following specific principles: 生產有機加工食品尤其應以下列特定原則為基礎：

- (a) the production of organic food from organic agricultural ingredients; 用有機農業原料生產有機食品；
- (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 cases of essential technological need or for particular nutritional purposes; 限制使用食品添加物、主要具有技術和感官功能之非有機原料、及微量元素和加工助劑，俾使用量最小化，且僅在必要的技術需要或特別營養目的使用之；
- (c) the exclusion of substances and processing methods that might be misleading as regards the true nature of the product; 排除可能誤導產品真實性質之物質和加工方法；
- (d) the processing of organic food with care, preferably through the use of biological, mechanical and physical methods; 有機食品的加工要謹慎為之，最好透過使用生物、機械及物理方法；
- (e) the exclusion of food containing, or consisting of, engineered nanomaterials. 不得使用含有工程奈米材料或由工程奈米材料組成之食品。

Article 8 Specific principles applicable to the processing of organic feed *Conserved*

Chapter III. PRODUCTION RULES 生產規則

Article 9 General production rules 一般生產規則

1. Operators shall comply with the general production rules laid down in this Article. 農產品經營者應遵循本條中所制定之一般生產規則。
2. The entire holding shall be managed in compliance with the requirements of this Regulation that apply to organic production. 整個經營主體在管理上，應符合本法適用於有機生產之要求。
3. For the purposes and uses referred to in Articles 24 and 25 and in Annex II, only products and substances that have been authorised pursuant to those provisions may be used in organic production, provided that their use in non-organic production has also been authorised in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law. 就第 24 條、第 25 條及附件 2 所指目的和用途而言，僅依該等規定獲得授權之產品和物質，才能用於有機生產，但前提是，該等產品和物質用在非有機生產中，亦已依歐盟法律之相關規定及以歐盟法律為基礎之國家規定(如適用)獲得授權。

The following products and substances referred to in Article 2(3) of Regulation (EC) No 1107/2009 shall be allowed for use in organic production, provided that they are authorised pursuant to that Regulation: (EC) 1107/2009 號規章第 2(3)條所指以下產品和物質，應被允許用於有機生產，但前提是這些產品和物質係依該規章獲得授權：

- (a) safeners, synergists and co-formulants as components of plant protection products; 作為植物保護產品成分之保護劑、協力劑及助劑；
- (b) adjuvants that are to be mixed with plant protection products. 與植物保護產品混合之輔助劑。

The use in organic production of products and substances for purposes other than those covered by this Regulation shall be allowed, provided that their use complies with the principles laid down in Chapter II. 允許產品和物質用於本法所涵蓋目的以外的有機生產，但前提是這些產品和物質之使用符合第 2 章所制定之原則。

4. Ionising radiation shall not be used in the treatment of organic food, and in the treatment of raw materials used in organic food. 處理有機食品及處理用於有機食品之原材料，不得使用游離輻射。
5. *Conserved*
6. Preventive and precautionary measures shall be taken, where appropriate, at every stage of production, preparation and distribution. 應在生產、調製及流通(配銷)的每個階段，採取預防及防護措施(如適當)。
7. Notwithstanding paragraph 2, a holding may be split into clearly and effectively separated production units for organic, in-conversion and non-organic production, provided that for the non-organic production units: 儘管有第 2 項規定，但經營主體得將有機生產、有機轉型期生產及非有機生產，分拆成為獨立生產單位，彼此之間區隔明確有效，但前提是，非有機生產單位要遵守以下規定：

- (a) *Conserved*
- (b) as regards plants, different varieties that can be easily differentiated are involved. 植物方面，包含能夠容易區分之不同品種。
8. By way of derogation from point (b) of paragraph 7, in the case of perennial crops which require a cultivation period of at least three years, different varieties that cannot be easily differentiated, or the same varieties, may be involved, provided that the production in question is within the context of a conversion plan, and provided that the conversion of the last part of the area related to the production in question to organic production begins as soon as possible and is completed within a maximum of five years. 作為來自第 7 項第(b)點之豁免，對於栽培年限要求至少為三年之多年生作物，得包含不易區分之不同品種或同一品種，但須符合兩個條件，一是所涉生產是在有機轉型期計畫背景內，另一是所涉生產相關區域中，屬於轉型至有機生產之最後部分要盡速開始，並在最多 5 年內完成轉型。
- In such cases: 在該等情況下：
- (a) the farmer shall notify TOC of the start of harvest of each of the products concerned at least 48 hours in advance; 農民在開始收穫每種有關產品前，應至少提前 48 小時通知慈心；
- (b) upon completion of the harvest, the farmer shall inform TOC of the exact quantities harvested from the units concerned and of the measures taken to separate the products; 收穫完成後，農民應將有關單位之確實收穫數量及為區隔產品所採取之措施，通知慈心；
- (c) the conversion plan and the measures to be taken to ensure the effective and clear separation shall be confirmed each year by TOC after the start of the conversion plan. 於有機轉型期計畫開始後，為確保有效明確區隔所採取之轉型計畫及措施，應每年由慈心確認之。
9. The requirements concerning different species and varieties, laid down in points (a) and (b) of paragraph 7, shall not apply in the case of research and educational centres, plant nurseries, seed multipliers and breeding operations. 第 7 項第(a)和(b)點對不同物種和品種所制定之要求，不得適用於研究和教育中心、植物苗圃、種子繁殖及育種操作。
10. Where, in the cases referred to in paragraphs 7, 8 and 9, not all production units of a holding are managed under organic production rules, the operators shall: 在第 7、8 及 9 項所指情況下，若某個經營主體中並非所有生產單位都依有機生產規則進行管理，則農產品經營者應：
- (a) keep the products used for the organic and in-conversion production units separate from those used for the non-organic production units; 將用於有機生產單位和有機轉型期生產單位之產品，與用於非有機生產單元之產品分開；
- (b) keep the products produced by the organic, in-conversion and non-organic production units separate from each other; 將有機、有機轉型期及非有機生產單位生產之產品彼此分開；
- (c) keep adequate records to show the effective separation of the production units and of the products. 保留足夠紀錄，以顯示生產單位和產品是有效分開的。
11. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraph 7 of this Article by adding further rules on the splitting of a holding into organic, in-conversion and non-organic production units, in particular in relation to products listed in Annex I,

or by amending those added rules.

歐盟執委會有權依第 54 條規定通過授權法，修訂本條第 7 項規定，據以針對將一個經營主體，分拆成有機、非有機生產單位，新增進一步規則，特別是涉及附件 1 所列產品，或據以修訂該等新增規則。

Article 10 Conversion 有機轉型期

1. *Conserved*
2. *Conserved*
3. No previous period may be retroactively recognised as being part of the conversion period, except where: 最早開始日以前之期間，不得追溯認可為有機轉型期之一部分，但以下情況除外：
 - (a) the operator's land parcels were subject to measures which were defined in a programme implemented pursuant to Regulation (EU) No 1305/2013 for the purpose of ensuring that no products or substances other than those authorised for use in organic production have been used on those land parcels; or 農產品經營者之地塊，依(EU) 1305/2013 號規章規定，遵守實施方案所定義之措施，目的是確保該等地塊上已經使用之有機生產，在該有機生產中所使用之產品或物質，都是獲授權可用於有機生產者。

the operator shall submit to TOC the official documents from the relevant competent authorities proving that the land parcels for which the retroactive recognition of a previous period is requested were subject to measures which were defined in a programme implemented pursuant to Regulation (EU) No 1305/2013 and that no products or substances other than those authorised for use in organic production have been used on those land parcels.

農產品經營者應當向慈心提交相關主管機關的官方文件，證明要求追溯承認先前期限的地塊遵守(EU) 1305/2013 號規章執行方案中界定的措施。

- (b) the operator can provide proof that the land parcels were natural or agricultural areas that, for a period of at least three years, have not been treated with products or substances that are not authorised for use in organic production. 農產品經營者可以提供證據，證明地塊是自然或農業區域，至少三年內，未曾使用非允用於有機生產之產品或物質。

the operator shall submit to TOC the following documents: 農產品經營者須向慈心提交下列文件：

- (i) maps identifying clearly each land parcel covered by the request for retroactive recognition and information on the total surface of those land parcels and, if relevant, on the nature and the volume of the on-going production and, where available, their geolocation coordinates; 清楚標別各追溯承認請求所涵蓋的地塊的地圖及其總面資料 (如適用)，正在進行生產的性質和數量，及其地理座標位置；
 - (ii) the detailed risk analysis carried out by the control authority or control body to assess whether any land parcel covered by the request for retroactive recognition has been treated with products or substances that are not authorised for use in organic production for a period of at least three years,

taking into account in particular the size of the total surface to which the request relates and the agronomic practices carried out during that period on each land parcel subject to the request; 由管制機關或管制機構進行的詳細風險分析，以評估任何在追溯承認請求範圍內的地塊是否在至少三年間曾施用非允用於有機生產的產品或物質，特別考慮到請求所涉及的總面積，及在該期間各地塊上根據要求所進行的農藝做法；

- (iii) the laboratory analyses results from accredited laboratories on soil and/or plant samples taken by the control authority or control body from each land parcel identified as presenting the risk of being contaminated as a result of being treated with products and substances that are not authorised for use in organic production following the detailed risk analysis referred in point (b); 由管制機關或管制機構根據第(b)點所述詳細風險分析，確定具有遭非允用於有機生產的產品和物質污染風險的地塊，由認證實驗室對該地塊土壤和/或植物樣本進行檢驗分析結果；
 - (iv) an inspection report from the control authority or control body following a physical inspection of the operator for the purpose of verifying the consistency of the information collected on the land parcels covered by the request for retroactive recognition; 管制機關或管制機構在對農產品經營者現場查驗後提交稽查報告，以核實在追溯承認要求所涵蓋的地塊上所收集的資料之一致性。
 - (v) any other relevant documents deemed necessary by the control authority or control body to assess the request for retroactive recognition; 管制機關或管制機構認為對評估追溯承認請求有必要的任何其他相關文件；
 - (vi) a final written statement of the control authority or control body indicating whether a retroactive recognition of a previous period as being part of the conversion period is justified and indicating the starting period considered as organic for each land parcel concerned as well as the total surface of the land parcels benefiting from a retroactive recognition of a period. 管制機關或管制機構以最終書面陳述說明是否有理由追溯承認先前作為有機轉型期的一部分，指出各地塊被視為有機的起始期，及受益於追溯承認的地塊總面積。
4. Products produced during the conversion period shall not be marketed as organic products or as in-conversion products. 有機轉型期間生產之產品，不得以有機產品或有機轉型期產品銷售。 However, the following products produced during the conversion period and in compliance with paragraph 1 may be marketed as in-conversion products: 但是，在有機轉型期間生產並符合第 1 項規定之以下產品，得以有機轉型期產品銷售：
- (a) plant reproductive material, provided that a conversion period of at least 12 months has been complied with; 植物繁殖材料，前提是已符合至少 12 個月之有機轉型期規定；
 - (b) food products of plant origin, provided that the product contains only one agricultural crop ingredient, and provided that a conversion period of at least 12 months before the harvest has been complied with. 植物來源食品，前提是該產品僅包含一種農作物原料，且在收穫前已符合至少 12 個月之有機轉型期規定。

Article 11 Prohibition of the use of GMOs 禁止使用基因改造生物

1. GMOs, products produced from GMOs, and products produced by GMOs shall not be used in food, or as food, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, or micro-organisms in organic production. 在有機生產中，基因改造生物、生產自基因改造生物之產品及由基因改造生物生產之產品，不得用於食品、或用作食品、加工助劑、植物保護產品、肥料、土壤改良劑、植物繁殖材料、或微生物。
2. For the purposes of the prohibition laid down in paragraph 1, with regard to GMOs and products produced from GMOs for food, operators may rely on the labels of a product that have been affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) No 1829/2003 of the European Parliament and of the Council or Regulation (EC) No 1830/2003 of the European Parliament and of the Council or any accompanying document provided pursuant thereto. 基於第 1 項禁止規定之目的，對於基因改造生物和生產自基因改造生物做為食品之產品，農產品經營者可以依賴依據歐洲議會及歐盟理事會第 2001/18/EC 號指令黏貼或提供之產品標示、(EC) 1829/2003 號規章、或歐洲議會及歐盟理事會(EC) 1830/2003 號規章、或依該等規章指令所提供之任何隨附文件。
3. Operators may assume that no GMOs and no products produced from GMOs have been used in the manufacture of purchased food where such products do not have a label affixed or provided, or are not accompanied by a document provided, pursuant to the legal acts referred to in paragraph 2, unless they have obtained other information indicating that the labelling of the products concerned is not in conformity with those legal acts. 農產品經營者購買食品，若這些產品未貼上或提供標示，或無隨附提供第 2 項所述之文件，則農產品經營者得假設所購買之食品於製造時未曾使用基因改造生物、生產自基因改造生物之產品，但若農產品經營者業已取得其他資訊，顯示有關產品的標示不符合上述法律法案者，則不在此限。
4. For the purposes of the prohibition laid down in paragraph 1, with regard to products not covered by paragraphs 2 and 3, operators using non-organic products purchased from third parties shall require the vendor to confirm that those products are not produced from GMOs or produced by GMOs. 基於第 1 項禁止規定之目的，對於第 2 項和第 3 項未涵蓋之產品，農產品經營者使用從第三方購買之非有機產品，應要求供應商確認，該等產品非生產自基因改造生物、或由基因改造生物生產之產品。

Article 12 Plant production rules 植物之生產規則

1. Operators that produce plants or plant products shall comply, in particular, with the detailed rules set out in Part I of Annex II. 生產植物或植物產品之農產品經營者，應特別遵循附件 2 第 1 部分列載之詳細規則。

Article 13 Specific provisions for the marketing of plant reproductive material of organic heterogeneous material 有機異質材料植物繁殖材料行銷之特定規定

1. Plant reproductive material of organic heterogeneous material may be marketed without complying with the requirements for registration and without complying with the certification categories of

pre-basic, basic and certified material or with the requirements for other categories, which are set out in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC or acts adopted pursuant to those Directives. 行銷有機異質材料之植物繁殖材料，得無需遵循註冊要求，及無需遵循原原種(pre-basic)材料、原種(basic)材料及驗證(材料之驗證類別或其他類別要求，這些規定列載於 66/401/EEC、66/402/EEC、68/193/EEC、98/56/EC、2002/53/EC、2002/54/EC、2002/55/EC、2002/56/EC、2002/57/EC、2008/72/EC 及 2008/90/EC 等號指令中，或列載於依前述指令所通過之法案中。

2. Plant reproductive material of organic heterogeneous material as referred to in paragraph 1 may be marketed following a notification of the organic heterogeneous material by the supplier to the responsible official bodies referred to in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC, made by means of a dossier containing: 行銷第 1 項所指有機異質材料之植物繁殖材料，得在供應商將有機異質材料，通知 66/401/EEC, 66/402/EEC、68/193/EEC、98/56/EC、2002/53/EC、2002/54/EC、2002/55/EC、2002/56/EC、2002/57/EC、2008/72/EC 及 2008/90/EC 等號指令所指負責官方機構後為之，通知之申請文件含：
- (a) the contact details of the applicant; 申請人之聯絡詳情；
 - (b) the species and denomination of the organic heterogeneous material; 有機異質材料之物種和名稱；
 - (c) the description of the main agronomic and phenotypic characteristics that are common to that plant grouping, including breeding methods, any available results from tests on those characteristics, the country of production and the parental material used; 對該植物群共有的主要農藝和表型特徵之描述，包括育種方法、對該等特徵進行測試之任何現有結果、生產國及使用之親本材料；
 - (d) a declaration by the applicant concerning the truth of the elements in points (a), (b) and (c); and 申請人關於第(a)、(b)及(c)點內容真實性之聲明；及
 - (e) a representative sample. 代表性樣品。

That notification shall be sent by registered letter, or by any other means of communication accepted by the official bodies, with confirmation of receipt requested. 該通知應以掛號信或以官方機構接受之任何其他通訊方式發送，並要求簽收回執聯。

Three months after the date shown on the return receipt, provided that no additional information was requested or that no formal refusal for reasons of incompleteness of the dossier or non-compliance as defined in Article 3(57) was communicated to the supplier, the responsible official body shall be deemed to have acknowledged the notification and its content. 在回執聯上顯示之日期後三個月，若未要求提供額外資訊，或未因申請文件不完整或第 3(57)條定義的不符合規定之理由，而通知供應商正式拒絕，則負責的官方機構應被視為已承認通知及其內容。 After having expressly or implicitly acknowledged the notification, the responsible official body may proceed to the listing of the notified organic heterogeneous material. That listing shall be free of charge to the supplier. 在明示或默示承認通知後，負責的官方機構得著手將被通知之有機

異質材料列入清單。該清單應免費提供給供應商。

The listing of any organic heterogeneous material shall be communicated to the competent authorities of the other Member States and to the Commission. 任何有機異質材料清單應通知其他會員國之主管機關及歐盟執委會。

Such organic heterogeneous material shall fulfil the requirements laid down in the delegated acts adopted in accordance with paragraph 3. 該有機異質材料應滿足依第 3 項通過之授權法規定的各項要求。

3. The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation by setting out rules governing the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species, as regards: 歐盟執委會有權依第 54 條規定通過授權法，補充本法，據以制定針對特定屬或種有機異質材料之植物繁殖材料之生產和行銷的規則，關於：
 - (a) the description of the organic heterogeneous material, including the relevant breeding and production methods and parental material used; 對有機異質材料之描述，包括相關育種和生產方法及使用之親本材料；
 - (b) the minimum quality requirements for seeds lots, including identity, specific purity, germination rates and sanitary quality; 種子批次之最低品質要求，包括特性、特定純度、發芽率及衛生品質；
 - (c) labelling and packaging; 標示和包裝；
 - (d) information and samples of production to be kept by the professional operators; 由專業農產品經營者保存生產資訊和樣品；
 - (e) where applicable, maintenance of the organic heterogeneous material. 維護有機異質材料 (如適用)。

Article 14 Livestock production rules *Conserved*

Article 15 Production rules for algae and aquaculture animals *Conserved*

Article 16 Production rules for processed food 加工食品之生產規則

1. Operators that produce processed food shall comply, in particular, with the detailed production rules set out in Part IV of Annex II and in any implementing acts referred to in paragraph 3 of this Article. 生產加工食品之農產品經營者，特別應遵循附件 2 第 4 部分所列載之詳細生產規則和本條第 3 項所指之任何施行法案。
2. *Conserved*
3. The Commission may adopt implementing acts laying down the techniques authorised in the processing of food products. 歐盟委員會可通過施行法案，規定食品加工中授權的技術。Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2). 該等施行法案應根據第 55 (2) 條所述之審查程序通過。

Article 17 Production rules for processed feed *Conserved*

Article 18 Production rules for wine *Conserved*

Article 19 Production rules for yeast used as food 用作食品的酵母之生產規則

1. Operators that produce yeast to be used as food shall comply, in particular, with the detailed production rules set out in Part VII of Annex II. 生產用作食品的酵母之農產品經營者，尤應遵循附件 2 第 7 部分列載之詳細生產規則。

Article 20 Absence of certain production rules for specific livestock species and species of aquaculture animals *Conserved*

Article 21 Production rules for products not falling within the categories of products referred to in Articles 12 to 19 *Conserved*

Article 22 Adoption of exceptional production rules *Conserved*

Article 23 Collection, packaging, transport and storage 收集、包裝、運輸及儲存

1. Operators shall ensure that organic products and in-conversion products are collected, packaged, transported and stored in accordance with the rules set out in Annex III. 農產品經營者應確保依附件 3 列載之規則，收集、包裝、運輸及儲存有機產品和有機轉型期產品。

Article 24 Authorisation of products and substances for use in organic production 用於有機生產的產品和物質之授權

1. The Commission may authorise certain products and substances for use in organic production, and shall include any such authorised products and substances in restrictive lists, for the following purposes: 歐盟執委會得授權某些產品和物質用於有機生產，並應將任何該等授權的產品和物質列入限制性清單，用於以下目的：
 - (a) as active substances to be used in plant protection products; 用於植物保護產品之活性物質(有效成分)；

only the active substances listed in Annex VII-1 may be contained in plant protection products used in organic production as set out in that Annex, provided that those plant protection products: 只有附件 VII-1 所列活性物質才可包含在該附件所列有機生產中使用的植物保護產品中，前提是這些植物保護產品：
 - (i) have been authorised pursuant to Regulation (EC) No 1107/2009 of the European Parliament and of the Council; 根據(EC)1107/2009 獲得授權；

- (ii) are used in accordance with the conditions for use as specified in the authorisations of the products containing them, granted by the Member States; and 按照成員國批准的含有這些產品的授權中規定的使用條件使用；及
 - (iii) are used in compliance with the conditions set out in the Annex to Commission Implementing Regulation (EU) No 540/2011. 符合(EU) 540/2011 號附件所載條件使用。
 - (b) as fertilisers, soil conditioners and nutrients; 作為肥料、土壤改良劑和養分；
only the products and substances listed in Annex VII-2 may be used in organic production as fertilisers, soil conditioners and nutrients for plant nutrition, provided that they are compliant with the relevant provisions of Union law, in particular with Regulation (EC) No 2003/2003 of the European Parliament and of the Council, the relevant applicable Articles of Regulation (EU) 2019/1009 of the European Parliament and of the Council, Regulation (EC) No 1069/2009 of the European Parliament and of the Council and Commission Regulation (EU) No 142/2011.
只有附件 VII-2 所列產品和物質可用作有機生產中的肥料、土壤改良劑和植物營養，但須符合歐盟法有關規定，特別是(EC)2003/2003、(EU) 2019/1009 相關適用條款、(EC) 1069/2009 和(EU) 142/2011。
 - (c) *Conserved*
 - (d) *Conserved*
 - (e) *Conserved*
 - (f) as products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding; 用於植物生產的建築物和設施的清潔和消毒用品，包括用於存放在農業倉內的產品；
only the products listed in Part B of Annex VII-3 may be used for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding, provided that those products comply with the provisions of Union law, in particular Regulation (EC) No 648/2004 and Regulation (EU) No 528/2012. 只有附件 VII-3 B 所列的產品可用於清潔和消毒作物生產用的建築物和設施，包括農業倉中的存放物，但該等產品須符合歐盟法之規定，特別是(EC) 648/2004 號規章及(EU) 528/2012 號規章。
 - (g) as products for cleaning and disinfection in processing and storage facilities. 作為加工和儲存設施的清潔和消毒產品。
only the products listed in Part C of Annex VII-3 may be used for cleaning and disinfection in processing and storage facilities, provided that those products comply with the provisions of Union law, in particular Regulation (EC) No 648/2004 and Regulation (EU) No 528/2012. 只有附件 VII-3 C 所列的產品可用於清潔和消毒加工和倉儲設施，但該等產品須符合歐盟法之規定，特別是(EC) 648/2004 號規章及(EU) 528/2012 號規章。
2. In addition to products and substances authorised in accordance with paragraph 1, the Commission may authorise certain products and substances for use in the production of processed organic food and of yeast used as food, and shall include any such authorised products and substances in restrictive lists, for the following purposes: 除依第 1 項授權之產品和物質外，歐盟執委會得授

權某些產品和物質，用於生產有機加工食品 and 作為食品的酵母，並應將任何該等授權產品和物質列入限制性清單，用於以下目的：

- (a) as food additives and processing aids; 作為食品添加物和加工助劑；
only the products and substances listed in Part A of Annex VII-4 may be used as food additives, including food enzymes to be used as food additives, and processing aids in the production of processed organic food, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 1333/2008. 只有附件 VII-4 A 所列產品和物質可用作食品添加劑，包括用作食品添加劑的食物酶，及用於有機加工食品的加工助劑，但其使用須符合歐盟法之相關規定，特別是(EC) 1333/2008 號規章。
 - (b) as non-organic agricultural ingredients to be used for the production of processed organic food; 作為用於生產有機加工食品之非有機農業原料；
only the non-organic agricultural ingredients listed in Part B of Annex VII-4 may be used for the production of processed organic food, provided that their use is in accordance with the relevant provisions of Union law. 只有附件 VII-4 B 所列的非有機農業成分才可用於生產有機加工食品，但其使用須符合歐盟法之相關規定。
 - (c) as processing aids for the production of yeast and yeast products. 作為生產酵母和酵母產品之加工助劑。
only the products and substances listed in Part C of Annex VII-4 may be used as processing aids for the production of yeast and yeast products for food, provided that their use is in accordance with the relevant provisions of Union. 只有附件 VII-4 C 所列產品和物質才可用作生產用於食品的酵母和酵母產品的加工助劑，但這些產品和物質的使用必須符合歐盟法之相關規定。
3. The authorisation of the products and substances referred to in paragraph 1 for use in organic production shall be subject to the principles laid down in Chapter II and to the following criteria, which shall be evaluated as a whole: 第 1 項所指授權用於有機生產之產品和物質，應遵守第 2 章規定之原則和以下準則，並應做整體評量：
- (a) they are essential for sustained production and for the use for which they are intended; 該等授權攸關永續生產和預期用途；
 - (b) all of the products and substances concerned are of plant, algal, animal, microbial or mineral origin, except in cases where products or substances from such sources are not available in sufficient quantities or qualities or where alternatives are not available; 所有有關產品和物質均為植物、藻類、動物、微生物或礦物源，但若該等來源之產品或物質的供應數量或品質不足或無替代品者，不在此限；
 - (c) in the case of products referred to in point (a) of paragraph 1: 對於第 1 項第(a)點所指產品：
 - (i) their use is essential for the control of a pest for which other biological, physical or breeding alternatives, cultivation practices or other effective management practices are not available; 為防治有害生物且無法取得其他生物、物理或育種替代物、栽培作法或其他有效管理作法，該等產品的使用是必需的；
 - (ii) if such products are not of plant, algal, animal, microbial or mineral origin and are not identical to

their natural form, their conditions for use preclude any direct contact with the edible parts of the crop; 若該等產品不是植物、藻類、動物、微生物或礦物來源，又與其天然形式不同，則其使用條件為不得與作物可食用部分有任何直接接觸；

- (d) in the case of products referred to in point (b) of paragraph 1, their use is essential for building or maintaining the fertility of the soil or to fulfil specific nutritional requirements of crops, or for specific soil-conditioning purposes; 對於第 1 項第(b)點所指產品，其使用攸關建立或維持土壤肥力，或滿足作物之特定營養要求，或用於特定土壤改良目的；
- 4. The authorisation of the products and substances referred to in paragraph 2 for use in the production of processed organic food or for the production of yeast used as food shall be subject to the principles laid down in Chapter II and to the following criteria, which shall be evaluated as a whole: 第 2 項所指用於生產有機加工食品或用於生產酵素(用作食品)之產品和物質的授權，應遵守第 2 章制定之原則和以下準則，並應做整體評量：
 - (a) alternative products or substances authorised in accordance with this Article or techniques compliant with this Regulation are not available; 無法獲得依本條授權之替代產品或物質或符合本法之技術；
 - (b) it would be impossible to produce or preserve the food or to fulfil given dietary requirements provided for on the basis of Union legislation without having recourse to those products and substances; 若不使用該等產品和物質，就不可能生產或保存食品或滿足依歐盟法規規定的特定飲食要求；
 - (c) they are to be found in nature and may only have undergone mechanical, physical, biological, enzymatic or microbial processes, except in cases where products or substances from such sources are not available in sufficient quantities or qualities; 該等產品和物質存在於自然界中，又僅能經過機械、物理、生物、酵素或微生物過程，但若該等來源之產品或物質的供應數量或品質不足或無替代品者，不在此限；
 - (d) the organic ingredient is not available in sufficient quantity. 有機原料無法足量供應。
- 5. The authorisation of the use of chemically synthesised products and substances, in accordance with paragraphs 1 and 2 of this Article, shall be strictly limited to cases where the use of external inputs referred to in point (g) of Article 5 would contribute to unacceptable impacts on the environment. 依本條第 1 項和第 2 項規定，化學合成產品和物質之使用授權，應嚴格限於使用第 5 條第 (g)點所指外部投入之情況，將對環境造成不可接受之影響。

Article 25 Authorisation of non-organic agricultural ingredients for processed organic food by Member States *Conserved*

Article 26 Collection of data concerning the availability on the market of organic and in-conversion plant reproductive material, organic animals and organic aquaculture juveniles *Conserved*

Article 27 Obligations and actions in the event of suspicion of non-compliance 不符合之因應義務和

行動

Where an operator suspects that a product it has produced, prepared, imported or has received from another operator does not comply with this Regulation, that operator shall, subject to Article 28(2): 若農產品經營者懷疑其生產、調製、進口或從其他農產品經營者處接收之產品，不符合本法之規定，該農產品經營者應遵守第 28(2)條規定：

- (a) identify and separate the product concerned; 找出和分離區隔有關產品；
- (b) check whether the suspicion can be substantiated; 查核該懷疑是否能夠得到證實；
- (c) not place the product concerned on the market as an organic or in-conversion product and not use it in organic production, unless the suspicion can be eliminated; 不得將該等有關產品作為有機或有機轉型期產品投放市場，亦不得將其用於有機生產，但懷疑盡釋後不在此限；
- (d) where the suspicion has been substantiated or where it cannot be eliminated, immediately inform TOC, and provide it with available elements, where appropriate; 若懷疑業已得到證實或無法盡釋，則立即通知慈心，並提供可用訊息；
- (e) fully cooperate with TOC, in verifying and identifying the reasons for the suspected non-compliance. 與慈心充分合作，查證和找出涉嫌不符合之原因。

Article 28 Precautionary measures to avoid the presence of non-authorised products and substances 避免出現未經授權產品和物質之防護措施

1. In order to avoid contamination with products or substances that are not authorised in accordance with the first subparagraph of Article 9(3) for use in organic production, operators shall take the following precautionary measures at every stage of production, preparation and distribution: 為避免未經第 9(3)條第 1 款授權之產品或物質用於有機生產而污染產品，農產品經營者應在生產、調製及流通(配銷)每個階段，採取以下防護措施：
 - (a) put in place and maintain measures that are proportionate and appropriate to identify the risks of contamination of organic production and products with non-authorised products or substances, including systematic identification of critical procedural steps; 實施並保持相稱及適當之措施，以找出有機生產和產品被未經授權產品或物質污染之風險，包括系統地鑑別關鍵程序步驟；
 - (b) put in place and maintain measures that are proportionate and appropriate to avoid risks of contamination of organic production and products with non-authorised products or substances; 實施並保持相稱及適當之措施，以避免有機生產和產品被未經授權產品或物質污染之風險；
 - (c) regularly review and adjust such measures; and 定期審查和調整該等措施；及
 - (d) comply with other relevant requirements of this Regulation that ensure the separation of organic, in-conversion and non-organic products. 遵循本法之其他相關要求，確實區隔有機產品、有機轉型期產品及非有機產品。
2. Where an operator suspects, due to the presence of a product or substance that is not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production in a product that is

intended to be used or marketed as an organic or in-conversion product, that the latter product does not comply with this Regulation, the operator shall: 若農產品經營者懷疑，擬以有機產品或有機轉型期產品使用或販售之產品，存在非屬第 9(3)條第 1 款授權使用於有機生產之產品或物質，從而使有機產品或有機轉型期產品不符合本法之規定，則農產品經營者應：

- (a) identify and separate the product concerned; 找出和分離區隔有關產品；
- (b) check whether the suspicion can be substantiated; 查核該懷疑是否能夠得到證實；
- (c) not place the product concerned on the market as an organic or in-conversion product and not use it in organic production unless the suspicion can be eliminated; 不得將該等有關產品作為有機產品或有機轉型期產品投放市場，亦不得將其用於有機生產，但懷疑盡釋後不在此限；
- (d) where the suspicion has been substantiated or where it cannot be eliminated, immediately inform TOC, and provide it with available elements, where appropriate; 若懷疑業已得到證實或無法盡釋，則立即通知慈心，並提供可用訊息；
- (e) fully cooperate with TOC, in identifying and verifying the reasons for the presence of non-
authorised products or substances. 與慈心充分合作，找出及查證存在未經授權產品或物質之原因。

2.1 Procedural steps to be followed by the operator in case of a suspicion of non-compliance due to the presence of non-authorised products or substances 在懷疑因存在未經授權產品或物質而不符合的情況下，農產品經營者應採取的流程步驟

- (1) In order to check whether the suspicion can be substantiated in accordance with point (b) of this Article, the operator shall take into account the following elements: 為了檢查是否可以根據本條第(b)項證實懷疑，農產品經營者應考慮以下因素：
 - (a) where the suspicion of non-compliance concerns an incoming organic or in-conversion product, the operator shall check whether: 如果懷疑進貨的有機或有機轉型期產品涉及不符合的情況，農產品經營者應檢查是否：
 - (i) the information on the label of the organic or in-conversion product and the information on the accompanying documents match; 有機或有機轉型期產品的標示與隨附文件的資訊相符；
 - (ii) the information on the certificate provided by the supplier relates to the product actually purchased; 供應商提供的證書上的資訊與實際購買的產品相關；
 - (b) where there is a suspicion that the cause of the presence of the non-authorised products or substances lies under the control of the operator, the operator shall examine any possible cause for the presence of non-authorised products or substances. 如果懷疑未經授權的產品或物質的存在原因是在經營者管制之下，農產品經營者應審查非允用產品或物質存在的任何可能原因。
- (2) When the operator informs TOC in accordance with Article 28(2)(d) about a substantiated suspicion or when the suspicion cannot be eliminated, the operator shall provide, if relevant and where available, the following elements: 如果經營者根據第 28(2)(d)條向慈心通報了經證實的疑慮，或在疑慮無法消除的情況下，經營者應酌情提供下列訊息：

- (a) information and documents about the supplier (delivery note, invoice, certificate of the supplier, Certificate of Inspection for organic products (COI)); 有關供應商的資料和文件 (送貨單、發票、供應商證書、有機產品檢驗報告)；
- (b) the traceability of the product with the lot identification, stock quantity, and quantity of product sold; 產品的可追蹤性與所售產品的批號、庫存量 and 數量；
- (c) laboratory results, from accredited laboratory when relevant and available; 在相關和可用的情況下，由經認證的實驗室所出的檢驗結果；
- (d) the sampling sheet detailing the time, place and method used to take the sample; 詳細說明採樣時間、地點和方法的採樣單；
- (e) any information about any previous suspicion with regard to the specific non-authorised product or substance; 關於以前對該特定非授權產品或物質的任何懷疑的任何資訊；
- (f) every other relevant document to clarify the case. 澄清案件的所有其他相關文件。

Article 29 Measures to be taken in the event of the presence of non-authorised products or substances
存在非經授權產品或物質時應採取之措施

1. Where TOC receives substantiated information about the presence of products or substances that are not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production, or has been informed by an operator in accordance with point (d) of Article 28(2), or detects such products or substances in an organic or an in-conversion product: 慈心若收到經證實資訊，指出用於有機生產之產品或物質，非屬第 9(3)條第 1 款授權者，或業已收到農產品經營者依第 28(2)條第(d)點之通報，或在有機產品或有機轉型期產品中偵測到存在該未經授權產品或物質，則：
 - (a) it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 with a view to determining the source and the cause in order to verify compliance with the first subparagraph of Article 9(3) and with Article 28(1); such investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case; 應立即依(EU)2017/625 號規章進行正式調查，以確定來源和原因，查證是否符合第 9(3)條第 1 款和第 28(1)條規定；該調查應在合理期限內盡快完成，並應考慮產品耐久性及案件複雜性；
 - (b) it shall provisionally prohibit both the placing on the market of the products concerned as organic or in-conversion products and their use in organic production pending the results of the investigation referred to in point (a). 在第(a)點所指調查結果出來前，應暫時禁止將有關產品作為有機產品或有機轉型期產品投放市場及用於有機生產。
2. The product concerned shall not be marketed as an organic or in-conversion product or used in organic production where TOC has established that the operator concerned: 若慈心已確定農產品經營者有以下行為，則相關產品不得以有機產品或有機轉型期產品販售或用於有機生產：
 - (a) has used products or substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production; 使用了非依第 9(3)條第 1 款所授權之產品或物質於有機生產；

- (b) has not taken the precautionary measures referred to in Article 28(1); or 未採取第 28(1)條所指防護措施；或
 - (c) has not taken measures in response to relevant previous requests from TOC. 未針對慈心先前提出的相關要求採取措施。
3. The operator concerned shall be given an opportunity to comment on the results of the investigation referred to in point (a) of paragraph 1. The competent authority, or, where appropriate, the control authority or control body, shall keep records of the investigation it has carried out. 對於第 1 項第 (a)點所指調查結果，應給相關農產品經營者解釋之機會。慈心對於所做之調查應保存紀錄。

Where required, the operator concerned shall take such corrective measures as necessary to avoid future contamination.

如有需要，有關農產品經營者應採取必要之改正措施，以避免未來發生污染。

- 4. *Conserved*
 - 5. *Conserved*
 - 6. *Conserved*
 - 7. *Conserved*
 - 8. *Conserved*
9. By 31 March of each year, TOC shall electronically transmit to the Commission relevant information about cases involving contamination with non-authorised products or substances in the previous year, including information collected at border control posts, concerning the nature of contamination detected, and in particular the cause, the source and the level of contamination as well as the volume and nature of products contaminated. This information shall be collected by the Commission through the computer system made available by the Commission and shall be used to facilitate the formulation of best practices for avoiding contamination. 每年 3 月 31 日前，慈心應將上一年涉及非經授權產品或物質污染案件之相關資訊，以電子方式傳送給歐盟委員會，包括在邊境管制站收集偵測到有關污染性質之資訊，特別是污染之原因、來源及程度，以及被污染產品之數量和性質。本資訊應由歐盟執委會透過由歐盟執委會提供之電腦系統收集，並應用於促進制定避免污染之最佳作法。

Chapter IV. LABELLING 標示

Article 30 Use of terms referring to organic production 使用關於有機生產之用詞

- 1 For the purposes of this Regulation, a product shall be regarded as bearing terms referring to organic production where, in the labelling, advertising material or commercial documents, such a product or its ingredients used for its production are described in terms suggesting to the purchaser that the product or ingredients have been produced in accordance with this Regulation. In particular, the terms listed in Annex IV and their derivatives and diminutives, such as 'bio' and 'eco', whether alone or in combination, may be used throughout the Union and in any language listed in that Annex for the labelling and advertising of products referred to in Article 2(1) which comply with this Regulation. 就本法之目的而言，若在標示、廣告材料或商業文件中，以有機生產指名之用詞，描述該產品或其原料，則產品應被視為帶有有機生產之用詞，向購買者表明，該產品或原料係依本法生產。特別是附件 4 所列用詞及其衍生用詞或縮寫用詞，例如「生物」(bio)和「生態」(eco)，無論單獨使用或組合使用，得在整個歐盟中以該附件列任何語言，用於第 2(1) 條中所指產品之標示及廣告符合本法之規定。
 - 2 For the products referred to in Article 2(1), the terms referred to in paragraph 1 of this Article shall not be used anywhere in the Union, in any language listed in Annex IV, for the labelling, advertising material or commercial documents of a product which does not comply with this Regulation. 就第 2(1)條所指產品，若有產品不符合本法規定，則該產品之標示、廣告材料或商業文件，在歐盟任何地方，不得以附件 4 所列任何語言使用本條第 1 項所指用詞。Furthermore, no terms, including terms used in trademarks or company names, or practices shall be used in labelling or advertising if they are liable to mislead the consumer or user by suggesting that a product or its ingredients comply with this Regulation. 此外，任何用詞，包括商標或公司名稱中使用之用詞、或慣例，若可能藉由暗示產品或其原料符合本法而誤導消費者或用戶，則不得在標示或廣告中使用這些用詞。
 - 3 Products that have been produced during the conversion period shall not be labelled or advertised as organic products or as in-conversion products. 有機轉型期內生產之產品，不得貼上有機產品或有機轉型期產品之標示或廣告。
However, plant reproductive material and food products of plant origin that have been produced during the conversion period, which comply with Article 10(4), may be labelled and advertised as in-conversion products by using the term 'in-conversion' or a corresponding term, together with the terms referred to in paragraph 1. 但是，在有機轉型期內生產，且符合第 10(4)條規定之植物繁殖材料及植物源食品，得使用「有機轉型期」用詞或相對應用詞，連同第 1 項所指用詞。
- 3.1 The indication provided for in-conversion products of plant origin as referred to in Article 30(3) of this Regulation shall appear in: 第 30(3)條所述植物源有機轉型期產品說明應呈現下述：
 - (a) a colour, size and style of lettering that is not more prominent than the sales description of the product, while the entire indication shall have the same size of letters; 其字體顏色、大小和樣式不比產品的銷售說明突出，而整體標示須採相同大小字體。

- (b) the same visual field as the code number of the control authority or control body as referred to in Article 32(1)(a) of this Regulation. 與慈心代碼號(如第 32(1)(a)條所述)相同視覺的欄位。
- 4 The terms referred to in paragraph 1 and 3 shall not be used for a product for which Union law requires the labelling or advertising to state that the product contains GMOs, consists of GMOs or is produced from GMOs. 歐盟法律要求，若有產品在標示或廣告中，聲明含基因改造生物、由基因改造生物組成或生產自基因改造生物，不得使用第 1 項和第 3 項所指用詞。
- 5 For processed food, the terms referred to in paragraph 1 may be used:
對於加工食品，得將第 1 項所指用詞用於下列情形：
- (a) in the sales description, and in the list of ingredients where such a list is mandatory pursuant to Union legislation, provided that: 用於銷售說明中，及依歐盟立法強制列出的原料清單，但須符合以下條件：
- (i) the processed food complies with the production rules set out in Part IV of Annex II and with the rules laid down in accordance with Article 16(3); 加工食品符合附件 2 第 4 部分所列載之生產規則和依第 16(3)條制定之規則；
- (ii) at least 95 % of the agricultural ingredients of the product by weight are organic; and 按重量計，產品的有機農業原料含量至少 95%；及
- (iii) in the case of flavourings, they are only used for natural flavouring substances and natural flavouring preparations labelled in accordance with Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008 and all of the flavouring components and carriers of flavouring components in the flavouring concerned are organic; 如為調味品，僅用於依(EC) 1334/2008 號規章第 16 (2)、(3)、及(4)條標示為天然調味物質和天然調味製劑，以及所有有關調味品中之調味成分及調味成分載體是有機的；
- (b) only in the list of ingredients, provided that: 僅用於原料清單中，但須符合以下條件：
- (i) less than 95 % of the agricultural ingredients of the product by weight are organic, and provided that those ingredients comply with the production rules set out in this Regulation; and 按重量計算，該產品農業成分中有機成分少於 95%，但此類成分須符合本法規定生產規則；及
- (ii) the processed food complies with the production rules set out in points 1.5, 2.1(a), 2.1(b) and 2.2.1 of Part IV of Annex II and with the rules laid down in accordance with Article 16(3); 加工食品符合附件 2 第 4 部分第 1.5、2.1(a)、2.1(b)及 2.2.1 點所列載之生產規則，及符合依第 16(3)條規定所制定之規則；
- (c) in the sales description and in the list of ingredients, provided that:
用於銷售說明和原料清單中，但須符合以下條件：
- (i) *Conserved*
- (ii) the term referred to in paragraph 1 is clearly related in the sales description to another ingredient which is organic and different from the main ingredient; 第 1 項所指用詞，在銷售說明中與另一種不同於主要原料之有機原料相關；
- (iii) all other agricultural ingredients are organic; and 所有其他農業原料都是有機；及
- (iv) the food complies with points 1.5, 2.1(a), 2.1(b) and 2.2.1 of Part IV of Annex II and with the rules

laid down in accordance with Article 16(3). 食品符合附件 2 第 4 部分第 1.5、2.1(a)、2.1(b)及 2.2.1 點，以及符合依第 16(3)條所制定之規則。

The list of ingredients referred to in points (a), (b) and (c) of the first subparagraph shall indicate which ingredients are organic. The references to organic production may only appear in relation to the organic ingredients. 本項第(a)、(b)及(c)點所指原料清單，應指明哪些原料是有機。所指有機生產得僅呈現與有機原料相關。

The list of ingredients referred to in points (b) and (c) of the first subparagraph shall include an indication of the total percentage of organic ingredients in proportion to the total quantity of agricultural ingredients. 本項第(b)和(c)點所指原料清單，應包括農業原料總量中有機原料所占之百分比的說明。

The terms referred to in paragraph 1, when used in the list of ingredients referred to in points (a), (b), and (c) of the first subparagraph of this paragraph, and the indication of the percentage referred to in the third subparagraph of this paragraph shall appear in the same colour, identical size and style of lettering as the other indications in the list of ingredients. 第 1 項所指用詞，當用於本項第(a)、(b)及(c)點所指原料清單時，以及用於本項第(c)點所指標示百分比時，應與原料清單中其他標示，呈現相同顏色、同等大小及字體樣式。

Article 31 Labelling of products and substances used in crop production 用於作物生產的產品和物質之標示

Notwithstanding the scope of this Regulation as set out in Article 2(1), products and substances used in plant protection products or as fertilisers, soil conditioners or nutrients that have been authorised in accordance with Articles 9 and 24 may bear a reference indicating that those products or substances have been authorised for use in organic production in accordance with this Regulation. 就用於植物保護產品，或用作肥料、土壤改良劑或營養物之產品和物質而言，儘管本法第 2(1)條列載相關範圍，但依第 9 條和第 24 條獲得授權者，得帶有表示該等產品或物質業已依本法獲授權用於有機生產之證明文字。

Article 32 Compulsory indications 強制性標示

1. Where products bear terms as referred to in Article 30(1), including products labelled as in-conversion products in accordance with Article 30(3): 若產品帶有第 30(1)條所指用詞，包括依第 30(3)條規定標示為有機轉型期產品者，則：
 - (a) the code number of organic control system to which the operator that carried out the last production or preparation operation is subject shall also appear in the labelling; 標示中亦應就進行最後生產或調製操作之農產品經營者，列出有機驗證機構之代碼編號；及 the indication of the code number of organic control system shall appear in the same visual field as the organic production logo of the European Union, where it is used in the labelling; and 在標示中有機驗證機構代碼應出現在與歐盟有機標章相同的視覺欄位中；及

- (b) in the case of prepacked food, the organic production logo of the European Union referred to in Article 33 shall also appear on the packaging, except in cases referred to in Article 30(3) and points (b) and (c) of Article 30(5). 對於預包裝食品，包裝上亦應出現第 33 條所指歐盟有機生產標章，但第 30(3)條及第 30(5)條第(b)和(c)點所指情況，不在此限。
2. Where the organic production 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 appear in the same visual field as the logo and shall take one of the following forms, as appropriate: 若使用歐盟有機生產標章，則就構成產品之農業原材料，應在標章同一目視欄位內標示種植地，並應採取以下任一格式(如適當)：
- (a) ‘EU Agriculture’, where the agricultural raw material has been farmed in the Union;
「歐盟農業」，若該農業原材料在歐盟內種植；
- (b) “non-EU Agriculture”, where the agricultural raw material has been farmed in third countries; "非
「非歐盟農業」，若該農業原材料在第三國種植；
- (c) EU/non-EU Agriculture’, where a part of the agricultural raw materials has been farmed in the Union and a part of it has been farmed in a third country.
「歐盟/非歐盟農業」，若農業原材料中有一部分在歐盟境內種植，又有一部分在第三國種植。

For the purposes of the first subparagraph, the words ‘EU’ and ‘non-EU’ may be replaced or supplemented by the name of a country, or by the name of a country and a region, if all of the agricultural raw materials of which the product is composed have been farmed in that country and, if applicable, in that region.

就第 1 款而言，若構成該產品之所有農業原材料，都在某個國家及在某個地區(如適用)種植，則「歐盟」及「非歐盟」文字，得以該國家名稱或該國家及該地區名稱代之或補充之。

For the indication of the place where the agricultural raw materials of which the product is composed have been farmed, as referred to in the first and third subparagraphs, small quantities by weight of ingredients may be disregarded, provided that the total quantity of the disregarded ingredients does not exceed 5 % of the total quantity by weight of agricultural raw materials.

對構成產品之農業原材料，如第 1、3 款所指標示種植地，若含量少的原料，其總重量佔農業原材料總重量比例不到 5%，則該成分得不予標示。

The indication of the place where the agricultural raw materials of which the product is composed have been farmed shall be placed immediately below the code number referred to in paragraph 2 of this Article. 產品所含農業原材料種植地說明，應緊接在本條第 2 項規定的代號以下。

The words ‘EU’ or ‘non-EU’ shall not appear in a colour, size and style of lettering that is more prominent than the name of the product. 「歐盟」或「非歐盟」一詞，不得採較產品名稱更突出的顏色、大小和字體。

3. The indications referred to in paragraphs 1 and 2 of this Article and in Article 33(3) shall be marked in a conspicuous place in such a way as to be easily visible, and shall be clearly legible and

indelible. 本條第 1 及 2 項及第 33(3)條所指標示，應在顯眼處以易見方式做標誌，並應清晰易讀及無法擦掉。

Article 33 Organic production logo of the European Union 歐盟有機生產標章

1. The organic production logo of the European Union may be used in the labelling, presentation and advertising of products which comply with this Regulation. 符合本法之產品，其標示、展示及廣告得使用歐盟有機生產標章。

The organic production logo of the European Union may also be used for information and educational purposes related to the existence and advertising of the logo itself, provided that such use is not liable to mislead the consumer as regards the organic production of specific products, and provided that the logo is reproduced in accordance with the rules set out in Annex V. In such case, the requirements of Article 32(2) and point 1.7 of Annex V shall not apply. 歐盟有機生產標章，亦得用於與標章本身存在和廣告相關之資訊和教育目的，但須符合兩個條件，一是該使用不會在特定產品之有機生產方面誤導消費者，二是標章係依附件 5 所載規則複製者。在這種情況下，第 32(2)條和附件 5(1.7)之要求不適用。

The organic production logo of the European Union shall not be used for processed food as referred to in points (b) and (c) of Article 30(5) and for in-conversion products as referred to in Article 30(3). 第 30(5)條第(b)和(c)點所指加工食品和第 30(3)條所指有機轉型期產品，不得使用歐盟有機生產標章。

2. Except where used in accordance with the second subparagraph of paragraph 1, the organic production logo of the European Union is an official attestation in accordance with Articles 86 and 91 of Regulation (EU) 2017/625. 除依第 1 項第 2 段使用歐盟有機生產標章外，歐盟有機生產標章是依(EU)2017/625 號規章第 86 條及 91 條規定之官方證明。
3. The use of the organic production logo of the European Union shall be optional for products imported from third countries. Where that logo appears in the labelling of such products, the indication referred to in Article 32(2) shall also appear in the labelling. 從第三國進口之產品，得選擇使用歐盟有機生產標章。若該標章出現在該等產品之標示中，則標示中亦應出現第 32(2)條所指標示。
4. The organic production logo of the European Union shall follow the model set out in Annex V, and shall comply with the rules set out in that Annex. 歐盟有機生產標章應遵守附件 5 所列載範本，並應遵循該附件所列載規則。
5. National logos and private logos may be used in the labelling, presentation and advertising of products which comply with this Regulation. 若產品符合本法，則該產品之標示、展示及廣告得使用國家標章和私人標章。

Chapter V. CERTIFICATION 驗證

Article 34 Certification system 驗證系統

1. Prior to placing any products on the market as ‘organic’ or as ‘in-conversion’ or prior to the conversion period, operators and groups of operators referred to in Article 36 which produce, prepare, distribute or store organic or in-conversion products, which import such products from a third country or export such products to a third country, or which place such products on the market, shall notify their activity to the competent authorities of the Member State in which it is carried out and in which their undertaking is subject to the control system. 在將任何產品作為「有機產品」或「有機轉型期產品」投放市場前，或在有機轉型期前，第 36 條所指農產品經營者和農產品經營者集團，生產、調製、流通(配銷)或儲存有機產品或有機轉型期產品，從第三國進口或向第三國出口該等產品，或將該等產品投放市場，農產品經營者和農產品經營者集團應將其活動，通知活動進行所在會員國之主管機關，承諾會遵守該主管機關之管制系統。

The operators or groups of operators shall indicate in the notification referred to in the first subparagraph TOC verifies whether their activity complies with this Regulation and provides the certificate referred to in Article 35(1). 農產品經營者或農產品經營者集團應在第 1 款所指通知中指明，慈心查證其活動是否符合本法，並提供第 35(1)條所指證書。

2. Operators that sell prepacked organic products directly to the final consumer or user shall be exempted from the notification obligation referred to in paragraph 1 of this Article and from the obligation to be in the possession of a certificate referred to in Article 35(2) provided that they do not produce, prepare, store other than in connection with the point of sale, or import such products from a third country, or subcontract such activities to another operator. 直接向最終消費者或用戶販售預包裝有機產品之農產品經營者，應免除本條第 1 項所指通知義務，亦免除持有第 35(2)條所指證書，惟該等農產品經營者不做以下活動：生產、調製、儲存(與販售點有關者除外)、或從第三國進口該等產品、或將該等活動委外給另一農產品經營者。
3. Where operators or groups of operators subcontract any of their activities to third parties, both the operators or groups of operators and the third parties to whom those activities have been subcontracted shall comply with paragraph 1, unless the operator or group of operators has declared in the notification referred to in paragraph 1 that it remains responsible as regards organic production and that it has not transferred that responsibility to the subcontractor. In such cases, TOC shall verify that the subcontracted activities comply with this Regulation, in the context of the control it carries out on the operators or groups of operators that have subcontracted their activities. 若農產品經營者或農產品經營者集團將其任何活動委外給第三方，農產品經營者或農產品經營者集團及承包這些活動之第三方，均應遵守第 1 項規定，但若農產品經營者或農產品經營者集團已在第 1 項所指通知中聲明，其仍然對有機生產負責，又其未將該責任移轉給分包商。在這種情況下，慈心應對已將活動委外之農產品經營者或農產品經營者集團進行管制的情形下，查證委外活動是否符合本法。

4. *Conserved*
5. Operators, groups of operators and subcontractors shall keep records in accordance with this Regulation on the different activities they engage in. 農產品經營者、農產品經營者集團和分包商，應依法保存其參與不同活動之紀錄。
6. TOC shall keep updated lists containing the names and addresses of operators and groups of operators that have notified their activities in accordance with paragraph 1 and shall make public in an appropriate manner, including by means of links to a single internet website, a comprehensive list of this data, together with the information relating to the certificates provided to those operators and groups of operators in accordance with Article 35(1). When doing so, TOC shall comply with the requirements for the protection of personal data under Regulation (EU) 2016/679 of the European Parliament and of the Council. 慈心應隨時更新清單，包含農產品經營者和農產品經營者集團依第 1 項通知其活動之名稱和地址，並應以適當方式公布，包括藉由連結單一網路網站，本資料完整清單，連同依第 35(1)條規定，頒發給該等農產品經營者及農產品經營者集團證書所涉資訊。如此作為時，慈心應遵循歐洲議會及歐盟理事會(EU) 2016/679 號規章中，關於保護個人資料之要求。
7. TOC shall ensure that any operator or group of operators that complies with this Regulation and, in cases where a fee is collected in accordance with Articles 78 and 80 of Regulation (EU) 2017/625, that pays a reasonable fee covering the cost of controls is entitled to be covered by the control system. TOC shall ensure that any fees that may be collected are made public. 慈心應確保，遵循本法之任何農產品經營者或農產品經營者集團，若依(EU) 2017/625 號規章第 78 條和第 80 條收取費用，則支付合理費用以涵蓋由管制系統承擔管制成本。慈心應確保公開所收取之任何費用。

Article 35 Certificate 證書

1. TOC shall provide a certificate to any operator or group of operators that has notified its activity in accordance with Article 34(1) and complies with this Regulation. The certificate shall: 任何農產品經營者或農產品經營者集團依第 34(1)條通知其活動並遵守本法之規定，慈心應對該等農產品經營者或農產品經營者集團提供證書。證書應：
 - (a) be issued in electronic form wherever possible; 盡可能以電子形式頒發；
 - (b) allow at least the identification of the operator or group of operators including the list of the members, the category of products covered by the certificate and its period of validity; 至少能夠識別農產品經營者或農產品經營者集團，包括成員清單、證書涵蓋之產品類別及其有效期；
 - (c) certify that the notified activity complies with this Regulation; and 證明所通知之活動符合本法；及
 - (d) be issued in accordance with the model set out in Annex VI of this Regulation. 參照本法規附件六所載範本頒發。
2. Without prejudice to paragraph 8 of this Article and to Article 34(2), operators and groups of

operators shall not place products referred to in Article 2(1) on the market as organic products or in-conversion products unless they are already in possession of a certificate as referred to in paragraph 1 of this Article. 在不影響本條第 8 項和第 34(2)條情況下，農產品經營者和農產品經營者集團不得將第 2(1)條所指產品，作為有機產品或有機轉型期產品投放市場，但若農產品經營者和農產品經營者集團已經持有本條第 1 項所指證書者，不在此限。

3. The certificate referred to in this Article shall be an official certificate within the meaning of point (a) of Article 86(1) of Regulation (EU) 2017/625. 本條所指證書應為(EU)2017/625 號規章第 86(1)條第(a)點含義內之官方證書。
4. An operator or a group of operators shall not be entitled to obtain a certificate from more than one control body in relation to activities carried out in the same Member State regarding the same category of products, including cases in which that operator or group of operators operates at different stages of production, preparation and distribution. 一個農產品經營者或一個農產品經營者集團無權從一個以上管制機構，取得與在同一會員國內展開同類別產品活動有關之證書，包括該農產品經營者或農產品經營者集團在生產、調製及流通(配銷)不同階段之運作。
5. Members of a group of operators shall not be entitled to obtain an individual certificate for any of the activities covered by the certification of the group of operators to which they belong. 農產品經營者集團之成員，不得就其所隸屬農產品經營者集團之驗證所涵蓋的任何活動取得個人證書。
6. Operators shall verify the certificates of those operators that are their suppliers. 農產品經營者對於其供應商，應查證該供應商之農產品經營者證書。
7. For the purposes of paragraphs 1 and 4 of this Article, products shall be classified in accordance with the following categories: 就本條第 1 項和第 4 項之目的而言，產品應依以下類別進行分類：
 - (a) unprocessed plants and plant products, including seeds and other plant reproductive material; 未加工植物及植物產品，包括種子及其他植物繁殖材料；
 - (b) *Conserved*
 - (c) *Conserved*
 - (d) processed agricultural products, including aquaculture products, for use as food; 用作食品之加工農產品；
 - (e) *Conserved*
 - (f) *Conserved*
 - (g) *Conserved*
8. TOC may exempt from the obligation to be in the possession of a certificate, provided for in paragraph 2, operators that sell unpacked organic products directly to the final consumer, provided that those operators do not produce, prepare, store other than in connection with the point of sale, or import such products from a third country, or subcontract such activities to a third party, and provided that: 直接向最終消費者販售未包裝有機產品之農產品經營者，慈心得免除其第 2 項規定持有證書之義務，惟該等農產品經營者不做以下活動：生產、調製、貯存(與販售點

有關者除外)、或從第三國進口該等產品、或將該等活動委外給第三方，但須先符合以下條件：

- (a) such sales do not exceed 5,000 kg per year; 該等銷售量每年不超過 5,000 公斤；
- (b) such sales do not represent an annual turnover in relation to unpacked organic products exceeding EUR 20,000; or 未包裝有機產品的年營業額不超過 20,000 歐元；或
- (c) the potential certification cost of the operator exceeds 2% of the total turnover on unpacked organic products sold by that operator. 農產品經營者之潛在驗證成本，超過該農產品經營者販售未包裝有機產品總營業額之 2%。

If a TOC decides to exempt the operators referred to in the first subparagraph, it may set stricter limits than those set in the first subparagraph. 若慈心決定免除第 1 款所指農產品經營者，則慈心可以設定比第 1 款設定之限制更嚴格。

TOC shall inform the Commission of any decision to exempt operators pursuant to the first subparagraph and of the limits up to which such operators are exempted. 慈心依第 1 款免除農產品經營者之任何決定，以及該等農產品經營者被免除之限制到哪個程度，應通知歐盟執委會。

Article 36 Group of operators 農產品經營者集團

- 1. Each group of operators shall: 每個農產品經營者集團：
 - (a) only be composed of members who are farmers or operators who in addition may be engaged in processing, preparation or placing on the market of food; 其成員應僅由農民或農產品經營者組成，這些成員得額外從事食品加工、調製或投放市場之工作；
 - (b) only be composed of members: 僅由以下成員組成：
 - (i) of which the individual certification cost represents more than 2 % of each member's turnover or standard output of organic production and whose annual turnover of organic production is not more than EUR 25 000 or whose standard output of organic production is not more than EUR 15 000 per year; or 個人驗證成本占每個成員有機產品營業額或標準產量之 2% 以上，且有機產品年營業額不超過 25,000 歐元、或有機產品標準產量不超過每年 15,000 歐元；或
 - (ii) who have each holdings of maximum: 擁有的每個經營主體最大：
 - five hectares, 5 公頃
 - 0,5 hectares, in the case of greenhouses, or 溫室的話 0.5 公頃，或
 - 15 hectares, exclusively in the case of permanent grassland; 15 公頃，僅限永久草原；
 - (c) be established in a third country; 在第三國設立；
 - (d) have legal personality; 具有法人資格；
 - (e) only be composed of members whose production activities take place in geographical proximity to each other; 僅由其生產活動或第(a)點所述可能的額外活動在同一第三國的地理位置附近進行的成員組成；
 - (f) set up a joint marketing system for the products produced by the group; and 為集團生產產品建立聯合行銷體系；及

- (g) establish a system for internal controls comprising a documented set of control activities and procedures in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group. 建立內控系統，包括一套有文件記錄的管制活動和程序，由特定個人或機構負責核查集團各成員是否符合本法。

The system for internal controls (ICS) shall comprise documented procedures on: 內控系統 (ICS) 應包括以下方面的文件程序：

- (i) the registration of the members of the group; 集團成員註冊；
 - (ii) the internal inspections, which include the annual internal physical on-the-spot inspections of each member of the group, and any additional risk-based inspections, in any case scheduled by the ICS manager and conducted by ICS inspectors, whose roles are defined in point (h); 內部稽查包括每年對集團成員進行內部現場稽核，及任何其他基於風險的檢查，在任何情況下，由內控系統管理者安排、內控系統稽查員進行，其職能均定義於第(h)點；
 - (iii) the approval of new members in an existing group or, where appropriate, the approval of new production units or new activities of existing members upon the approval by the ICS manager on the basis of the internal inspection report; 以內部稽查報告為基礎，由內控系統管理者核准現有集團的新成員，或新生產單位、現有成員新活動(如適用)。
 - (iv) the training of the ICS inspectors, which is to take place at least annually and to be accompanied by an assessment of the knowledge acquired by the participants; 對內控系統稽查員進行至少每年一次培訓，同時對受訓者所獲知識進行評估；
 - (v) the training of members of the group on the ICS procedures and the requirements of this Regulation; 就內控系統程序和本法的要求，對集團成員進行培訓；
 - (vi) the control of documents and records; 對文件和記錄的管制；
 - (vii) the measures in cases of non-compliance detected during the internal inspections, including their follow-up; 在內部稽核中發現不符合情況下採取的措施，包括他們的後續追蹤；
 - (viii) the internal traceability, which shows the origin of the products delivered in the joint marketing system of the group and allows the tracing of all products of all members throughout all stages, such as production, processing, preparation or placing on the market, including estimating and cross-checking the yields of each member of the group. 內部可追溯性，顯示在集團聯合行銷系統中的配售產品的來源，並允許在所有階段(如：生產、加工、調製或投放)追溯全體成員全數產品，包括估算和交叉檢查集團各成員產量。
- (h) appoint an ICS manager and one or more ICS inspectors who may be a member of the group. Their positions shall not be combined. The number of ICS inspectors shall be adequate and proportional in particular to the type, structure, size, products, activities and output of organic production of the group. The ICS inspectors shall be competent with regard to the products and activities of the group. 任命一名內控系統管理者和一或多名內控系統稽查員，其可能為該集團成員，其職位不得合併。特別就集團有機生產的類型、結構、規模、產品、活動和產出，內控系統稽查員人數應充足和與之相稱。內控系統稽查員應對集團的產品和活動具有能力。

The ICS manager shall: 內控系統管理者應：

- (i) verify the eligibility of each member of the group regarding the criteria set out in points (a), (b) and (e); 核實集團各成員是否符合第(a)、(b)、(e)項規定標準；
- (ii) ensure that there is a written and signed membership agreement between each member and the group, by which the members commit themselves to: 確保各成員與集團間有一書面簽署的成員協定，由成員承諾：
 - comply with this Regulation, 符合本法；
 - participate in the ICS and comply with the ICS procedures, including the tasks and responsibilities assigned to them by the ICS manager and the obligation for records keeping, 參與內控系統並遵守其程序，包括管理者分配的任務和責任、及保存記錄義務；
 - permit access to production units and premises and be present during the internal inspections carried out by the ICS inspectors and official controls carried out by TOC, make available to them all documents and records and countersign the inspection reports, 允許內控系統稽查員進行內部稽查以及慈心執行正式管制時進入生產單位和場所，並於期間在場，提供所有文件記錄，並簽署檢查報告。
 - accept and implement the measures in cases of non-compliances in accordance with the decision of the ICS manager or TOC, within the given time-frame, 在不符合情況下，根據內控系統管理者或慈心的決定，在規定時限內，接受並執行有關措施。
 - immediately inform the ICS manager on suspected non-compliance; 有不符合情況疑慮，立即通知內控系統管理者。
- (iii) develop the ICS procedures and the relevant documents and records, keep them up to date and make them readily available to the ICS inspectors, and where relevant, to the members of the group; 制定內控系統程序和相關文件記錄，隨時更新並隨時提供給內控系統稽查員，並向集團成員提出建議(如適用)；
- (iv) draw up the list of the members of the group and keep it up to date; 編制集團成員名單，並隨時更新；
- (v) assign tasks and responsibilities to the ICS inspectors; 分配任務和責任給內控系統稽查員；
- (vi) be the liaison between the members of the group and TOC, including requests for derogations; 集團成員與慈心間的聯絡，包括特例請求；
- (vii) verify annually the conflict of interest statements of the ICS inspectors; 每年核實內控系統稽查員的利益衝突聲明；
- (viii) schedule internal inspections and ensure their adequate implementation in accordance with the ICS manager's schedule referred to in point (g)(ii); 安排並確保內部稽查按照內控系統管理者根據第(g)(ii)點的時程表充分執行；
- (ix) ensure adequate trainings for the ICS inspectors and carry out an annual assessment of ICS inspectors' competences and qualifications; 確保對內控系統稽查員進行充分培訓，並對其能力和資格進行年度評估；
- (x) approve new members or new production units or new activities of existing members; 批准新成員、新生產單位或現有成員新活動；

- (xi) decide on measures in case of non-compliance in line with the ICS measures established by documented procedures in accordance with point (g) and ensure the follow-up of those measures; 不符合的裁定措施與根據第(g)點以文件化程序制定的內控系統措施一致，並確保此措施的後續追蹤；
- (xii) decide to subcontract activities, including the subcontracting of the tasks of ICS inspectors, and sign relevant agreements or contracts. 決定分包活動，包括分包內控系統稽查員的任務，並簽署相關協定合約。

The ICS inspector shall: 內控系統稽查員應：

- (i) carry out internal inspections of the members of the group according to the schedule and the procedures provided by the ICS manager; 根據內控系統管理者提供的時間表和程序，對集團成員進行內部稽查；
- (ii) draft internal inspection reports on the basis of a template and submit it within a reasonable time to the ICS manager; 根據範本起草內部稽查報告，並在合理時間內提交給內控系統管理者；
- (iii) submit at appointment a written and signed statement on conflict of interest and update it annually; 在任命時提交關於利益衝突的書面簽署聲明，並每年更新一次；
- (iv) participate in trainings. 參加培訓。

1.1 Official controls of groups of operators 對農產品經營者集團的官方管制

- (a) In order to certify and verify the compliance of a group of operators, TOC shall assign inspectors competent to assess systems for internal controls (ICS). 為驗證核查農產品經營者集團的符合性，慈心應指派有能力評估內部管制系統的稽查員。
- (b) For the purpose of evaluating the set-up, functioning and maintaining of the ICS of a group of operators, the competent authority or, where appropriate, the control authority or control body, shall determine at least that: 為評估農產品經營者集團的內控系統的建置、運作和維護，慈心至少應確定：
 - (i) the documented procedures of the ICS that have been put in place comply with the requirements; 內控系統已實施符合規定的文件程序；
 - (ii) the list of members of the group of operators with the required information for each member is continuously updated and aligned with the scope of the certificate; 持續更新具有各成員所需資訊的農產品經營者集團成員清冊，並與證書的範圍保持一致；
 - (iii) all members of the group of operators comply with the criteria set out in Article 36(1)(a), (b) and (e) throughout their participation in the group of operators; 集團所有成員在其參與集團經營的整個過程中，均符合第 36(1)(a)、(b)、(e)條；
 - (iv) the number, training and competence of ICS inspectors are proportionate and adequate and ICS inspectors are without conflicts of interest; 內控系統稽查員的人數、培訓和能力是相稱和適當的，且沒有利益衝突；
 - (v) the internal inspections of all members of the group of operators and their activities and production units or premises including purchase and collection centres have been carried out at least annually and are documented; 每年至少一次對集團所有成員及其活動和生產單位或場所(包括採購和

收集中心)進行內部稽查，並記錄在案；

- (vi) new members or new production units and new activities of existing members, including new purchase and collection centres, have been accepted only after they have been approved by the ICS manager on the basis of the internal inspection report according to the ICS documented procedures that have been put in place; 新成員或新生產單位和現有成員新活動（包括新採購和收集中心），唯有在根據內控系統已實施的文件化程序、由內控系統管理者根據內部稽查報告核准後，才被接受。
- (vii) the ICS manager takes appropriate measures in case of non-compliance, including their follow up, according to the ICS documented procedures that have been put in place; 內控系統管理者根據內控系統已實施的文件化程序，在出現不符合情況時採取適當措施，包括採取後續追蹤；
- (viii) the ICS manager's notifications to TOC are appropriate and sufficient; 內控系統管理者向慈心發出的通知適當且充分；
- (ix) the internal traceability for all products and members of the group of operators is ensured by estimating quantities and by cross-checking the yields of each member of the group of operators; 藉由估算數量和交叉檢查集團各成員的產量，確保所有產品和集團成員的內部可追溯性；
- (x) the members of the group of operators receive adequate training on the ICS procedures and the requirements of this Regulation. 集團成員接受根據內控系統程序和本法要求的充分培訓。
- (c) TOC shall apply risk assessment to select the sample of the members of the group of operators for the re-inspections in accordance with Article 38(4)(d). In doing so, it shall take into account at least the volume and the value of the production and the assessment of the likelihood of non-compliance with this Regulation. Re-inspections shall be carried out physically on the spot with the presence of the members selected. 慈心應採用風險評估方法，根據第 38(4)(d)條規定選擇供重新查驗的農產品經營者集團成員樣本。在此過程中，應至少考量生產的數量和價值，並評估其不符合可能性。重新查驗應在選定成員在場情況下，實地進行。
- (d) TOC shall allocate reasonable time for the control of a group of operators, proportional to the type, structure, size, the products, the activities and output of organic production of the group of operators. 慈心應依據經營主體的類型、結構、規模、產品、活動和產出，為農產品經營者集團的管制分配合理時間。
- (e) TOC shall carry out witness audits in order to verify the competence and knowledge of ICS inspectors. 慈心應進行見證稽核，以核查內控系統稽查員的能力和知識。
- (f) TOC shall assess whether there is a failure of the ICS based on the number of non-compliances undetected by the ICS inspectors and the result of the investigation of the cause and the nature of the non-compliances. TOC 應根據內控系統稽查員未發現的不符合情況的數量及其對不符合起因和性質的調查結果，評估內控系統是否有失誤。
- 2. TOC shall withdraw the certificate referred to in Article 35 for the whole group where deficiencies in the set-up or functioning of the system for internal controls referred to in paragraph 1, in particular as regards failures to detect or address non-compliance by individual members of the group of operators, affect the integrity of organic and in-conversion products. 在第 1 項所述內部

管制系統之建置或運作存在缺陷時，慈心應撤回整個集團第 35 條所指證書，尤其是未能偵測到或解決農產品經營者集團中個別成員有不符合者，會影響有機產品和有機轉型期產品之完整性。

At least the following situations shall be considered as deficiencies in the ICS: 至少下列情況應視為內控系統的缺陷：

- (a) producing, processing, preparing or placing on the market of products from suspended/withdrawn members or production units; 生產、加工、調製或投放暫停/退出的成員或生產單位的產品；
- (b) placing on the market of products for which the ICS manager has prohibited the use of reference to organic production in their labelling or advertising; 將內控系統管理者已禁止在其標示或廣告中提及有機生產的產品銷售；
- (c) adding new members to the list of members or changing the activities of existing members without following the internal approval procedure; 在成員名單中增加新成員或改變現有成員活動，但未遵循內部核准程序；
- (d) not carrying out the annual physical on-the-spot inspection of a member of the group in a given year; 未對集團成員進行當年度現場稽查；
- (e) failing to indicate the members which have been suspended or withdrawn in the list of members; 未在成員名單中註明被停權或撤銷的成員；
- (f) serious deviations in findings between internal inspections carried out by the ICS inspectors and official controls carried out by TOC; 內控系統稽查員進行的內部稽查與慈心進行官方管制的調查結果嚴重偏差；
- (g) serious deficiencies in imposing appropriate measures or carrying out the necessary follow-up in response to non-compliance identified by the ICS inspectors or by TOC; 針對內控系統稽查員或慈心查明的不符合情況，在採取適當措施或採取必要的後續追蹤方面存在嚴重缺陷；
- (h) inadequate number of ICS inspectors or inadequate competences of ICS inspectors for the type, structure, size, products, activities and output of organic production of the group. 內控系統稽查員人數不足或稽查員對該集團有機生產的類型、結構、規模、產品、活動和產出的職能不足。

3. Composition and dimension of a group of operators 農產品經營者集團的組成和規模

A member of a group of operators shall register to only one group of operators for a given product, also where the operator is engaged in different activities related to that product. 集團成員應只向一集團註冊為某一特定產品，及經營者從事與該產品有關不同活動的情況。

The maximum size of a group of operators shall be 2,000 members. 農產品經營者集團的最大規模應為 2,000 名成員。

4. Documents and records of a group of operators 農產品經營者集團文件記錄

The group of operators shall keep the following documents and records for the purposes of the system for internal controls (ICS): 為內部管制系統目的，農產品經營者集團應保存下列文件記錄：

- (a) the list of members of the group of operators based on their registration of each member and consisting of the following elements for each member of the group of operators: 集團成員清冊，以其各成員註冊為基礎，應包含各成員以下事項：
 - (i) name and identification (code number); 名稱和標識(代碼)；
 - (ii) contact details; 聯繫方式；
 - (iii) date of registration; 註冊日期；
 - (iv) total land surface under the management of the member and whether it is part of an organic, in-conversion or non-organic production unit; 由該成員管理的土地總面積，及該土地是有機、轉型期或非有機生產單位的一部分；
 - (v) information on each production unit and/or activity: size, location, including a map where available, product, date of the beginning of the conversion period and yield estimates; 關於各生產單位和/或活動資訊：規模、位置，包括現有地圖、產品、轉型期開始日期和預估產量；
 - (vi) date of the last internal inspection with the name of the ICS inspector; 最後一次內部稽查的日期及內控系統稽查員姓名；
 - (vii) date of the last official control performed by TOC with the name of the inspector; 由慈心稽查員具名所進行的最近一次官方管制日期；
 - (viii) date and version of the list; 清冊的日期版本；
- (b) the signed membership agreements between the member and the group of operators as legal person, which shall include the rights and responsibilities of the member; 成員與法人農產品經營者集團簽訂的成員協議，其中應包括成員的權利義務；
- (c) the internal inspection reports signed by the ICS inspector and the inspected member of the group of operators and including at least the following elements: 由內控系統稽查員和受查的集團成員簽署的內部稽查報告，其中至少包括以下內容：
 - (i) the name of the member and the location of the production unit or premises, including purchase and collection centres where the activities referred to in point (a) of paragraph (1) subject to the inspection take place; 成員名稱和生產單位或場所地點，包括進行第(1)(a)項所述稽查的採購和收集中心；
 - (ii) the date and starting and ending hour of the internal inspection; 內部稽查日期、開始時間和結束時間；
 - (iii) the findings of the inspection; 稽查結果；
 - (iv) the audit scope/perimeter; 稽查範圍/界線
 - (v) the date of issue of the report; 報告發表日期；
 - (vi) the name of the internal inspector; 內部稽查員姓名；
- (d) the training records of the ICS inspectors consisting of: 內控系統稽查員培訓記錄，包括：
 - (i) the dates of the training; 培訓日期；
 - (ii) the subject matter of the training; 培訓主題事項；
 - (iii) the name of the trainer; 培訓員姓名；
 - (iv) the signature of the trainee; 受訓者簽名；

- (v) where appropriate, an assessment of the knowledge acquired; 評量所獲知識評量(如適用)；
- (e) the training records of the members of the group of operators; 集團成員培訓記錄；
- (f) the records of the measures taken in case of non-compliance by the ICS manager, which shall include: 內控系統管理者在不符合情況下，所採取措施記錄，其中應包括：
- (i) the members subject to measures in case of non-compliance, including those suspended, withdrawn or required to comply with a new conversion period; 出現不符合情況時須採取措施的成員，包括被暫停、撤回或必須符合新轉型期的成員；
- (ii) documentation of identified non-compliance; 不符合情事查明文件；
- (iii) documentation of follow-up of the measures; 各項措施後續追蹤紀錄；
- (g) traceability records, including information on the quantities, on the following activities, where relevant: 有關下列活動的追溯記錄，包括相關數量資訊：
- (i) purchase and distribution of farm inputs including plant reproductive material by the group; 該集團採購和分配的農業投入物，包括植物繁殖材料；
- (ii) production including harvest; 包括採收在內的生產；
- (iii) storing; 儲存；
- (iv) preparation; 調製；
- (v) delivery of products from each member to the joint marketing system; 各成員配送給聯合行銷系統的產品；
- (vi) placing on the market of products by the group of operators; 農產品經營者集團將產品投放到市場；
- (h) the written agreements and contracts between the group of operators and subcontractors including information on the nature of the subcontracted activities; 農產品經營者集團和分包商間的書面協議合約，包括關於分包活動性質資料；
- (i) the appointment of the ICS manager; 內控系統管理者的任命；
- (j) the appointment of the ICS inspectors as well as the list of ICS inspectors. 內控系統稽查員的任命及其名單。

The list of members referred to in point (a) shall be updated by the ICS manager after any modification of the elements listed in point (a)(i) to (viii) and it shall be indicated whether any of the members has been suspended or withdrawn due to measures in case of non-compliance resulting from internal inspections or official controls. 第(a)點所指成員名單由內控系統管理者更新；經內部稽查或官方管制發現不符合情況所採取措施，在對第(a)(i)至(viii)點所列事項進行任何修改後，須註明是否有任何成員已被暫停或撤回。

5. Notifications from the ICS manager 內控系統管理者通知

The ICS manager shall immediately notify TOC of the following information: 內控系統管理者應立即將下列資訊通知慈心：

- (a) any suspicion of major and critical non-compliance; 對重大和關鍵不符合行為的任何疑慮；

- (b) any suspension or withdrawal of a member or a production unit or premises, including purchase and collection centres, from the group; 成員或生產單位或場所（包括採購和收集中心）暫停或退出該集團；
- (c) any prohibition of the placing on the market of a product as organic or in-conversion, including the name of the member or members concerned, the relevant quantities and lot identification. 任何禁止將產品作為有機或有機轉型期產品銷售的禁令，包括相關成員姓名、相關數量和批號識別。



Chapter VI. OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES 官方管制和其他官方活動

Article 37 Relationship with Regulation (EU) 2017/625 and additional rules for official controls and other official activities in relation to organic production and labelling of organic products

有機產品之有機生產及標示：與(EU)2017/625 號規章及官方管制及其他官方活動補充規則之關係

The specific rules of this Chapter shall apply, in addition to the rules laid down in Regulation (EU) 2017/625, save as otherwise provided for in Article 40(2) of this Regulation, and in addition to Article 29 of this Regulation, save as otherwise provided for in Article 41(1) of this Regulation, to the official controls and other official activities performed to verify throughout the entire process at all stages of production, preparation and distribution that the products referred to in Article 2(1) of this Regulation have been produced in compliance with this Regulation. 本章所列之特定規則、(EU) 2017/625 號規章所制定之規則(但本法第 40(2)條另有規定者除外)及本法第 29 條(但本法第 41(1)條另有規定者除外)，應適用之官方管制及其他官方活動，係針對本法第 2(1)條所指符合本法生產之產品，履行完整查證其生產、調製、流通(配銷)所有階段之整個過程。

Article 38 Additional rules on official controls and on action to be taken by the competent authorities 對官方管制和主管機關採取行動之附加規則

- 1 Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall include, in particular: 為查證對本法之符合性，依(EU)2017/625 號規章第 9 條履行之官方管制，應包括：
 - (a) the verification of the application by operators of preventive and precautionary measures, as referred to in Article 9(6) and in Article 28 of this Regulation, at every stage of production, preparation and distribution; 查證農產品經營者在生產、調製、流通(配銷)每個階段，應用本法第 9(6)條和第 28 條所指預防和防護措施之情況；
 - (b) where the holding includes non-organic or in-conversion production units, the verification of the records and of the measures or procedures or arrangements in place to ensure the clear and effective separation between organic, in-conversion and non-organic production units as well as between the respective products produced by those units, and of the substances and products used for organic, in-conversion and non-organic production units; such verification shall include checks on parcels for which a previous period was recognised retroactively as part of the conversion period, and checks on the non-organic production units; 若經營主體包含非有機或有機轉型期生產單位，則一方面查證實施之紀錄及措施或程序或安排，以確保有機或有機轉型期及非有機生產單位之間，以及這些單位各自生產的產品，彼此之間區隔明確有效，以及另一方面查證用於有機、有機轉型期及非有機生產單位之物質及產品；該等查證應包括查核追認上期地塊屬於有機轉型期的一部分，及查核非有機生產單位；

- (c) where organic, in-conversion and non-organic products are collected simultaneously by operators, are prepared or stored in the same preparation unit, area or premises, or are transported to other operators or units, the verification of the records and of the measures, procedures or arrangements in place to ensure that operations are carried out separated by place or time, that suitable cleaning measures and, where appropriate, measures to prevent substitution of products are implemented, that organic products and in-conversion products are identified at all times and that organic, in-conversion and non-organic products are stored, before and after the preparation operations, separated by place or time from each other; 若農產品經營者同時收集有機產品、轉型期產品及非有機產品，在同一調製單位、區域或場所調製或儲存，或運送給其他農產品經營者或單位，則查證實施之紀錄及措施或程序或安排，以確保該等作業係按地點或時間分開執行，其次，確保實施合適之清潔措施及預防產品替代措施(如適當)，第三，確保在所有時間都能分辨出有機產品及有機轉型期產品，及第四，確保有機產品、有機轉型期產品及非有機產品，在調製操作之前及之後，都能以按地點或時間彼此區隔之方式儲存；業
- (d) the verification of the set-up and functioning of the internal control system of groups of operators; 查證農產品經營者集團內部管制系統之建立和運作；
- (e) where operators are exempted from the notification obligation in accordance with Article 34(2) of this Regulation, the verification that the requirements for that exemption have been fulfilled and the verification of the products sold by those operators. 若農產品經營者依本法第 34(2)條規定免除通知義務，或依本法第 35(8)條規定免除持有證書義務，則查證是否已經滿足該免除之要求，並查證該等農產品經營者販賣之產品。
- 2 Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall be performed throughout the entire process at all stages of production, preparation and distribution on the basis of the likelihood of non-compliance as defined in point (57) of Article 3 of this Regulation, which shall be determined taking into account, in addition to the elements referred to in Article 9 of Regulation (EU) 2017/625, in particular the following elements: 為查證對本法之符合性，依(EU) 2017/625 號規章第 9 條規定履行之官方管制，應在生產、調製及流通(配銷)所有階段之整個過程完整履行，基於不符合可能性(如本法第 3 條第(57)點所定義者)，除(EU) 2017/625 號規章第 9 條所指要素外，還應決定要考慮哪些元素，尤其是以下元素：
- (a) the type, size and structure of the operators and groups of operators; 農產品經營者和農產品經營者集團之類型、規模及結構；
- (b) the length of time during which operators and groups of operators have been involved in organic production, preparation and distribution; 農產品經營者和農產品經營者集團參與有機生產、調製及流通(配銷)之時間長度；
- (c) the results of the controls performed in accordance with this Article; 依本條履行管制之結果；
- (d) the point in time relevant for the activities carried out; 與活動進行相關之時間點；
- (e) the product categories; 產品類別；

- (f) the type, quantity and value of products and their development over time; 產品之類型、數量及價值，以及產品隨時間之發展；
- (g) the possibility of commingling of products or contamination with non-authorized products or substances; 產品遭混雜，或受到非授權產品或物質污染之可能性；
- (h) the application of derogations or exceptions to the rules by operators and groups of operators; 農產品經營者和農產品經營者集團對規則應用之豁免或例外；
- (i) the critical points for non-compliance and the likelihood of non-compliance at every stage of production, preparation and distribution; 在生產、調製及流通(配銷)每個階段，不符合之關鍵點及不符合之可能性；
- (j) subcontracting activities. 委外活動。

2.1 Methodology of an official investigation 官方調查的方法

- (a) Without prejudice to paragraph 2 of this Article, when carrying out an official investigation referred to in Article 29(1)(a) of this Regulation, TOC shall determine at least the following: 在不影響本條第 2 項的情況下，在進行本法第 29(1)(a)條所述正式調查時，慈心應至少確定下列事項
 - (i) the name, lot identification, ownership and physical location of the organic or in-conversion products concerned; 有關有機產品或有機轉型期產品的名稱、批次標識、所有權和實際位置；
 - (ii) whether the products concerned are still placed on the market as organic or in-conversion products or used in organic production; 有關產品是否仍作為有機或有機轉型期產品投放市場或用於有機生產；
 - (iii) the type, name, quantity and other relevant information of the present non-authorized products or substances; 非授權之產品或物質的類型、名稱、數量及其他有關資料；
 - (iv) at which stage of production, preparation, storing or distribution and where exactly the presence of non-authorized products or substances has been detected, in particular for plant production, whether the sample was taken pre-harvest or post-harvest; 在生產、調製、儲存或流通(配銷)的哪個階段，以及在哪裡檢測到非授權的產品或物質，特別是在植物生產中，樣品是在採收前還是採收後採集；
 - (v) whether other operators in the supply chain are affected; 供應鏈的其他農產品經營者是否受到影響；
 - (vi) the results of previous official investigations on the organic or in-conversion products and operators concerned. 先前對有機或有機轉型期產品及有關農產品經營者的正式調查結果。
- (b) The official investigation shall be pursued by using appropriate methods and techniques, including those referred to in Article 14 and Article 137(3) of Regulation (EU) 2017/625 of the European Parliament and of the Council. 正式調查應採用適當的方法和技術，包括(EU)2017/625 號規章第 14 條和第 137(3)條所述的方法和技術。
- (c) The official investigation shall at least conclude on: 正式調查應至少得出結論：
 - (i) the integrity of organic and in-conversion products; 有機和有機轉型期產品的完整性；
 - (ii) the source and the cause of the presence of non-authorized products or substances; 非授權產品或

物質的來源和原因；

- (iii) the elements provided in Article 29(2)(a), (b) and (c) of this Regulation. 第 29(2)(a)、(b)和(c)條規定的要素。
 - (d) TOC shall draw up a final report for each official investigation. That final report shall contain: 慈心應為每次正式調查起草最後報告。最後報告應包括：
 - (i) the records of the specific elements required pursuant to this Article; 根據本條要求的具體內容的記錄；
 - (ii) the records of the information exchanged with other control authorities and control bodies and the Commission related to this official investigation. 與其他管制機關和管制機構及歐盟執委會就這項正式調查交換資料的記錄。
- 3 In any case, all operators and groups of operators, with the exception of those referred to in Articles 34(2), shall be subject to a verification of compliance at least once a year. 在任何情況下，除第 34(2)條和第 35(8)條所指農產品經營者和農產品經營者集團外，所有農產品經營者和農產品經營者集團應至少每年接受一次符合性查證。

The verification of compliance shall include a physical on-the-spot inspection, except where the following conditions have been satisfied: 符合性查證應包括實體現場查驗，但若滿足以下條件者除外：

- (a) the previous controls of the operator or group of operators concerned have not revealed any non-compliance affecting the integrity of organic or in-conversion products during at least three consecutive years; and 有關農產品經營者或農產品經營者集團以前之管制措施，在至少連續三年內，未發現影響有機或有機轉型期產品完整性之任何不符合行為；及
- (b) the operator or group of operators concerned has been assessed on the basis of the elements referred to in paragraph 2 of this Article and in Article 9 of Regulation (EU) 2017/625 as presenting a low likelihood of non-compliance. 以本條第 2 項和(EU)2017/625 號規章第 9 條所指元素為基礎，評估有關農產品經營者或農產品經營者集團，認為不合規可能性低。

In this case, the period between two physical on-the-spot inspections shall not exceed 24 months. 在這種情況下，兩次實體現場查驗之間的時間間隔不得超過 24 個月。

3.1 Checks of documentary accounts 紀錄帳目核對

- (a) The physical on-the-spot inspection shall include a traceability check and a mass balance check of the operator or group of operators carried out by means of checks of documentary accounts. 實地現場查驗應包括可追溯性檢查，和藉由紀錄帳目檢查對農產品經營者或農產品經營者集團進行進出平衡檢查。
- (b) TOC shall perform the traceability and mass balance check according to the standard template documented in the written record referred to in paragraph 6. 慈心應根據第 6 項所述書面記錄的文件化標準範本進行可追溯性和進出平衡檢查。
- (c) For the purpose of the traceability check and mass balance check, the selection of products, groups of products and period under verification shall be made on a risk basis. 為進行可追溯性和進出平衡檢查，應在風險基礎上選擇產品、類別和查核期間。

- (d) The traceability check shall cover at least the following elements justified by appropriate documents including stock and financial records: 可追溯性檢查至少應包括下列適當文件所證明的要件，包括庫存和財務記錄：
- (i) the name and address of the supplier and, where different, of the owner or the seller, or the exporter of the products; 供應商名稱和地址，如不同，產品所有者或銷售者或出口商名稱地址；
 - (ii) the name and address of the consignee and, where different, of the buyer or importer of the products; 收貨人姓名地址，如不同，產品買方或進口商姓名地址；
 - (iii) the certificate of the supplier in accordance with Article 35(6); 供應商按照第 35(6)條簽發的證書；
 - (iv) the information referred to in point 2.1 of Annex III; 附件 III 第 2.1 點所述信息；
 - (v) the appropriate lot identification. 適當的批次識別。
- (e) Where relevant, the mass balance check shall cover at least the following elements justified by appropriate documents including stock and financial records: 相關情況下，進出平衡應至少包括下列由適當文件證明合理的要素，包括庫存和財務記錄：
- (i) the nature and the quantities of products delivered to the unit and, where relevant, of materials bought and the use of such materials, and, where relevant, the composition of products; 送達該單位的產品性質/數量，及在相關情況下，材料購買/使用、產品組成；
 - (ii) the nature and the quantities of products held in storage at the premises; 處所存放的產品性質數量；
 - (iii) the nature and the quantities of the products that have left the unit of operator or group of operators to the consignee's premises or storage facilities; 自農產品經營者或農產品經營者集團單位離開，發往收貨人處所或儲存設施的產品性質和數量
 - (iv) in case of operators who buy and sell the product(s) without physically handling the product(s), the nature and the quantities of products that have been bought and sold, and the suppliers, and where different, the sellers or the exporters and the buyers, and where different, the consignees; 若農產品經營者在未實際處理產品情況下買賣產品，則該產品的性質數量、供應商及，如不同，賣方或出口商和買方及，如不同，收貨人；
 - (v) the yield of the products obtained, collected or harvested over the previous year; 上年度取得、收集或採收的產品產量；
 - (vi) the actual yield of the products obtained, collected or harvested over the current year; 本年度取得、收集或採收的產品實際產量；
 - (vii) any losses, increase or decrease in quantity of products at any stage of production, preparation and distribution; 產品在生產、加工和流通任何階段的損失、增加或減少；
 - (viii) organic or in-conversion products that are sold on the market as non-organic. 作為非有機產品在市場上銷售的有機或有機轉型期產品。
- 4 Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall: 為查證對本法之符合性，依(EU)2017/625號規章第 9 條規定履行之官方管制應：

- (a) be performed in accordance with Article 9(4) of Regulation (EU) 2017/625 while ensuring that a minimum percentage of all official controls of operators or groups of operators are carried out without prior notice; 依(EU)2017/625 號規章第 9(4)條規定履行之，同時確保對農產品經營者或農產品經營者集團之所有官方管制的最低百分比是在沒有事先通知的情況下進行；
- (b) ensure that a minimum percentage of additional controls to those referred in paragraph 3 of this Article are carried out; 確保在本條第 3 項所指之附加管制，以最低百分比為之；
- (c) be carried out by taking a minimum number of the samples that have been taken in accordance with point (h) of Article 14 of Regulation (EU) 2017/625; (EU)2017/625 號規章第 14 條第(h)點規定，收集最少數量樣品為之；
- (d) ensure that a minimum number of operators that are members of a group of operators are controlled in connection with the verification of compliance referred to in paragraph 3 of this Article. 確保與本條第 3 項所指符合性查證相關之農產品經營者集團中，有最低數量的農產品經營者受到管制。

4.1 Minimum percentages of controls and sampling 管制和取樣之最低百分比

The following rules on minimum percentages shall apply to the official controls to be carried out by TOC according to the risk of non-compliance: 下列關於最低百分比的規則適用於由慈心根據不符合性的風險進行的官方管制：

- (a) minimum 10 % of all official controls of operators or groups of operators shall be carried out without prior notice every year; 每年至少應對 10%農產品經營者或農產品經營者集團，在不作事先通知的情況下，進行官方管制；
- (b) minimum 10 % of additional controls to those referred to in paragraph 3 of this Article shall be carried out every year; 每年至少應對 10%第 3 項所稱對象執行額外管制；
- (c) minimum 5 % of the number of operators, excluding operators exempted in accordance with Articles 34(2) of this Regulation shall be subject to sampling in accordance with Article 14(h) of Regulation (EU) 2017/625 every year; 每年至少應對 5%農產品經營者，不包括根據第 34(2)條豁免者，根據(EU)2017/625 號規章第 14(h)條進行取樣；
- (d) minimum 2 % of the members of each group of operators shall be subject to sampling in accordance with Article 14(h) of Regulation (EU) 2017/625 every year; 每年至少應對各農產品經營者集團中 2%成員，根據(EU)2017/625 號規章第 14(h)條進行取樣。
- (e) minimum 5 % of the operators that are members of a group of operators, but not less than 10 members, shall be subject to re-inspection every year. Where the group of operators has 10 members or less, all members shall be controlled in connection with the verification of compliance referred to in paragraph 3 of this Article. 每年至少應對不少於 10 名成員的農產品經營者集團之 5%成員重新查驗。如果農產品經營者集團有 10 名(含)名以下成員，則所有成員都應受到與本條第 3 項所述符合性查證有關的管制。

- 5 The delivery or renewal of the certificate referred to in Article 35(1) shall be based on the results of the verification of compliance referred to in paragraphs 1 to 4 of this Article. 第 35(1)條所指證書的頒發或展延，應以本條第 1 至第 4 項所指符合性查證結果為基礎。

- 6 The written record to be drawn up regarding each official control that has been performed to verify compliance with this Regulation in accordance with Article 13(1) of Regulation (EU) 2017/625 shall be countersigned by the operator or groups of operators as confirmation of their receipt of that written record. 依(EU)2017/625 號規章第 13(1)條，為查證是否符合本法而執行之每項官方管制，其書面紀錄應由農產品經營者或農產品經營者集團會簽以確認其收到該書面紀錄。
- 7 Article 13(1) of Regulation (EU) 2017/625 shall not apply to audits and inspections carried out by competent authorities in the context of their supervisory activities over control bodies to which certain official control tasks or certain tasks related to other official activities have been delegated. 若有管制機構已被授權某些官方管制任務或其他官方活動所涉某些任務，又在其主管機關之監督活動背景下，則該主管機關所進行之稽核及查驗，不適用(EU) 2017/625 號規章第 13(1)條規定。

Article 39 Additional rules on actions to be taken by the operators and groups of operators 農產品經營者和農產品經營者集團採取行動之附加規則

1. In addition to the obligations laid down in Article 15 of Regulation (EU) 2017/625, operators and groups of operators shall: 除(EU)2017/625 號規章第 15 條所制定之義務外，農產品經營者和農產品經營者集團應：
- (a) keep records to demonstrate their compliance with this Regulation; 保存紀錄證明符合本法；
 - (b) make all declarations and other communications that are necessary for official controls; 做出官方管制所需之所有聲明及其他通訊文件；
 - (c) take relevant practical measures to ensure compliance with this Regulation; 採取相關實務措施確保符合本法；
 - (d) provide, in form of a declaration to be signed and updated as necessary: 以需要簽署和更新之聲明形式提供：
 - (i) the full description of the organic or in-conversion production unit and of the activities to be performed in accordance with this Regulation; 完整描述有機或有機轉型期生產單位，以及完整描述依本法施行之活動；
 - (ii) the relevant practical measures to be taken to ensure compliance with this Regulation; 為確保符合本法而採取之相關實務措施；
 - (iii) an undertaking: 一份保證：
 - to inform in writing and without undue delay buyers of the products and to exchange relevant information with TOC in the event that a suspicion of non-compliance has been substantiated, that a suspicion of non-compliance cannot be eliminated, or that non-compliance that affects the integrity of the products in question has been established, 若懷疑不符合業已得到證實或無法盡釋，或不符合業已確定影響所涉產品之完整性，則書面及時通知產品購買者，並與主管機關或管制機關(如適當)或管制機構(如適當)交換相關資訊，
 - to accept the transfer of the control file in the case of change of control authority or control body or, in the case of withdrawal from organic production, the keeping of the control file for at least five

years by the last control authority or control body, 若管制機關或管制機構變更、或若退出有機生產，接受管制檔案之移轉，最後的管制機關或管制機構保存管制檔案至少五年，

- to immediately inform TOC in the event of withdrawal from organic production, and 若退出有機生產，立即通知慈心，或立即通知依第 34(4)條規定所指定之機關或機構，及
- to accept the exchange of information among those authorities or bodies in the event that subcontractors are subject to controls by different control authorities or control bodies. 若分包商受到不同管制機關或管制機構之管制，接受該等機關或機構之間的資訊交流。

Article 40 Additional rules on the delegation of official control tasks and tasks related to other official activities 委託官方管制任務和其他官方活動所涉任務之附加規則

1. *Conserved*
2. *Conserved*
3. *Conserved*
4. *Conserved*
5. *Conserved*
6. *Conserved*
7. *Conserved*
8. *Conserved*
9. *Conserved*

10. TOC shall transmit to the competent authorities: 慈心應向主管機關提交：

- (a) a list of the operators which were subject to their controls on 31 December of the previous year by 31 January of each year; and 應在每年 1 月 31 日前，將截至上年 12 月 31 日止在慈心管制下之農產品經營者清冊，傳送給主管機關；及
- (b) information on the official controls and other official activities carried out in the previous year to support the preparation of the part on organic production and labelling of organic products of the annual report referred to in Article 113 of Regulation (EU) 2017/625 by 31 March of each year. 應在每年 3 月 31 日前，將上年為支援(EU)2017/625 號規章第 113 條所指年度報告中，關於調製有機產品之有機生產及標示部分，所進行官方管制和其他官方活動之資訊，傳送給主管機關。

Article 41 Additional rules on actions in case of non-compliance 不符合因應行動之附加規則

1. Subject to Article 29, where TOC suspects or receives substantiated information, including information from other competent authorities, or, where appropriate, from other control authorities or control bodies, that an operator intends to use or to place on the market a product which may not be in compliance with this Regulation but which bears terms referring to the organic production, or where such competent authority, control authority or control body has been informed by an operator of a suspicion of non-compliance in accordance with Article 27: 當慈心根據第 29 條懷疑或收到經證實的資料(包括其他管制機構提供資訊)關於經營者打算銷售的產品可能不符合

本法、卻帶有提及有機生產的術語；或若農產品經營者依第 27 條規定，將懷疑的不符合通知主管機關、管制機關(如適當)或管制機構(如適當)，則：

- (a) it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 with a view to verifying compliance with this Regulation; such investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case; 應立即依(EU)2017/625 號規章進行正式調查，以查證是否符合本法；該調查應在合理期限內盡快完成，並應考慮產品耐久性及案件複雜性；
- (b) it shall provisionally prohibit both the placing on the market of the products concerned as organic or in-conversion products and their use in organic production pending the results of the investigation referred to in point (a). Before taking such a decision, the competent authority, or, where appropriate, the control authority or control body, shall give the operator an opportunity to comment. 在第(a)點所指調查結果出來前，應暫時禁止將有關產品，作為有機產品或有機轉型期產品投放市場及用於有機生產。在做出該決定前，慈心應給農產品經營者解釋的機會。
2. In the event that the results of the investigation referred to in point (a) of paragraph 1 do not show any non-compliance affecting the integrity of organic or in-conversion products, the operator shall be allowed to use the products concerned or to place them on the market as organic or in-conversion products. 若第 1 項第(a)點所指調查結果，顯示無任何不符合，有機產品或有機轉型期產品完整性不受影響，則應允許農產品經營者使用有關產品，或將該等產品作為有機產品或有機轉型期產品投放市場。
3. TOC shall take any measures, and provide for any necessary sanctions, to prevent fraudulent use of the indications referred to in Chapter IV of this Regulation. 慈心應採取任何措施，並規定任何必要之制裁措施，以防止詐欺性使用本法第 4 章所指標示。
4. *Conserved*

Article 42 Additional rules on measures in the event of non-compliance 不符合時因應措施之附加規則

1. In the event of non-compliance affecting the integrity of organic or in-conversion products throughout any of the stages of production, preparation and distribution, for example as result of the use of non-authorised products, substances or techniques, or commingling with non-organic products, competent authorities, and, where appropriate, control authorities and control bodies, shall ensure, in addition to the measures to be taken in accordance with Article 138 of Regulation (EU) 2017/625, that no reference is made to organic production in the labelling and advertising of the entire lot or production run concerned. 若在生產、調製及流通(配銷)之任何階段出現不符合，影響有機產品或有機轉型期產品完整性，例如由於使用非授權產品、物質或技術，或混用非有機產品，則慈心除依(EU)2017/625 號規章第 138 條採取措施外，亦應確保整個批次或有關生產運行，不得在標示和廣告中提及有機生產。

2. In the event of serious, or repetitive or continued non-compliance, competent authorities, and, where appropriate, control authorities and control bodies, shall ensure that the operators or the groups of operators concerned, in addition to the measures laid down in paragraph 1 and any appropriate measures taken in particular in accordance with Article 138 of Regulation (EU) 2017/625, are prohibited from marketing products which refer to organic production for a given period, and that their certificate referred to in Article 35 be suspended or withdrawn, as appropriate. 若發生嚴重、重複或持續不符合，則慈心應確保，有關農產品經營者或農產品經營者集團採取第 1 項制定之措施，及特別是依(EU)2017/625 號規章第 138 條規定採取任何適當措施。除此之外，在特定期間內禁止行銷指稱有機生產之產品，並對該農產品經營者或農產品經營者集團暫停或撤回第 35 條所指證書(如適當)。

Article 43 Additional rules on the exchange of information 關於資訊交換之附加規則

1. In addition to the obligations laid down in Article 105(1) and Article 106(1) of Regulation (EU) 2017/625, TOC shall immediately share information with other competent authorities, as well as with the Commission, on any suspicion of non-compliance that affects the integrity of organic or in-conversion products. 除(EU)2017/625 號規章第 105(1)條和第 106(1)條制定之義務外，慈心應立即與歐盟執委會共享關於任何懷疑會影響有機產品或有機轉型期產品完整性的不符合資訊。
TOC shall share that information with other competent authorities and the Commission via a computer system that enables the electronic exchanges of documents and information made available by the Commission. 慈心應經由電腦系統與歐盟執委會共享該資訊，該電腦系統能夠以電子方式交換歐盟執委會提供之文件和資訊。
2. In cases where suspected or established non-compliance has been identified with regard to products under the control of other control authorities or control bodies, TOC shall immediately inform those other control authorities or control bodies. 若懷疑或確定其他管制機關或管制機構管制下之產品，存在疑似或確定不符合，慈心應立即通知其他管制機關或管制機構。
3. TOC shall exchange other relevant information with other control authorities and control bodies. 慈心應與其他管制機關或管制機構交換其他相關資訊。
4. Upon receiving a request for information that is justified by the need to guarantee that a product has been produced in accordance with this Regulation, TOC shall exchange with other competent authorities, as well as with the Commission, information on the results of their controls. 其他主管機關以保證產品依本法生產需要為由，請求慈心提供資訊，慈心收到資訊請求後，應就下轄管制結果之資訊，交換給其他主管機關及歐盟執委會。

Chapter VII. TRADE WITH THIRD COUNTRIES 與第三國貿易

Article 44 Export of organic products *Conserved*

Article 45 Import of organic and in-conversion products 有機和有機轉型期產品進口

1. A product may be imported from a third country for the purpose of placing that product on the market within the Union as an organic product or as an in-conversion product, provided that the following three conditions are met: 產品得從第三國進口，目的是將該產品作為有機產品或有機轉型期產品，投放歐盟市場，惟須先滿足以下三個條件：
 - (a) the product is a product as referred to in Article 2(1); 該產品是第 2(1)條所指產品；
 - (b) one of the following applies: 下列情況之一適用：
 - (i) the product complies with Chapters II, III and IV of this Regulation, and all operators and groups of operators referred to in Article 36, including exporters in the third country concerned, have been subject to controls by TOC recognised in accordance with Article 46, and TOC has provided all such operators, groups of operators and exporters with a certificate confirming that they comply with this Regulation; 產品符合本法第 2、3、4 章規定，又第 36 條所指所有農產品經營者和農產品經營者集團，包括有關第三國之出口商，都已受到依第 46 條被認可之慈心管制，慈心已向所有該等農產品經營者、農產品經營者集團及出口商，提供其符合本法之證書；
 - (ii) *Conserved*
 - (iii) in cases where the product comes from a third country which is recognised in accordance with Article 48, that product complies with the equivalent production and control rules of that third country and is imported with a certificate of inspection confirming this compliance that was issued by TOC; and 若產品來自依第 48 條被認可之第三國，則該產品符合該第三國同等生產和管制規則，又進口時檢附慈心頒發之確認符合性查驗證書；及
 - (c) the operators in third countries are able at any time to provide the importers and the national authorities in the Union and in those third countries with information allowing the identification of the operators that are their suppliers and the control authorities or control bodies of those suppliers, with a view to ensuring the traceability of the organic or in-conversion product concerned. That information shall also be made available to the control authorities or control bodies of the importers.
第三國農產品經營者為歐盟和第三國進口商和國家機關之供應商，前者可以隨時提供資訊給後者，一方面能夠辨識前者為後者之供應商，另一方面能夠辨識該等供應商之管制機關或管制機構，以確保有關有機產品或有機轉型期產品之可追溯性。該等資訊亦應提供給進口商之管制機關或管制機構。
- 1.1 TOC shall provide operators, groups of operators and exporters in third countries that have been subject to the controls referred to in point (b)(i) with a certificate confirming that such operators, groups of operators and exporters comply with this Regulation. 慈心應向受到第(b)(i)點所述管制

的第三國農產品經營者、農產品經營者集團和出口商提供證書，確認其遵守本法。

The certificate shall: 此證書應：

- (a) be issued in electronic form, in accordance with the model set out in Annex VI, and by using the electronic Trade Control and Expert System (TRACES) referred to in point (36) of Article 2 of Commission Implementing Regulation (EU) 2019/1715 (2); 按照附件 VI 所載模式，並使用 (EU) 2019/1715 號規章第 2(36)條所述電子貿易管制專家系統(TRACES)，以電子形式發出；
 - (b) allow the identification of: 允許識別以下內容：
 - (i) the operator, group of operators or exporter covered by the certificate, including the list of members of a group of operators; 證書所涵蓋的農產品經營者、農產品經營者集團或出口商，包括農產品經營者集團成員列表；
 - (ii) the category of products covered by the certificate, classified in the same way as provided for in Article 35(7); and 證書所涵蓋的產品類別，同第 35(7)條規定的方式分類；及
 - (iii) its period of validity; 有效期
 - (c) certify that the activity of the operator, group of operators or exporter complies with this Regulation; and 證明農產品經營者、農產品經營者集團或出口商的活動符合本法
 - (d) be updated whenever changes occur concerning the data included in it. 每當其中所含資料發生異動時進行更新。
2. *Conserved*
 3. *Conserved*
 4. *Conserved*
 5. Compliance with the conditions and measures for the import of organic products and in-conversion products referred to in paragraph 1 into the Union shall be ascertained at border control posts, in accordance with Article 47(1) of Regulation (EU) 2017/625. The frequency of the physical checks referred to in Article 49(2) of that Regulation shall depend on the likelihood of non-compliance as defined in point (57) of Article 3 of this Regulation. 依 (EU) 2017/625 號規章第 47(1)條規定，進口第 1 項所指有機產品和有機轉型期產品進入歐盟，應在邊境管制站查明是否符合條件及措施。該規章第 49(2)條所指實體查核頻率，應視本法第 3 條第(57)點針對不符合可能性之定義而定。

Article 46 Recognition of control authorities and control bodies *Conserved*

Article 47 Equivalence under a trade agreement *Conserved*

Article 48 Equivalence under Regulation (EC) No 834/2007 *Conserved*

Article 49 Report from the Commission on the application of Articles 47 and 48 *Conserved*

Chapter VIII. GENERAL PROVISIONS 通則

SECTION 1 Free movement of organic and in-conversion products 有機產品和有機轉型期產品之自由流通

Article 50 Non-prohibition and non-restriction of the marketing of organic and in-conversion products 不禁止不限制有機產品和有機轉型期產品之行銷

TOC shall not, on grounds that relate to the production, labelling or presentation of the products, prohibit or restrict the marketing of organic or in-conversion products subject to control by another competent authority, control authority or control body located in another Member State where those products comply with this Regulation. In particular, no official controls and other official activities other than those under Regulation (EU) 2017/625 shall be performed and no fees for official controls and other official activities other than those provided for in Chapter VI of that Regulation shall be collected. 若有機產品或有機轉型期產品符合本法規定，但由在另個會員國境內另個主管機關、管制機關或管制機構管制，慈心不得以涉及產品之生產、標示或展示為由，禁止或限制該等產品之行銷。尤其是，除 (EU)2017/625 號規章所列官方管制及其他官方活動外，概不得執行其他任何官方管制及官方活動，又除該規章第 6 章所定官方管制及其他官方活動之費用外，不得收取其他費用。

SECTION 2 Information, reporting and related derogations 資訊、報告及相關豁免

Article 51 Information relating to the organic sector and trade 有機部門和貿易所涉資訊

1. Each year TOC shall transmit to the Commission the information necessary for the implementation and monitoring of the application of this Regulation. As far as possible, such information shall be based on established sources of data. The Commission shall take into account the data needs and synergies between potential data sources, in particular their use for statistical purposes where appropriate. 慈心應每年將實施和監測採行本法所需資訊，傳送給歐盟執委會。該等資訊應盡可能以既定資料來源為基礎。歐盟執委會應考慮潛在資料來源之間的資料需要及合併，特別是將其用於統計目的(如適當)。

Article 52 Information relating to the competent authorities, control authorities and control bodies 主管機關、管制機關及管制機構所涉資訊

1. TOC shall keep a regularly updated list of: 慈心應保持一份定期更新之清單，含：
 - (a) *Conserved*
 - (b) the names, addresses and code numbers of the control authorities and control bodies. 管制機關及管制機構之名稱、地址及代碼編號。
2. Based on the information provided for under paragraph 1, the Commission shall regularly publish on the internet an updated list of control authorities and control bodies referred to in point (b) of paragraph 1. 歐盟執委會應以第 1 項提供之資訊為基礎，定期在網路上公布第 1 項第(b)點所指管制機關及管制機構之更新清單。

Article 53 Derogations, authorisations and report *Conserved*

Chapter IX. PROCEDURAL, TRANSITIONAL AND FINAL PROVISIONS *Conserved*



ANNEX I. OTHER PRODUCTS REFFERED TO IN ARTICLE 2(1) 第 2(1)條所指 其他產品

- Yeasts used as food, 用作食品之酵母，
- maté, sweetcorn, vine leaves, palm hearts, hop shoots, and other similar edible parts of plants and products produced therefrom, 馬黛茶、甜玉米、藤葉、棕櫚心、啤酒花芽，以及植物中其他類似可食用部分及由其生產之產品，
- sea salt and other salts for food, 海鹽及其他食品鹽，
- natural gums and resins, 天然樹膠和樹脂，
- beeswax, 蜂蠟；
- essential oils, 精油；
- cork stoppers of natural cork, not agglomerated, and without any binding substances, 天然軟木塞，未經結塊、不含任何結合物，
- cotton, not carded or combed, 棉，未梳理(粗疏)或精梳，
- wool, not carded or combed, 羊毛，未梳理(粗疏)或精梳，
- plant-based traditional herbal preparations. 植物基傳統草本製劑。



ANNEX II. DETAILED PRODUCTION RULES REFERRED TO IN CHAPTER III 第 3 章所指詳細生產規則

Part I: Plant production rules 植物之生產規則

In addition to the production rules laid down in Articles 9 to 12, the rules set out in this Part shall apply to organic plant production. 除第 9 條至第 12 條制定之生產規則外，本部分所載規則適用於有機植物生產。

1 General requirements 一般要求

- 1.1. Organic crops, except those which are naturally grown in water, shall be produced in living soil, or in living soil mixed or fertilised with materials and products allowed in organic production, in connection with the subsoil and bedrock. 有機作物應生產在活土或在有機生產允用的材料和產品混合或施肥的活土中，與底土和基岩有關，但在水中自然生長之有機作物，不在此限。
- 1.2. Hydroponic production, which is a method of growing plants which do not naturally grow in water with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited. 水耕生產是一種在水中非自然生長的植物生長方法，其根部僅在營養液中或在添加營養液之惰性介質中生長，因此被禁止。
- 1.3. By way of derogation from point 1.1, the following shall be allowed:
作為來自第 1.1 點之豁免，以下方式應予允許：
 - (a) the production of sprouted seeds, which include sprouts, shoots and cress, solely living on the nutritional reserves available in the seeds, by moistening them in clear water, provided that the seeds are organic. The use of growing medium shall be prohibited, except the use of an inert medium intended solely to keep the seeds moist when the components of that inert medium are authorised in compliance with Article 24; 發芽種子的生產，包括芽菜、嫩芽及水芹，須以有機種子，僅靠種子內養分存活以清水保濕。除非使用由第 24 條授權的成分組成的種子保濕專用惰性介質外，禁止使用生長介質；
 - (b) the obtaining of chicory heads, including by dipping them in clear water, provided that the plant reproductive material is organic. The use of a growing medium shall be allowed only when its components are authorised in compliance with Article 24. 菊苣頭(以浸泡清水等方式)，須為有機的植物繁殖材料所獲得。僅可使用由第 24 條授權的成分組成的生長介質；
- 1.4. By way of derogation from point 1.1, the following practices shall be allowed: 作為來自第 1.1 點之豁免，應允許以下作法：
 - (a) growing plants for the production of ornamentals and herbs in pots to be sold together with the pot to the final consumer; 種植用於生產觀賞植物和藥草之盆栽，並與盆子一併銷售給最終消費者；
 - (b) growing seedlings or transplants in containers for further transplanting. 在容器中種植種苗或移植植物以供進一步移植。

1.5. Conserved

- 1.6. All plant production techniques used shall prevent or minimise any contribution to the contamination of the environment. 使用的所有植物生產技術應防止或儘量減少對環境污染的任何影響。
- 1.7 Conversion 有機轉型期
- 1.7.1 For plants and plant products to be considered as organic products, the production rules laid down in this Regulation shall have been applied with respect to the parcels during a conversion period of at least two years before sowing, or, in the case of perennial crops other than forage, during a period of at least three years before the first harvest of organic products. 對於被視為有機產品的植物和植物產品之生產地塊，在其播種前至少兩年的轉型期間應遵行本法所定生產規則；或，除草料以外之多年生作物，在有機產品首次收穫前，地塊至少有三年有機轉型期。
- 1.7.2 *Conserved*
- 1.7.3 *Conserved*
- 1.7.4 In the cases referred to in points 1.7.2 and 1.7.3, the length of the conversion period shall be fixed taking into account the following requirements: 在第 1.7.2 和 1.7.3 點所指情況，應考慮以下要求訂定有機轉型期之長度：
- (a) the process of degradation of the product or substance concerned must guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant; 有關產品或物質之降解過程必須保證，在有機轉型期結束時，土壤中殘留量很少，若是多年生作物，則植物中殘留量很少；
 - (b) the harvest following the treatment may not be placed on the market as organic or in-conversion products. 處理後之收穫物，不得作為有機產品或有機轉型期產品投放市場。
- 1.7.4.1 *Conserved*
- 1.7.4.2 *Conserved*
- 1.7.5 *Conserved*
- 1.8 Origin of plants including plant reproductive material 植物源，包括植物繁殖材料
- 1.8.1 For the production of plants and plant products other than plant reproductive material, only organic plant reproductive material shall be used. 生產植物繁殖材料以外之植物和植物產品，應僅能使用有機植物繁殖材料。
- 1.8.1.1 By way of derogation from point 1.8.1, for the production of plants and plant products other than plant reproductive material, non-organic plant reproductive material may be used when the use of organic or in conversion plant reproductive material is not possible, provided that point 1.8.5.3 and, where appropriate, the requirements set out in point 1.7 are complied with. 在生產植物繁殖材料以外的植物和植物產品時，如果不能使用有機植物繁殖材料或有機轉型期植物繁殖材料，在遵守第 1.8.5.3 點和第 1.7 點(在適當情況下)規定的要求下，則可使用非有機植物繁殖材料。
- 1.8.2 To obtain organic plant reproductive material to be used for the production of products other than plant reproductive material, the mother plant and, where relevant, other plants intended for plant reproductive material production shall have been produced in accordance with this Regulation for

at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons. 就生產除植物繁殖材料以外之產品而言，為取得所使用之有機植物繁殖材料，母本植物(母株)及其他旨在用於植物繁殖材料生產之其他植物(如相關)應依本法生產至少一代，或多年生作物則在兩個生長季期間至少一代。

1.8.3 When choosing organic plant reproductive material, operators shall give preference to organic plant reproductive material suitable for organic agriculture. 農產品經營者在選擇有機植物繁殖材料時，應優先選擇適合有機農業之有機植物繁殖材料。

1.8.4 For the production of organic varieties suitable for organic production, the organic breeding activities shall be conducted under organic conditions and shall focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions. 就生產適合有機生產之有機品種而言，有機育種活動應在有機條件下進行，並應聚焦提高遺傳多樣性，依靠自然繁殖能力，以及農藝性能、抗病性及適應不同當地的土壤和氣候條件。

All multiplication practices except meristem culture shall be carried out under certified organic management. 除分生組織培養外之所有繁殖作業，均應在驗證合格之有機管理下進行。

1.8.5 Use of in-conversion and non-organic plant reproductive material 使用有機轉型期和非有機植物繁殖材料

1.8.5.1 By way of derogation from point 1.8.1, where the data collected in the database referred to in Article 26(1) or the system referred to in point (a) of Article 26(2) shows that the qualitative or quantitative needs of the operator regarding relevant organic plant reproductive material, excluding seedlings, are not met, TOC may authorise the use of in-conversion or non-organic plant reproductive material under the conditions laid down in points 1.8.5.3, 1.8.5.4 and 1.8.5.5. 作為來自第 1.8.1 點之豁免，在第 26(1)條所指資料庫或第 26(2)條第(a)點所指系統中所收集之資料，顯示相關有機植物繁殖材料(不包括種苗)之品質或數量，無法滿足農產品經營者之需要，慈心得根據第 1.8.5.3、1.8.5.4 及 1.8.5.5 點制定之條件，批准使用有機轉型期或非有機植物繁殖材料。

Prior to requesting any such derogation, the operator shall consult the database referred to in Article 26(1) or the system referred to in point (a) of Article 26(2) in order to verify whether his or her request is justified. 在請求任何該豁免前，農產品經營者應查閱第 26(1)條所指資料庫或第 26(2)條第(a)點所指系統，以查證其請求是否合理。

1.8.5.2 TOC may authorise operators in third countries to use in-conversion or non-organic plant reproductive material in an organic production unit when organic plant reproductive material is not available in sufficient quality or quantity in the territory of the third country in which the operator is located, under the conditions laid down under points 1.8.5.3, 1.8.5.4 and 1.8.5.5. 當有機植物繁殖材料品質或數量供應不足時，慈心得授權在第三國之農產品經營者，依第 1.8.5.3、1.8.5.4 及 1.8.5.5 點制定之條件，在農產品經營者所在第三國領土內，在有機生產單位中，使用有機轉型期植物繁殖材料或非有機植物繁殖材料。

1.8.5.3 Non-organic plant reproductive material shall not be treated with plant protection products other than those authorised for the treatment of seed in accordance with Article 24(1) of this Regulation, unless chemical treatment has been prescribed in accordance with Regulation (EU) 2016/2031 for phytosanitary purposes by the competent authority of the Member State concerned for all varieties of a given species in the area in which the plant reproductive material is to be used. 非有機植物繁殖材料除依本法第 24(1)條授權用於處理種子者以外，不得使用其它的植物保護產品處理，但有關會員國之主管機關就使用該植物繁殖材料之地區內，針對某個特定物種之所有品種，依(EU)2016/2031 號規章為植物檢疫目的規定之化學處理，不在此限。

1.8.5.4 The authorisation to use in-conversion or non-organic plant reproductive material shall be obtained before the sowing of the crop. 應在作物播種前，取得使用有機轉型期或非有機植物繁殖材料之授權。

1.8.5.5 The authorisation to use in-conversion or non-organic plant reproductive material shall be granted only to individual users for one season at a time, and TOC responsible for authorisations shall list the quantities of the authorised plant reproductive material. 使用有機轉型期或非有機植物繁殖材料之授權，一次僅能授予個別用戶一個季節，負責授權之慈心，應列出授權植物繁殖材料之數量。

1.9 Soil management and fertilization 土壤管理和施肥

1.9.1 In organic plant production, tillage and cultivation practices shall be used that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion. 在有機植物生產中，應使用耕作和栽培作法保持或增加土壤有機質，增強土壤穩定性和土壤生物多樣性，防止土壤壓實和土壤沖蝕。

1.9.2 The fertility and biological activity of the soil shall be maintained and increased: 應保持和增加土壤之肥力和生物活性：

- (a) except in the case of grassland or perennial forage, by the use of multiannual crop rotation including mandatory leguminous crops as the main or cover crop for rotating crops and other green manure crops; 除草地或多年生草料外，使用多年輪作，包括強制性豆科作物，作為輪作作物和其他綠肥作物之主要或覆蓋作物；
- (b) in the case of greenhouses or perennial crops other than forage, by the use of short-term green manure crops and legumes as well as the use of plant diversity; and 在溫室或除草料以外之多年生作物情況下，藉由使用短期綠肥作物和豆類及利用植物多樣性；及
- (c) in all cases, by the application of livestock manure or organic matter, both preferably composted, from organic production. 在所有情況下，使用來自有機生產之家畜廐肥或有機物質，兩者最好是腐熟。

1.9.3 Where the nutritional needs of plants cannot be met by the measures provided for in points 1.9.1 and 1.9.2, only fertilisers and soil conditioners that have been authorised pursuant to Article 24 for use in organic production shall be used, and only to the extent necessary. Operators shall keep records of the use of those products, including the date or dates on which each product was used,

the name of the product, the amount applied and the crop and parcels concerned. 若第 1.9.1 點和第 1.9.2 點規定之措施不能滿足植物營養需要，僅可使用依第 24 條規定用於有機生產之肥料和土壤改良劑，而且僅在必要範圍內。農產品經營者應保存該等產品之使用紀錄，包括使用每種產品的日期、產品名稱、施用量以及相關作物和地塊。

- 1.9.4 The total amount of livestock manure, as defined in Directive 91/676/EEC, used in the in-conversion and organic production units shall not exceed 170 kg of nitrogen per year/hectare of agricultural area used. That limit shall only apply to the use of farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrement, including poultry manure, composted farmyard manure and liquid animal excrement. 依 91/676/EEC 號指令之定義，在有機轉型期和有機生產單位使用家畜廐肥總量，不得超過每年 170 公斤/公頃（氮重量）。該限制僅適用於使用農家廐肥(farmyard manure)、農家乾廐肥及脫水家禽廐肥、腐熟動物排泄物，包括家禽廐肥、腐熟農家廐肥及液態動物排泄物。
- 1.9.5 Operators of agricultural holdings may establish written cooperation agreements exclusively with operators of other agricultural holdings and undertakings which comply with the organic production rules, for the purpose of spreading surplus manure from organic production units. The maximum limit referred to in point 1.9.4 shall be calculated on the basis of all of the organic production units involved in such cooperation. 農產品經營者，得與符合有機生產規則之其他農企業和業者之農產品經營者，訂立書面合作協議，以分散來自有機生產單位過剩的廐肥。第 1.9.4 點所指最高限額，應以參與該合作之所有有機生產單位為基礎計算。
- 1.9.6 Preparations of micro-organisms may be used to improve the overall condition of the soil or to improve the availability of nutrients in the soil or in the crops. 微生物製劑得用於改善土壤整體狀況，或提高土壤或作物中養分供應。
- 1.9.7 For compost activation, appropriate plant-based preparations and preparations of micro-organisms may be used. 為使堆肥活化，得使用適當之植物基製劑及微生物製劑。
- 1.9.8 Mineral nitrogen fertilisers shall not be used. 不得使用礦物氮肥。
- 1.9.9 Biodynamic preparations may be used. 得使用生物動力製劑。
- 1.10 Pest and weed management 有害生物(害蟲)和雜草管理
- 1.10.1 The prevention of damage caused by pests and weeds shall rely primarily on the protection by:
預防蟲害和雜草造成之損害，應主要依靠以下防護措施：
- natural enemies, 天敵；
 - the choice of species, varieties and heterogeneous material, 物種、品種和異質資材的選擇；
 - crop rotation, 輪作；
 - cultivation techniques such as 蟲害, mechanical and physical methods, and 栽培技術，如生物燻蒸(biofumigation)、機械及物理方法，及
 - thermal processes such as solarisation and, in the case of protected crops, shallow steam treatment of the soil (to a maximum depth of 10 cm). 熱處理，例如日曬，在受保護作物之情況，對土壤進行淺層蒸汽處理(最大深度為 10 公分)。

- 1.10.2 Where plants cannot adequately be protected from pests by measures provided for in point 1.10.1 or in the case of an established threat to a crop, only products and substances authorised pursuant to Articles 9 and 24 for use in organic production shall be used, and only to the extent necessary. Operators shall keep records proving the need for the use of such products, including the date or dates on which each product was used, the name of the product, its active substances, the amount applied, the crop and parcels concerned, and the pest or disease to be controlled. 若無法藉由第 1.10.1 條規定之措施，充分保護植物受害蟲侵害，或在作物受到既有威脅之情況下，僅可使用依第 9 條和第 24 條授權用於有機生產之產品和物質，而且僅在必要範圍內。農產品經營者應保存紀錄，證明使用該等產品之必要性，包括每種產品的使用日期、產品名稱、其活性物質、施用量、相關作物和地塊以及要管制的病蟲害。
- 1.10.3 In relation to products and substances used in traps or in dispensers of products and substances other than pheromones, the traps or dispensers shall prevent the products and substances from being released into the environment and shall prevent contact between the products and substances and the crops being cultivated. All traps, including pheromone traps, shall be collected after use and shall be safely disposed of. 產品和物質(費洛蒙除外)型誘引器或分配器，就其所使用之產品和物質而言，誘引器或分配器應防止產品和物質釋放到環境中，並應防止產品和物質與正在種植之作物接觸。所有誘引器，包括費洛蒙誘引器，使用後應收集做安全處置。
- 1.11 Products used for cleaning and disinfection 用於清潔和消毒的產品
Only those products for cleaning and disinfection in plant production authorised pursuant to Article 24 for use in organic production shall be used for that purpose. Operators shall keep records of the use of those products including the date or dates on which each product was used, the name of the product, its active substances, and the location of such use. 在植物生產中，僅可使用依第 24 條為清潔消毒目的授權用於有機生產之產品，進行清潔消毒。農產品經營者應保存這些產品的使用記錄，包括每個產品的使用日期、產品名稱、其活性物質以及此類使用的位置。
- 1.12 Record-keeping obligation 保存記錄的義務
Operators shall keep records regarding the parcels concerned and the amount of the harvest. In particular, operators shall keep records of any other external input used on each parcel and, where applicable, keep available documentary evidence on any derogation from production rules obtained in accordance with point 1.8.5. 農產品經營者應保存有關地塊和收穫量之紀錄。尤其是，農產品經營者應保留每個地塊上使用的任何其他外來投入的記錄，並在適用的情況下保存關於根據第 1.8.5 點對生產規則的任何豁免之可用文件證據。
- 1.13 Preparation of unprocessed products 非加工產品的製備
If preparation operations other than processing are carried out on plants, the general requirements laid down in points 1.2, 1.3, 1.4, 1.5 and 2.2.3 of Part IV shall apply mutatis mutandis to such operations. 若在植物上進行加工以外之調製操作，第 5 部分第 1.2、1.3、1.4、1.5 及 2.2.3 點規定之一般要求，應比照適用於該等操作。

2 Detailed rules for specific plants and plant products 特定植物及其產品的詳細規則

2.1 Rules on mushroom production 蕈類生產規則

For the production of mushrooms, substrates may be used if they are composed only of the following components: 對於生產蕈類，僅可使用由以下成分組成之基質：

- (a) farmyard manure and animal excrement: 農家厩肥及動物廐肥：
 - (i) either from organic production units or from in-conversion units in their second year of conversion; or 來自有機生產單位或來自轉型期第二年之有機轉型期單位者；或
 - (ii) referred to in point 1.9.3, only when the product referred to in point (i) is not available, provided that that farmyard manure and animal excrement do not exceed 25% of the weight of total components of the substrate, excluding the covering material and any added water, before composting; 第 1.9.3 點所指者，僅在不能取得第(i)點所指產品時，前提是農家厩肥及動物廐肥不超過基質總重量之 25%，不包括醱酵前之覆蓋材料和任何添加的水；
- (b) products of agricultural origin, other than those referred to in point (a), from organic production units; 來自有機生產單位之農業源產品，但第(a)點所指者除外；
- (c) peat, not treated with chemical products; 泥炭，未經化學產品處理；
- (d) wood, not treated with chemical products after felling; 木材，砍伐後未經化學產品處理；
- (e) mineral products referred to in point 1.9.3, water and soil. 礦產品(第 1.9.3 點所指者)、水及土壤。

2.2 Rules concerning the collection of wild plants 野生植物採集規則

The collection of wild plants and parts thereof growing naturally in natural areas, forests and agricultural areas is considered as organic production, provided that: 在自然區域、森林及農業區域中自然生長之野生植物及其部分，其採集視為有機生產，但須符合以下條件：

- (a) for a period of at least three years before the collection, those areas were not treated with products or substances other than those authorised pursuant to Articles 9 and 24 for use in organic production; 在採集前至少三年時間裡，針對第 9 條和第 24 條授權用於有機生產之產品或物質，該等區域概無違反情事；
- (b) the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area. 採集不影響採集區域內自然棲息地之穩定性或物種之維持。

Operators shall keep records of the period and location of the collection, the species concerned and the quantity of wild plants collected.

農產品經營者應當記錄採集的時間和地點、所涉物種和採集的野生植物數量。

Part II: Livestock production rules *Conserved*

Part III: Production rules for algae and aquaculture animals *Conserved*

Part IV: Processed food production rules 加工食品生產規則

In addition to the general production rules laid down in Articles 9, 11 and 16, the rules laid down in this Part shall apply to the organic production of processed food. 除第 9、11 及 16 條制定之一般生產規則外，本部分制定之規則，適用於加工食品之有機生產。

- 1 General requirements for the production of processed food 加工食品生產的一般要求
 - 1.1 Food additives, processing aids and other substances and ingredients used for processing food and any processing practice applied, such as smoking, shall comply with the principles of good manufacturing practice. 食品添加物、加工助劑和用於食品加工的其他物質、成分及任何加工方式（如煙熏），都應當符合 GMP 良好作業規範。
 - 1.2 Operators producing processed food shall establish and update appropriate procedures based on a systematic identification of critical processing steps. 生產加工食品的經營者應在系統性地鑑別關鍵加工步驟的基礎上建立和更新適當的程序。
 - 1.3 The application of the procedures referred to in point 1.2 shall ensure that the produced processed products comply with this Regulation at all times. 第 1.2 點所指程序的應用應確保生產的加工產品在任何時候都符合本法。
 - 1.4 Operators shall comply with and implement the procedures referred to in point 1.2, and, without prejudice to Article 28, shall in particular, 經營者應當遵守並執行第 1.2 點所述程序，在不影響第 28 條的情況下，特別應：
 - (a) take precautionary measures and keep records of those measures; 採取防護措施並保留這些措施的記錄；
 - (b) implement suitable cleaning measures, monitor their effectiveness and keep records of those operations; 實施合適之清潔措施，監測其有效性並保存這些操作之紀錄；
 - (c) guarantee that non-organic products are not placed on the market with an indication referring to organic production. 保證非有機產品不會以宣稱有機生產名義投放市場。
 - 1.5 The preparation of processed organic, in-conversion and non-organic products shall be kept separate from each other in time or space. Where organic, in-conversion and non-organic products, in any combination, are prepared or stored in the preparation unit concerned, the operator shall: 調製加工有機、有機轉型期及非有機產品，應在時間或空間上彼此區隔。若有機產品、有機轉型期產品及非有機產品在相同區域，以任意組合方式調製或儲存，則農產品經營者：
 - (a) inform TOC; 應據實通知慈心
 - (b) carry out the operations continuously until the production run has been completed, separately in place or time from similar operations performed on any other kind of product (organic, in-conversion or non-organic); 在生產運行完成以前持續該等作業，若有任何其他種類產品(有機、有機轉型期或非有機)之進行類似的作業，則應在地點或時間上作出區隔；
 - (c) store organic, in-conversion and non-organic products, before and after the operations, separate by place or time from each other; 在有機產品、有機轉型期產品及非有機產品作業前後，將彼此依地點或時間分開儲存；

- (d) keep available an updated register of all operations and quantities processed; 保留所有作業和加工數量之最新記錄；
 - (e) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges between organic, in-conversion and non-organic products; 採取必要措施確保批次辨識，及避免有機產品、有機轉型期產品及非有機產品之間混合或交換；
 - (f) carry out operations on organic or in-conversion products only after suitable cleaning of the production equipment. 僅在對生產設備進行適當清潔後，始能對有機產品或有機轉型期產品進行作業。
- 1.6 Products, 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 organic food, or that otherwise may be misleading as to the true nature of products intended to be marketed as organic food, shall not be used. 產品、物質及技術若涉及以下情況，一是用於重建在有機食品加工和儲存過程中喪失之特性，二是改正在加工有機食品中之疏忽結果，或三是對於擬以有機食品銷售之產品，以其他可能誤導產品之真實性的方式，則不得使用該等產品、物質及技術。
- 1.7 Operators shall keep available documentary evidence on authorisations for the use of non-organic agricultural ingredients for the production of processed organic food in accordance with Article 25 if they have obtained or used such authorisations. 農產品經營者在取得或使用非有機農業原料生產有機食品加工食品時，應當按照第 25 條的規定，保留使用非有機農業原料的授權證明文件。
- 2 Detailed requirements for the production of processed food 加工食品生產之詳細要求
- 2.1 The following conditions shall apply to the composition of processed organic food: 下列條件應適用於有機加工食品之成分：
- (a) the product shall be produced mainly from agricultural ingredients or products intended for use as food listed in Annex I; for the purpose of determining whether a product has been produced mainly from those products, added water and salt shall not be taken into account; 產品應主要產自農業原料或附件 1 所列擬用作食品之產品；就決定產品是否主要產自該等產品之目的，添加之水及鹽不在考慮之列；
 - (b) an organic ingredient shall not be present together with the same ingredient in non-organic form; 有機原料不得與非有機形式之相同原料並存；
 - (c) an in-conversion ingredient shall not be present together with the same ingredient in organic or non-organic form. 有機轉型期原料不得與有機或非有機形式之相同原料並存。
- 2.2 Use of certain products and substances in processing of food 在食品加工中使用某些產品和物質
- 2.2.1 Only food additives, processing aids and non-organic agricultural ingredients authorised pursuant to Article 24 or Article 25 for use in organic production, and the products and substances referred to in point 2.2.2 may be used in the processing of food, with the exception of yeast, for which point 1.3 of Part VII shall apply. 僅依第 24 條或第 25 條授權用於有機生產之食品添加物、加

工助劑及非有機農業原料，以及第 2.2.2 點所指產品和物質，才能用於食品加工，但針對第 7 部分第 1.3 點適用之酵母除外。

2.2.2 In the processing of food, the following products and substances may be used: 在食品加工過程中，得使用以下產品和物質：

- (a) preparations of micro-organisms and food enzymes normally used in food processing, provided that food enzymes to be used as food additives have been authorised pursuant to Article 24 for use in organic production; 通常用於食品加工之微生物製劑和食品酶，但前提是用作食品添加物之食品酶，已獲得第 24 條授權用於有機生產；
- (b) substances and products defined in points (c) and (d)(i) of Article 3(2) of Regulation (EC) No 1334/2008 that have been labelled as natural flavouring substances or natural flavouring preparations in accordance with Article 16(2), (3) and (4) of that Regulation; (EC)第 1334/2008 號規章第 3(2)條第(c)和(d)(i)點中定義之物質和產品，已依第該規章第 16(2)、(3)及(4)條規定，經標示為天然香料物質或天然香料製劑；
- (c) *Conserved*
- (d) *Conserved*
- (e) drinking water and organic or non-organic salt (with sodium chloride or potassium chloride as basic components) generally used in food processing; 食品加工中常用之飲用水和有機或非有機鹽(以氯化鈉或氯化鉀為基本成分)；
- (f) minerals (trace elements included), vitamins, amino acids and micronutrients, provided that: 礦物質(包括微量元素)、維生素、氨基酸及微量營養素，前提是：
- (i) their use in food for normal consumption is ‘directly legally required’, in the meaning of being directly required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if those minerals, vitamins, amino acids or micronutrients are not added; or 在正常食用型食品中使用是「法律直接要求的」，意即歐盟法律規定或與歐盟法律相符之國家法律規定直接要求，其結果是若不添加該等礦物質、維生素、氨基酸或微量營養素，根本不能以正常食用型食品投放市場；或
- (ii) as regards food placed on the market as having particular characteristics or effects in relation to health or nutrition or in relation to needs of specific groups of consumers: 關於投放市場之食品，針對健康或營養方面或針對特定消費者族群的需求，具有特別之特性或效應：
 - in products referred to in points (a) and (b) of Article 1(1) of Regulation (EU) No 609/2013 of the European Parliament and of the Council their use is authorised by that Regulation and acts adopted on the basis of Article 11(1) of that Regulation for the products concerned, or 在歐洲議會及歐盟理事會(EU)第 609/2013 號規章()第 1(1)條第(a)和(b)點所指產品中，其使用授權來自該規章，以及來自針對有關產品以該規章第 11(1)條為基礎所通過之法案，或
 - in products regulated by Commission Directive 2006/125/EC, their use is authorised by that Directive. 由歐盟執委會 2006/125/EC 號指令監管之產品中，其使用授權來自該指令。

- 2.2.3 Only the products for cleaning and disinfection authorised pursuant to Article 24 for use in processing shall be used for that purpose. Operators shall keep records of the use of those products, including the date or dates on which each product was used, the name of the product, its active substances and the location of such use. 只能使用依第 24 條授權用於加工的清潔和消毒產品。農產品經營者應保存這些產品的使用記錄，包括每個產品的使用日期、產品名稱、其活性物質和使用地點。
- 2.2.4 For the purpose of the calculation referred to in Article 30(5), the following rules shall apply: 就第 30(5)條所指的計算，應適用以下規則：
- (a) certain food additives authorised pursuant to Article 24 for use in organic production shall be calculated as agricultural ingredients; 依第 24 條授權用於有機生產之某些食品添加物，應以農業原料計算；
 - (b) preparations and substances referred to in points (a), (c), (d), (e) and (f) of point 2.2.2 shall not be calculated as agricultural ingredients; 第 2.2.2 點第(a)、(c)、(d)、(e)及(f)點中所指製劑和物質，不得以農業原料計算；
 - (c) yeast and yeast products shall be calculated as agricultural ingredients. 酵母和酵母產品應以農業原料計算。
- 2.3 Operators shall keep records of any input used in the food production. In case of production of composite products, complete recipes/formulae showing the quantities of input and output shall be kept available for TOC. 農產品經營者應保存食品生產中使用的任何投入的記錄。在生產複方產品的情況下，應保留顯示投入和產出數量的完整配方，供慈心查核。

Part V: Processed feed production rules *Conserved*

Part VI: Wine *Conserved*

Part VII: Yeast used as food or feed 用作食品之酵母

In addition to the general production rules laid down in Articles 9, 11, 16, 17 and 19, the rules laid down in this Part shall apply to the organic production of yeast used as food or feed. 除第 9、11、16、17 及 19 條制定之一般生產規則外，本部分制定之規則，應適用於用作食品之酵母有機生產。

1 General requirements 一般要求

- 1.1 For the production of organic yeast, only organically produced substrates shall be used. However, until 31 December 2024, the addition of up to 5 % non-organic yeast extract or autolysate to the substrate (calculated in weight of dry matter) is allowed for the production of organic yeast where operators are unable to obtain yeast extract or autolysate from organic production. 對於有機酵母之生產，僅可使用有機生產之基質。但在 2024 年 12 月 31 日前，若農產品經營者無法自有有機生產取得酵母萃取物或自溶物，則允許在基質中添加最多 5% 之非有機酵母萃取物或自溶物(以乾燥物重量計算)。

- 1.2 Organic yeast shall not be present in organic food or feed together with non-organic yeast. 有機食品中不得同時使用有機和非有機酵母。
- 1.3 The following products and substances may be used in the production, confection and formulation of organic yeast: 以下產品和物質得用於有機酵母之生產、製作及配製中：
 - (a) processing aids authorised pursuant to Article 24 for use in organic production; 依第 24 條授權用於有機生產之加工助劑；
 - (b) products and substances referred to in points (a), (b) and (e) of point 2.2.2 of Part IV. 第 4 部分第 2.2.2 點第(a)、(b)及(e)點所指產品和物質。
- 1.4 Only the products for cleaning and disinfection authorised pursuant to Article 24 for use in processing shall be used for that purpose. 僅依第 24 條針對清潔消毒之產品授權用於加工者，始得為該目的使用之。
- 1.5 Operators shall keep records of any product and substance used for yeast production and for cleaning and disinfection, including the date or dates on which each product was used, the name of the product, its active substances, and the location of such use. 農產品經營者應保存用於酵母生產以及清潔和消毒的任何產品和物質的記錄，包括使用每種產品的日期、產品名稱、其活性物質以及此類使用的位置。



ANNEX III. COLLECTION, PACKAGING, TRANSPORT AND STORAGE OF PRODUCTS 產品收集、包裝、運輸和儲存

1. Collection of products and transport to preparation units 產品的收集及運輸至調製單位
Operators may carry out the simultaneous collection of organic, in-conversion and non-organic products only where appropriate measures have been taken to prevent any possible mixture or exchange between organic, in-conversion and non-organic products and to ensure the identification of the organic and in-conversion products. The operator shall keep the information relating to collection days, hours, the circuit and date and time of the reception of the products available to TOC. 僅在業已採取適當措施以防止有機、有機轉型期及非有機產品之間任何可能之混雜或交換，並確保識別有機和有機轉型期產品之情況下，農產品經營者始得同時收集有機產品、有機轉型期產品及非有機產品。農產品經營者應保留產品之收集天數、小時數、週期及接收日期和時間等相關資訊，以供慈心查核。
2. Packaging and transport of products to other operators or units 產品之包裝和運輸到其他農產品經營者或單位
 - 2.1. Information to be provided 資訊提供
 - 2.1.1. Operators shall ensure that organic products and in-conversion products are transported to other operators or units, including wholesalers and retailers, only in appropriate packaging, containers or vehicles closed in such a manner that alteration, including 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 Union law: 農產品經營者應確保，僅在適當密閉的包裝、容器或車輛，才能將有機產品和有機轉型期產品運往其他農產品經營者或單位(包括批發商和零售商)；該方式係指在不篡改或損壞封條情況下、無法對內容進行更改(含替換)、並提供標示說明。在不妨礙歐盟法規定任何其他指示情況下：
 - (a) the name and address of the operator and, where different, of the owner or seller of the product; 經營者姓名和地址，及產品所有人或銷售人姓名和地址(如非同一人)；
 - (b) the name of the product; 產品名稱；
 - (c) the name or the code number of control body to which the operator is subject; and 農產品經營者所屬管制機構名稱或代碼；
 - (d) where relevant, the lot identification mark in accordance with a marking system either approved at national level or agreed with TOC and which permits the linking of the lot with the records referred to in Article 34(5). 在相關情況下，按照標記系統確定的批號(為國家級批准/同意或為慈心同意)，可使該批號連結第 34(5)條所述記錄。
 - 2.2. The closing of packaging, containers or vehicles shall not be required where: 在下列情況下不要求密閉式包裝、容器或車輛：
 - (a) the transport takes place directly between two operators, both of which are subject to the organic control system; 在同屬一家有機管制系統的兩個農產品經營者之間的直接運輸進行；

- (b) the transport includes only organic or only in-conversion products; 僅有有機產品或僅有有機轉型期產品的運輸；
- (c) the products are accompanied by a document giving the information required under point 2.1; and 產品隨附文件提供第 2.1 點要求之資訊；及
- (d) both the expediting and the receiving operators keep documentary records of such transport operations available for TOC. 發貨方和收貨方的農產品經營者，都應保留該等運輸作業的文件紀錄，提供 TOC 稽核。

3. *Conserved*

4. *Conserved*

5. Reception of products from other operators of units 接收來自其他單位農產品經營者之產品
On receipt of an organic or in-conversion product, the operator shall check the closing of the packaging, container or vehicle where it is required and the presence of the indications provided for in Section 2. 收到有機產品或有機轉型期產品後，農產品經營者應查核包裝、容器或車輛之密封情況(如有要求)，以及查核第 2 節中規定之標示內容。

The operator shall cross-check the information on the label referred to in Section 2 with the information on the accompanying documents. The result of those verifications shall be explicitly mentioned in the records referred to in Article 34(5). 農產品經營者應將第 2 節所規定的標示上之資訊，與隨附文件上之資訊進行交叉查核。該等查證結果應明確登錄在第 34(5)條所指紀錄。

6. Special rules for the reception of products from a third country 接收來自第三國產品之特定規則
Where organic or in-conversion products are imported from a third country, they shall be transported in appropriate packaging or containers, closed in a manner that prevents the substitution of the content and bearing the identification of the exporter and any other marks and numbers that serve to identify the lot, and shall be accompanied by the certificate of control for import from third countries where appropriate. 若從第三國進口有機產品或有機轉型期產品，則應使用適當的包裝或容器運輸，以封閉方式防止內容物被替換，並帶有出口商辨識及任何其他標誌及編號，用以辨識批次，並應的附有從第三國進口之管制證書(如適當)。

On receipt of an organic or in-conversion product imported from a third country, the natural or legal person to whom the imported consignment is delivered and who receives it for further preparation or marketing shall check the closing of the packaging or container and, in the case of products imported in accordance with point (b)(iii) of Article 45(1), shall check that the certificate of inspection referred to in that Article covers the type of product contained in the consignment. The result of this verification shall be explicitly mentioned in the records referred to in Article 34(5). 若自第三國進口之有機產品或有機轉型期產品，將該等進口託運貨物交付給自然人或法人做進一步調製或行銷，則該自然人或法人於收到進口之有機產品或有機轉型期產品後，應查核包裝或容器密封情況，又若是依(EU)2018/848 號規章第 45 條第(1)(b)(iii)點進口之產品，則應查核該條所指查驗證書是否涵蓋託運貨物中包含的產品類型。該查證結果應明確登錄在(EU)2018/848 號規章第 34(5)條所指紀錄中。

7. Storage of products 產品儲存

- 5.1 Areas for the storage of products shall be managed in such a way as to ensure identification of lots and to avoid any mixing or contamination with products or substances not in compliance with the organic production rules. Organic and in-conversion products shall be clearly identifiable at all times. 產品儲存區域之管理方式，應確保批次辨識，並避免與不符合有機生產規則之產品或物質混雜或被後者污染。有機產品和有機轉型期產品應始終清晰可辨識。
- 5.2 No input products or substances other than those authorised pursuant to Articles 9 and 24 for use in organic production shall be stored in organic or in-conversion plant and livestock production units. 有機或有機轉型期植物生產單位，僅可儲存依第 9 條和第 24 條授權用於有機生產之投入產品或物質，不得儲存其他類型之投入產品或物質。
- 5.3 *Conserved*
- 5.4 Where operators handle organic, or in-conversion or non-organic products in any combination and the organic or in-conversion products are stored in storage facilities in which also other agricultural products or foodstuffs are stored: 若農產品經營者以任何組合方式處理有機產品、有機轉型期產品或非有機產品，又有機產品或有機轉型期產品儲放在儲存設施中，而其他農產品或食品亦儲存在其中，則：
- (a) the organic or in-conversion products shall be kept separate from the other agricultural products or foodstuffs; 有機產品或有機轉型期產品應與其他農產品或食品分開存放；
 - (b) every measure shall be taken to ensure identification of consignments and to avoid mixtures or exchanges between organic, in-conversion and non-organic products; 應採取一切措施確保貨物辨識，並避免有機產品、有機轉型期產品及非有機產品之間混雜或交換；
 - (c) suitable cleaning measures, the effectiveness of which has been checked, shall have been carried out before the storage of organic or in-conversion products and the operators shall keep records of those operations. 在儲存有機產品或有機轉型期產品前，應執行業經查核有效之適當清潔措施，又農產品經營者應保留該等作業紀錄。
- 5.5 Only the products for cleaning and disinfection authorised pursuant to Article 24 for use in organic production shall be used in storage facilities for that purpose. 僅依第 24 條授權用於有機生產的清潔消毒產品，始得為該目的用於儲存設施中。

ANNEX IV. TERMS REFERRED TO IN ARTICLE 30

第 30 條所指用語

BG: биологичен. (Bulgarian 保加利亞文)
ES: ecológico, biológico, orgánico. (Spanish 西班牙文)
CS: ekologické, biologické. (Czech 捷克文)
DA: økologisk. (Danish 丹麥文)
DE: ökologisch, biologisch. (German 德文)
ET: mahe, ökoloogiline. (Estonian 愛沙尼亞文)
EL: βιολογικό. (Greek 希臘文)
EN: organic. (English 英文)
FR: biologique. (French 法文)
GA: orgánach. (Irish 愛爾蘭文)
HR: ekološki. (Croatian 克羅埃西亞文)
IT: biologico. (Italian 義大利文)
LV: bioloģisks, ekoloģisks. (Latvian 拉脫維亞文)
LT: ekologiškas. (Lithuanian 立陶宛文)
LU: biologesch, ökologesch. (Luxembourg 盧森堡文)
HU: ökológiai. (Hungarian 匈牙利文)
MT: organiku. (Maltese 馬爾他文)
NL: biologisch. (Dutch 荷蘭文)
PL: ekologiczne. (Polish 波蘭文)
PT: biológico. (Portuguese 葡萄牙文)
RO: ecologic. (Romanian 羅馬尼亞文)
SK: ekologické, biologické. (Slovak 斯洛伐克文)
SL: ekološki. (Slovenian 斯洛維尼亞文)
FI: luonnonmukainen. (Finnish 芬蘭文)
SV: ekologisk. (Swedish 瑞典文)

ANNEX V. ORGANIC PRODUCTION LOGO OF THE EUROPEAN UNION AND CODE NUMBERS 歐盟有機生產標章和代碼編號

1. Logo 標章

- 1.1 The organic production logo of the European Union shall comply with the model below: 歐盟有機生產標章應符合下列模式：



- 1.2 The reference colour in Pantone is Green Pantone No 376 and Green (50 % Cyan + 100 % Yellow), when a four-colour process is used. 當使用四色印刷時，潘通色卡(Pantone)之參考顏色為潘通綠色 376 號與綠色(50%青色 + 100% 黃色)。
- 1.3 The organic production logo of the European Union may also be used in black and white as shown, only where it is not practicable to apply it in colour: 僅當使用彩色不可行時，歐盟有機生產標章也能用黑色與白色表示：



- 1.4 If the background colour of the packaging or label is dark, the symbols may be used in negative format, using the background colour of the packaging or label. 若包裝或標示的背景顏色是黑色，則標誌可用相反格式，使用包裝或標示顏色作為背景顏色。
- 1.5 If a logo is used in colour on a coloured background which makes it difficult to see, a delimiting outer line around the logo can be used to improve contrast with the background colours. 若在彩色背景使用彩色標章，難以看清楚時，可在標章周圍劃定外線，以增加與背景色的對比。
- 1.6 Where there are indications in a single colour on the packaging, the organic production logo of the European Union may be used in the same colour. 當包裝有指定單一顏色時，歐盟有機生產標章得使用相同顏色。
- 1.7 The organic production logo of the European Union shall 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. 歐盟有機生產標章，必需具有至少 9 毫米高度與 13.5 毫米寬度；長寬的比例應始終為 1:1.5。在例外情況下，最小尺寸可降至高 6 毫米為非常小的包裝。
- 1.8 The organic production logo of the European Union may be associated with graphical or textual elements referring to organic production under the condition that they do not modify or change the nature of the organic production logo of the European Union, nor any of the indications defined in

accordance with Article 32. When associated to national or private logos using a green colour different from the reference colour provided for in point 1.2, the organic production logo of the European Union may be used in that non-reference colour. 歐盟有機標章可以與有機農作相關圖形或文字內容有關聯，條件是不能修改或改變歐盟有機標章的本質，也沒有任何第 32 條所提及的情形。當關聯到國家或私人標章使用的綠色，不同於第 1.2 點所提到的參考顏色時，歐盟有機生產標章得使用該非參考顏色。

2. Code numbers 代碼編號

The general format of the code numbers shall be as follows: 代碼編號之一般格式如下：

AB-CDE-999

where: 其中：

- (a) 'AB' is the ISO code for the country where the controls take place; 「AB」是進行管制的國家 ISO 代碼；
- (b) '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 organic production; and 「CDE」是用詞，由三個字母表示，由歐盟執委會或每個會員國決定，如「bio」或「öko」或「org」或「eko」，與有機生產建立連結；及
- (c) '999' is the reference number, indicated in maximum three digits, to be assigned by the Commission, to the TOC recognised by the Commission pursuant to Article 46. 「999」是參考編號，最多以三位數字表示：由歐盟執委會來分配給依(EU) 2018/848 號規章認可的 TOC。

TOC

ANNEX VII. AUTHORISING CERTAIN PRODUCTS AND SUBSTANCES FOR USE IN ORGANIC PRODUCTION AND ESTABLISHING THEIR LISTS 授權用於有機生產的產品和物質清單

Annex VII-1. Active substances contained in plant protection products authorised for use in organic production as referred to in Point (a) of Article 24(1) of Regulation (EU) 2018/848 就用於 (EU)2018/848 號規章第 24(1)條第(a)點所指授權用於有機生產之植物保護產品中所含的活性物質

The active substances listed in this Annex may be contained in plant protection products used in organic production as set out in this Annex, provided that these plant protection products are authorised pursuant to Regulation (EC) No 1107/2009. These plant protection products shall be used in compliance with the conditions set out in the Annex to Implementing Regulation (EU) 540/2011 and in accordance with the conditions specified in the authorisations granted by the Member States where they are used. More restrictive conditions for use in organic production are specified in the last column of each table below.

本附件所列活性物質，得含在本附件所指用於有機生產之植物保護產品中，前提是該等植物保護產品獲得(EC)第1107/2009號規章之授權。該等植物保護產品之使用，應符合(EU)第540/2011號實施規章附件所載條件，並符合使用該等植物保護產品之會員國對授予授權所規定的條件。下列每個表中最後一欄，針對用於有機生產指明更多限制條件。

In accordance with Article 9(3) of Regulation (EU) 2018/848, safeners, synergists and co-formulants as components of plant protection products, and adjuvants that are to be mixed with plant protection products shall be allowed for use in organic production, provided that they are authorised pursuant to Regulation (EC) No 1107/2009. The substances in this Annex may only be used for the control of pests as defined in Article 3(24) of Regulation (EU) 2018/848.

依(EU) 2018/848號規章第9(3)條規定，做為植物保護產品成分的保護劑、協力劑和助劑，以及與植物保護產品混合之佐劑，應被允許用於有機生產，前提是這些成分獲得(EC)第1107/2009號規章授權。本附件中之物質，僅可用於控制(EU)2018/848號規章第3(24)條定義之害蟲。

In accordance with point 1.10.2 of Part I of Annex II to Regulation (EU) 2018/848, these substances may only be used where plants cannot be adequately protected from pests by measures provided for in point 1.10.1 of that Part I, in particular by the use of biological control agents, such as beneficial insects, mites and nematodes complying with the provisions of Regulation (EU) 1143/2014 of the European Parliament and of the Council.

依(EU) 2018/848號規章附件2 第2部分第1.10.2點規定，僅在無法藉由該第2部分第1.10.1點規定之措施，充分保護植物免受害蟲侵害之情況下，特別是藉由使用符合歐洲議會及歐盟理事會(EU)第1143/2014號規章規定之生物防治物(biological control agent)，例如益蟲、蠕蟲和線蟲，才可使用這些物質。

For the purposes of this Annex, active substances are divided into following subcategories:
就本附件而言，活性物質分為以下子類別：

1. Basic substances 基本物質

Basic substances listed in Part C of the Annex to Implementing Regulation (EU) 540/2011, from plant or animal origin and based on food as defined in Article 2 of Regulation (EC) 178/2002 of the European Parliament and of the Council may be used for plant protection in organic production. Such basic substances are marked with an asterisk in the table below. They shall be used in accordance with the uses, conditions and restrictions set in the relevant review reports ⁽¹⁾ and taking into account the additional restrictions, if any, in the last column of the table below.

基本物質屬(EU)540/2011號實施規章附件第C部分所列者，及屬以歐洲議會及歐盟理事會(EC)178/2002號規章第2條定義之植物或動物源為基礎者，得用於有機生產中之植物保護。該等基本物質在下表中標有星號。使用該等基本物質，應依相關審查報告所列用途、條件及限制為之，並考慮下表最後一欄之附加限制(如有)。

Other basic substances listed in Part C of the Annex to Implementing Regulation (EU) 540/2011 may be used for plant protection in organic production only when they are listed in the table below. Such basic substances shall be used in accordance with the uses, conditions and restrictions set in the relevant review reports and taking into account the additional restrictions, if any, in the right column of the table below.

其他基本物質屬(EU)540/2011號實施規章附件第C部分所列者，只有在下表中列出時才可用於有機生產中之植物保護。使用該等基本物質，應依相關審查報告所列用途、條件及限制為之，並考慮下表最後一欄之附加限制(如有)。

Basic substances shall not be used as herbicides.

基本物質不得用作除草劑。

Number and Part of Annex ⁽²⁾ 編碼	CAS 化學物質 登錄號	Name 名稱	Specific conditions and limits 特定條件和限制
1C		<i>Equisetum arvense</i> L.* 問荊萃取物*	
2C	70694-72-3	Chitosan hydrochloride* 甲殼素鹽酸鹽*	obtained from <i>Aspergillus</i> or organic aquaculture or from sustainable fisheries, as defined in Art. 2 of (EU) 1380/2013 of the European Parliament and of the Council. 取自麴菌屬或有機水產或取自永續漁業，定義見歐洲議會及理事會(EU) 1380/2013第2條
3C	57-50-1	Sucrose* 蔗糖*	
4C	1305-62-0	Calcium Hydroxide 氫氧化鈣	
5C	90132-02-8	Vinegar* 醋	
6C	8002-43-5	Lecithins* 卵磷脂*	
7C	-	<i>Salix</i> spp. Cortex* 柳屬皮質*	
8C	57-48-7	Fructose* 果糖*	
9C	144-55-8	Sodium hydrogen carbonate 碳酸氫鈉	

Number and Part of Annex ⁽²⁾ 編碼	CAS 化學物質 登錄號	Name 名稱	Specific conditions and limits 特定條件和限制
10C	92129-90-3	Whey* 乳清*	
11C	7783-28-0	Diammonium phosphate 磷酸二銨	only in traps 僅在誘引器中
12C	8001-21-6	Sunflower oil* 葵花籽油	
14C	84012-40-8 90131-83-2	<i>Urtica</i> spp. (<i>Urtica dioica</i> extract) (<i>Urtica urens</i> extract) * 蕁麻(異株蕁麻葉萃取物) (歐蕁麻葉萃取物)*	
15C	7722-84-1	Hydrogen peroxide 過氧化氫	
16C	7647-14-5	Sodium chloride 氯化鈉	
17C	8029-31-0	Beer* 啤酒*	
18C	-	Mustard seeds powder* 黃芥末籽粉*	
19C	14807-96-6	Magnesium hydrogen metasilicate silicate mineral (Talc E553b) 氫氧化鎂矽酸鹽 矽酸鹽礦物 (滑石 E553b)	food grade in conformity with Commission Regulation (EU) No 231/2012 符合(EU) 231/2012的食品等級
20C	8002-72-0	Onion oil* 洋蔥油*	
21C	52-89-1	L-cysteine (E 920) L-半胱氨酸	
22C	8049-98-7	Cow milk* 牛乳*	
23C	-	<i>Allium cepa</i> * L. bulb extract 大蒜洋蔥鱗莖萃取物*	
24C	9012-76-4	Chitosan* 甲殼素	obtained from <i>Aspergillus</i> or organic aquaculture or from sustainable fisheries, as defined in Article 2 of Regulation (EU) No 1380/2013 取自麴菌屬或有機水產或永續漁業， 定義見 (EU) 1380/2013 第 2 條。
		Other basic substances from plant or animal origin and based on food* 其他以食品為基礎及來自植物源或動 物源之基本物質*	

2. Low risk active substances 低風險活性物質

Low risk active substances, other than micro-organisms, listed in Part D of the Annex to Implementing Regulation (EU) 540/2011 may be used for plant protection in organic production when they are listed in the table below or elsewhere in this Annex. Such low risk active substances shall be used in accordance with the uses, conditions and restrictions pursuant to Regulation (EC) 1107/2009 and taking into account the additional restrictions, if any, in the last column of the table below.

(EU) 540/2011號實施規章附件第D部分所列之低風險活性物質(微生物除外)，當列於下表或本附件其他地方時，得用於有機生產中之植物保護。使用該等低風險活性物質，應依(EC) 1107/2009號規章之用途、條件及限制為之，並考慮下表最後一欄之附加限制(如有)。

Number and Part of Annex ⁽²⁾ 編碼	CAS 化學物質 登錄號	Name 名稱	Specific conditions and limits 特定條件和限制
2D		COS-OGA 甲殼低聚糖-低聚半乳糖醛酸 (Chito-OligoSaccharides Oligo-Galacturonic Acid)	
3D		Cerevisane and other products based on fragments of cells of micro-organisms 釀酒酵母及以微生物細胞碎片為基礎之其他產品	Not from GMO origin 非來自基因改造生物源
5D	10045-86-6	Ferric phosphate (iron (III) orthophosphate) 磷酸鐵(正磷酸鐵(III))	
12D	9008-22-4	Laminarin 海帶多醣	Kelp shall be obtained from organic aquaculture or collected in a sustainable way in accordance with point 2.4 of Part III of Annex II to (EU) 2018/848 海帶應取自有機水產或永續漁業，定義見(EU) 1380/2013 第2條。
16D	CAS not allocated	ABE-IT 56 (components of lysate of <i>Saccharomyces cerevisiae</i> strain DDSF623) ABE-IT 56 (來自 DDSF623 酵母菌株的裂解物成分)	not from GMO origin not produced by using growing media of GMO origin 非來自基因改造生物源 且非使用基因改造來源的培養基生產
20D	10058-44-3	Ferric pyrophosphate 焦磷酸鐵	
19D	23960-07-8	Lavandulyl senecioate 薰衣草千里酸酯	
24D	144-55-8	Sodium hydrogen carbonate 碳酸氫鈉	
28D		Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> 甜白羽扇豆發芽種子的水萃取物	
32D	298-14-6	Potassium hydrogen carbonate 碳酸氫鉀	
38D		Straight chain lepidopteran pheromones (acetates) 直鏈鱗翅目昆蟲費洛蒙 (醋酸酯)	
39D	98999-15-6	Sheep fat 羊脂	use as repellent by smell

Number and Part of Annex ⁽²⁾ 編碼	CAS 化學物質 登錄號	Name 名稱	Specific conditions and limits 特定條件和限制
			以氣味為驅避劑用
44D	14808-60-7 and 7631-86-9	Quartz sand 石英砂 Silicon dioxide 二氧化矽	
		Other low risk substances from plant or animal origin* 其他植物或動物來源的低風險物質*	Herbicidal uses not allowed 禁作農藥用途

3. Micro-organisms 微生物

All micro-organisms listed in Parts A, B and D of the Annex to Implementing Regulation (EU) 540/2011 may be used in organic production, provided that they are not from GMO origin and only when used in accordance with the uses, conditions and restrictions set in the relevant review reports. Micro-organisms including viruses are biological control agents that are considered as active substances by Regulation (EC) 1107/2009.

(EU)540/2011號實施規章附件A、B及D部分列出之所有微生物，均可用於有機生產，但前提是，該等微生物非來自基因改造生物源，又使用該等微生物時，僅在符合相關審查報告3所列用途、條件及限制時始能為之。包括病毒在內之微生物是生物防治物，(EC)1107/2009號規章視其為活性物質。

4. Active substances not included in any of the above categories 非屬上述任何類別的活性物質

The active substances as approved pursuant to Regulation (EC) 1107/2009 and listed in the table below may be used as plant protection products in organic production only when they are used in accordance with the uses, conditions and restrictions pursuant to Regulation (EC) 1107/2009 and taking into account the additional restrictions, if any, in the right column of the table below.

依(EC)1107/2009號規章批准在案並列在下表之活性物質，在使用時，僅在符合(EC)1107/2009號規章規定之用途、條件及限制時，才能用作有機生產中之植物保護產品，並考慮下表右欄之附加限制(如有)。

Number and Part of Annex ⁽¹⁾ 編碼	CAS 化學物質 登錄號	Name 名稱	Specific conditions and limits 特定條件和限制
139A	131929-60-7 131929-63-0	Spinosad 賜諾殺	
225A	124-38-9	Carbon dioxide 二氧化碳	

Number and Part of Annex ⁽¹⁾ 編碼	CAS 化學物質 登錄號	Name 名稱	Specific conditions and limits 特定條件和限制
227A	74-85-1	Ethylene 乙烯	only on bananas and potatoes; however, it may also be used on citrus as part of a strategy for the prevention of fruit fly damage 僅適用於香蕉和馬鈴薯；但乙烯亦可用於柑桔，作為預防果蠅策略之一部分。
230A	i.a. 67701-09-1	Fatty acids 脂肪酸	all uses authorised, except herbicide 所有用途均已獲授權，但除草劑除外。
231A	8008-99-9	Garlic extract (<i>Allium sativum</i>) 大蒜萃取物	
234A	CAS No not allocated CIPAC No 901	Hydrolysed proteins excluding gelatine 水解蛋白質 (不含明膠)	
220A	1332-58-7	Aluminium silicate (kaolin) 矽酸鋁(高嶺土)	
236A	61790-53-2	Kieselgur (diatomaceous earth) 矽藻土	
247A	14808-60-7 7637-86-9	Quartz sand 石英砂	
343A	11141-17-6 84696-25-3	Azadirachtin (<i>Margosa</i> extract) 印楝素(楝子油諾楝樹萃取物)	extracted from Neem tree seeds (<i>Azadirachta indica</i>) 從印楝樹種子中萃取
240A	8000-29-1	Citronella oil 香茅油	all uses authorised, except herbicide 所有用途均已獲授權，但除草劑除外
241A	84961-50-2	Clove oil 丁香油	all uses authorised, except herbicide 所有用途均已獲授權，但除草劑除外
242A	8002-13-9	Rape seed oil 菜籽油	all uses authorised, except herbicide 所有用途均已獲授權，但除草劑除外
243A	8008-79-5	Spearmint oil 留蘭香油	all uses authorised, except herbicide 所有用途均已獲授權，但除草劑除外
56A	8028-48-6 5989-27-5	Orange oil 橙油	all uses authorised, except herbicide 所有用途均已獲授權，但除草劑除外
228A	68647-73-4	Tea tree oil 茶樹油	all uses authorised, except herbicide 除草劑以外之所有用途
246A	8003-34-7	Pyrethrins extracted from plants 萃取植物後之除蟲菊精	
292A	7704-34-9	Sulphur 硫磺	
294A 295A	64742-46-7 72623-86-0 97862-82-3 8042-47-5	Paraffin oils 石蠟油	
345A	1344-81-6	Lime sulphur (calcium polysulphide) 石灰硫(多硫化鈣)	

Number and Part of Annex ⁽¹⁾ 編碼	CAS 化學物質 登錄號	Name 名稱	Specific conditions and limits 特定條件和限制
44B	9050-36-6	Maltodextrin 麥芽糊精	
45B	97-53-0	Eugenol 丁香油	
46B	106-24-1	Geraniol 香葉醇	
47B	89-83-8	Thymol 百里酚	
153B and others		Pheromones and other semiochemicals 費洛蒙與其他半化學物質	
10E	20427-59-2	Copper hydroxide 氫氧化銅	in accordance with (EU) 540/2011 only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years may be authorized 依(EU)第 540/2011 號實施規章規定，僅在 7 年內每公頃總共施用最多 28 公斤銅，才可能獲得使用授權。
10E	1332-65-6 1332-40-7	Copper oxychloride 氧氯化銅	
10E	1317-39-1	Copper oxide 氧化銅	
10E	8011-63-0	Bordeaux mixture 波爾多液	
10E	12527-76-3	Tribasic copper sulphate 三元硫酸銅	
40A	52918-63-5	Deltamethrin 類除蟲菊精(僅溴氰菊酯或 δ-三氯氟)	only in traps with specific attractants against <i>Bactrocera oleae</i> and <i>Ceratitis capitata</i> 僅在具有針對油果實蠅和頭角實蠅之特定誘引物質這類誘引器中。
5E	91465-08-6	Lambda-cyhalothrin 類除蟲菊精(僅溴氰菊酯或 λ-三氯氟)	only in traps with specific attractants against <i>Bactrocera oleae</i> and <i>Ceratitis capitata</i> 僅在具有針對油果實蠅和頭角實蠅之特定誘引物質這類誘引器中。

⁽¹⁾ Listing according to Implementing Regulation (EU) No 540/2011, numbers and which category: Part A active substances deemed to have been approved under Regulation (EC) No 1107/2009, B, active substances approved under Regulation (EC) No 1107/2009, C basic substances, D low-risk active substances and E candidates for substitution. 根據(EU)540/2011 所列編號和類別：A 根據(EC)1107/2009 核准的活性物質，B 根據(EC)1107/2009 核准的活性物質，C 基本物質，D 低風險活性物質，E 替代候選物。

Annex VII-2. Authorised fertilisers, soil conditioners and nutrients referred to in Point (b) of Article 24(1) of (EU) 2018/848 (EU)2018/848 號規章第 24(1)條第(b)點所指授權肥料、土壤改良劑及養分

Fertilisers, soil conditioners and nutrients⁽¹⁾ listed in this Annex may be used in organic production, provided that they are compliant with

本附件所列肥料、土壤改良劑及養分 可用於有機生產，但前提是，該等肥料、土壤改良劑及養分符合：

- the relevant Union and national legislations on fertilising products, in particular, where applicable, Regulation (EC) 2003/2003 and Regulation (EU) 2019/1009; and
有關肥料產品之相關歐盟和國家立法，特別是(EC)第2003/2003號規章及(EU)2019/1009號規章(如適用)；及
- Union legislation on animal by-products, in particular Regulation (EC) 1069/2009 and Regulation (EU) 142/2011, in particular Annexes V and XI.
關於動物副產品之歐盟立法，特別是(EC)第1069/2009號規章及(EU)第142/2011號規章，特別是附件5及11。

In accordance with point 1.9.6 of Part I of Annex II to Regulation (EU) 2018/848, preparations of micro-organisms may be used to improve the overall condition of the soil or to improve the availability of nutrients in the soil or in the crops.

依(EU)2018/848號規章附件2第1部分第1.9.6點規定，微生物調製得用於改善土壤整體條件，或提高土壤或作物中養分供應。

They may only be used according to the specifications and restrictions of use of those respective Union and national legislations. More restrictive conditions for use in organic production are specified in the right column of the tables.

微生物調製在使用上，僅可依其各自歐盟及國家立法所定使用規格及限制為之。在表格右欄針對用於有機生產指明更多限制條件。

Name Compound products or products containing only materials listed hereunder 名稱 僅含有下列材料之複合物或產品	Description, specific conditions and limits 描述、特定條件和限制
Farmyard manure 廄肥	product comprising a mixture of animal excrements and vegetable matter (animal bedding and feed material) 產品含動物排泄物與植物物質之混合物(動物鋪墊料和飼料材料)。 factory farming origin forbidden 禁用集約畜牧源。
Dried farmyard manure and dehydrated poultry manure 乾燥廄肥及脫水家禽廄肥	factory farming origin forbidden 禁用集約畜牧源。
Composted animal excrements, including poultry manure and	factory farming origin forbidden 禁用集約畜牧源。

Name Compound products or products containing only materials listed hereunder 名稱 僅含有下列材料之複合物或產品	Description, specific conditions and limits 描述、特定條件和限制
composted farmyard manure included 動物糞便堆肥，包括家禽廢肥 及堆肥	
Liquid animal excrements 液態動物排泄物	use after controlled fermentation and/or appropriate dilution 在可控制條件下發酵後及/或適當稀釋後使用。 factory farming origin forbidden 禁用集約畜牧源。
Composted or fermented mixture of household waste (Directive 2008/98/EC of the European Parliament and of the Council) 堆肥或發酵過家用廢棄物混合 物（歐洲議會及理事會 2008/98/EC指令）	product obtained from source separated household waste, which has been submitted to composting or to anaerobic fermentation for biogas production 產品取自分離之家用廢棄物，已堆肥處理或厭氣發酵生產沼氣。 only vegetable and animal household waste 僅來自植物與動物畜舍廢棄物。 only when produced in a closed and monitored collection system, accepted by the Member State 僅限於會員國同意之密閉生產並監測收集系統。 maximum concentrations in mg/kg of dry matter: cadmium: 0.7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0.4; chromium (total): 70; chromium (VI): not detectable 乾燥物中元素最高濃度(mg/kg)：鎘：0.7；銅：70；鎳：25；鉛：45；鋅： 200；汞：0.4；總鉻：70；鉻(六價鉻)：0。
Peat 泥灰	use limited to horticulture (market gardening, floriculture, arboriculture, nursery) 限園藝用(市場園藝、花卉栽培、樹木培植、育苗)。
Mushroom culture wastes 菇類栽培廢棄物	the initial composition of the substrate shall be limited to products of this Annex 基質原始成分應限於本附件產品。
Dejecta of worms (vermicompost) and insect frass-substrate mixture 蠕蟲糞便(蚯蚓糞)及昆蟲糞便 基質混合物	where relevant in accordance with (EC) 1069/2009 依(EC)1069/2009在相關情況下。
Guano 鳥糞	
Composted or fermented mixture of vegetable matter 植物物質之堆肥或發酵混合物	product obtained from mixtures of vegetable matter, which have been submitted to composting or to anaerobic fermentation for biogas production 產品取自植物物質混合肥料，已堆肥處理或厭氣發酵生產沼氣。
Biogas digestate containing animal by-products co-digested with material of plant or animal origin as listed in this Annex 沼渣含有與本附件所列植物或 動物源物質共同消化之動物副 產品者	animal by-products (including by-products of wild animals) of category 3 and digestive tract content of category 2 (categories as defined in (EC) 1069/2009) 第3類動物副產品(包括野生動物副產品)和第2類消化道內容物(類別定義見 (EC)1069/2009)。 factory farming origin forbidden 禁用集約畜牧源。 the processes have to be in accordance with (EU) 142/2011 過程必須符合(EU)142/2011。 not to be applied to edible parts of the crop 不可施用在作物可食用部分。

Name Compound products or products containing only materials listed hereunder 名稱 僅含有下列材料之複合物或產品	Description, specific conditions and limits 描述、特定條件和限制
Products or by-products of animal origin as below: 動物源產品或副產品如下： Blood meal 血粉 Hoof meal 蹄粉 Horn meal 角粉 Bone meal or degelatinised bone meal 骨粉或脫膠骨粉 Fish meal 魚粉 Meat meal 肉粉 Feather, hair and skin meal ("chiquette") 毛髮及皮膚粉 Wool 羊毛 Fur (1) 毛皮 (1) Hair 毛髮 Dairy products 乳製品 Hydrolysed proteins (2) 水解蛋白質 (2)	(1) Maximum concentration in mg/kg of dry matter of chromium (VI): not detectable 乾燥物中，鉻(六價鉻)的最高濃度(mg/kg)：0 (2) Not to be applied to edible parts of the crop 不可施用在作物可食用部分。
Products and by-products of plant origin 植物源產品與副產品	e.g.: oilseed cake meal, cocoa husks, malt culms 如：油籽餅粉、椰子殼、麥桿
Hydrolysed proteins of plant origin 植物來源水解蛋白質	
Algae and algae products 藻類與藻類產品	as far as directly obtained by: 只要是直接由以下方法取得者： (i) physical processes including dehydration, freezing and grinding 物理過程包括脫水、冷凍及研磨。 (ii) extraction with water or aqueous acid and/or alkaline solution 以水或酸水及/或鹼性溶液萃取。 (iii) fermentation 發酵 only from organic or collected in a sustainable way in accordance with point 2.4 of Part III of Annex II to (EU) 2018/848 僅來自有機或永續藻類生產(符合(EU)2018/848 附錄二第三部份第 2.4 條規定) 或採收。
Sawdust and wood chips 鋸屑和木屑	wood not chemically treated after felling 砍伐後未經化學處理的木材。
Composted bark 樹皮堆肥	wood not chemically treated after felling 砍伐後未經化學處理的木材。
Wood ash 木灰	wood not chemically treated after felling 砍伐後未經化學處理的木材。
Soft ground rock phosphate 氟含量較低磷礦石粉	product obtained by grinding soft mineral phosphates and containing tricalcium phosphate and calcium carbonate as essential ingredients

Name Compound products or products containing only materials listed hereunder 名稱 僅含有下列材料之複合物或產品	Description, specific conditions and limits 描述、特定條件和限制
	<p>藉由研磨氟含量較低磷礦石取得之產品，含有磷酸三鈣和碳酸鈣作為必要原料。</p> <p>minimum content of nutrients (percentage by weight): 25% P₂O₅ 養分最低含量(重量百分比)：25% 五氧化二磷。</p> <p>phosphorus expressed as P₂O₅ soluble in mineral acids, at least 55% of the declared content of P₂O₅ being soluble in 2% formic acid 以P₂O₅可溶於無機酸表示之磷礦石，P₂O₅聲明含量中，至少55%可溶於2%甲酸。</p> <p>particle size: 粒徑</p> <ul style="list-style-type: none"> – at least 90% by weight able to pass through a sieve with a mesh of 0,063 mm 重量中至少90%，能夠通過0.063毫米網眼的篩子。 – at least 99% by weight able to pass through a sieve with a mesh of 0,125 mm 至少99%能夠通過 0.125毫米網眼的篩子。 <p>until 15 July 2022, cadmium content less than or equal to 90 mg/kg of P₂O₅; 在2022年7月15日以前，P₂O₅重量中，鎘含量小於或等於90 mg/kg； from 16 July 2022, the relevant limits for contaminants set in (EU) 2019/1009 apply. 自2022年7月16日起，適用(EU)2019/1009所載相關污染物限值。</p>
Aluminium-calcium phosphate 磷酸鋁-鈣	<p>product obtained in amorphous form by heat treatment and grinding, containing aluminium and calcium phosphates as essential ingredients 藉由熱處理及研磨取得無定形形式之產品，含有磷酸鋁和碳酸鈣作為必要原料者。</p> <p>minimum content of nutrients (percentage by weight): 30% P₂O₅ 養分最低含量(重量百分比)：30% 五氧化二磷。</p> <p>phosphorus expressed as P₂O₅ soluble in mineral acids, at least 75% of the declared content of P₂O₅ being soluble in alkaline ammonium citrate (Joulie) 以P₂O₅可溶於無機酸表示之磷礦石，P₂O₅聲明含量中，至少75%可溶於鹼性檸檬酸銨(Joulie)。</p> <p>particle size: 粒徑</p> <ul style="list-style-type: none"> – at least 90% by weight able to pass through a sieve with a mesh of 0,160 mm 重量中至少90%，能夠通過0.160毫米網眼的篩子。 – at least 98% by weight able to pass through a sieve with a mesh of 0,630 mm 至少98%能夠通過0.630毫米網眼的篩子。 <p>until 15 July 2022, cadmium content less than or equal to 90 mg/kg of P₂O₅; 在2022年7月15日以前，P₂O₅重量中，鎘含量小於或等於90 mg/kg； from 16 July 2022, the relevant limits for contaminants set in (EU) 2019/1009 apply. 自2022年7月16日起，(EU)2019/1009所定初級土壤(basic soil)之相關污染物限值適用。</p> <p>use limited to basic soils (pH > 7,5) 僅限適用於鹼性土壤(pH > 7.5)。</p>
Basic slag (Thomas phosphates or Thomas slag) 矽酸爐渣(湯馬斯磷肥或湯馬	<p>product obtained in iron-smelting by treatment of the phosphorus melts and containing calcium silicophosphates as its essential ingredients 以煉鐵方式處理磷熔體取得之產品，含有矽磷酸鈣作為必要原料。</p>

Name Compound products or products containing only materials listed hereunder 名稱 僅含有下列材料之複合物或產品	Description, specific conditions and limits 描述、特定條件和限制
斯熔渣)	<p>minimum content of nutrients (percentage by weight): 12% P₂O₅ 養分最低含量(重量百分比): 12% 五氧化二磷</p> <p>phosphorus expressed as phosphorus pentoxide soluble in mineral acids, at least 75% of the declared content of phosphorus pentoxide being soluble in 2% citric acid or 10% P₂O₅ phosphorus expressed as phosphorus pentoxide soluble in 2% citric acid or 10% P₂O₅.</p> <p>磷以可溶於礦物酸的磷酐表示，據稱至少75%磷酐可溶於2%檸檬酸。以P₂O₅可溶於無機酸表示之磷礦石，五氧化二磷聲明含量中，至少75%可溶於 2% 檸檬酸或10% P₂O₅ 中。</p> <p>phosphorus expressed as phosphorus pentoxide soluble in 2% citric acid 以可溶於2%檸檬酸表示磷礦石之五氧化二磷。</p> <p>particle size: 粒徑:</p> <ul style="list-style-type: none"> – at least 75% able to pass through a sieve with a mesh of 0,160 mm 重量中至少75%，能夠通過0.160毫米網眼的篩子。 – at least 96% able to pass through a sieve with a mesh of 0,630 mm 至少96%，能夠通過0.630毫米網眼的篩子。 <p>from 16 July 2022, the relevant limits for contaminants set in (EU) 2019/1009 apply. 自2022年7月16日起，適用(EU)2019/1009所載相關污染物限值。</p>
Crude potassium salt 粗鉀鹽	<p>product obtained from crude potassium salts 從粗鉀鹽取得之產品。</p> <p>minimum content of nutrients (percentage by weight): 養分最低含量(重量百分比):</p> <p>9% K₂O potassium expressed as water- soluble K₂O 9%氧化鉀 以水溶性氧化鉀表示鉀</p> <p>2% MgO magnesium in the form of water- soluble salts, expressed as magnesium oxide 2%氧化鎂 以水溶性鹽形式的鎂，表示為氧化鎂。</p> <p>from 16 July 2022, the relevant limits for contaminants set in (EU) 2019/1009 apply. 自2022年7月16日起，適用(EU)2019/1009所載相關污染物限值。</p>
Potassium sulphate, possibly containing magnesium salt 硫酸鉀 (可能含鎂鹽)	<p>product obtained from crude potassium salt by a physical extraction process, containing possibly also magnesium salts 產品從粗製硫酸鉀以物理萃取過程取得，可能亦含有鎂鹽。</p>
Stillage and stillage extract 蒸餾殘渣和蒸餾殘渣萃取物	<p>ammonium stillage excluded 不包括含銨蒸餾殘渣。</p>
Calcium carbonate, for instance: chalk, marl, ground limestone, Breton ameliorant (maerl), phosphate chalk 碳酸鈣 如：白堊、泥灰岩、重質碳酸鈣、布列塔尼改良劑(粉煤灰)、磷酸鹽白堊	<p>only of natural origin 僅限天然源。</p>
Mollusc waste	<p>only from organic aquaculture or from sustainable fisheries, in accordance with</p>

Name Compound products or products containing only materials listed hereunder 名稱 僅含有下列材料之複合物或產品	Description, specific conditions and limits 描述、特定條件和限制
軟體動物廢棄物	Article 2 of (EU) 1380/2013 僅來自有機水產或永續漁業者，符合(EU) 1380/2013第2條規定。
Egg shells蛋殼	factory farming origin forbidden 禁用集約畜牧源。
Magnesium and calcium carbonate 碳酸鎂鈣	only of natural origin 限天然來源 e.g., magnesian chalk, ground magnesium, limestone 如：鎂白堊、地層鎂、石灰石
Magnesium sulphate (kieserite) 硫酸鎂	only of natural origin 限天然來源
Calcium chloride solution 氯化鈣溶液	only for foliar treatment of apple trees, to prevent deficit of calcium 僅用於蘋果樹葉面處理，以防止鈣缺乏。
Calcium sulphate (gypsum) 硫酸鈣 (石膏)	product of natural origin containing calcium sulphate at various degrees of hydration 含有不同水合度硫酸鈣之天然源產品。 minimum content of nutrients (percentage per weight): 25% CaO 35% SO ₃ 養分最低含量(重量百分比)：25%氧化鈣 35%三氧化硫 calcium and sulphur expressed as total CaO + SO ₃ fineness of grind: 鈣和硫以總氧化鈣 + 三氧化硫研磨細度表示： – at least 80% to pass through a sieve with a 2 mm mesh width, 至少80%能夠通過2毫米網眼寬度的篩子 – at least 99% to pass through a sieve with a 10 mm mesh width 至少99%能夠通過10毫米網眼寬度的篩子 from 16 July 2022, the relevant limits for contaminants set in (EU) 2019/1009 apply 自 2022 年 7 月 16 日起，適用(EU)2019/1009 所載相關污染物限值。
Industrial lime from sugar production 製糖過程生產工業用石灰	by-product of sugar production from sugar beet and sugar cane 甜菜及甘蔗製糖過程生產的副產品
Industrial lime from vacuum salt production 真空製鹽過程生產工業用石灰	by-product of the vacuum salt production from brine found in mountains 山區鹽水真空製鹽過程生產的副產品
Elemental sulphur 硫素	until 15 July 2022: as listed in accordance with Part D of Annex I to (EC) 2003/2003 在2022年7月15日以前：依(EC)第2003/2003附件1第 D 部分所列 者。 from 16 July 2022, the relevant limits for contaminants set in (EU) 2019/1009 apply 自2022年7月16日起，適用(EU)2019/1009所載相關污染物限值。
Inorganic Micronutrient Fertilisers 無機微量元素肥料	until 15 July 2022: as listed in accordance with Part E of Annex I to (EC) 2003/2003; 在2022年7月15日以前：依(EC)第2003/2003附件1第 D 部分所列 者。 from 16 July 2022, the relevant limits for contaminants set in (EU) 2019/1009 apply 適用(EU)2019/1009所載相關污染物限值。
Sodium chloride 氯化鈉	

Name Compound products or products containing only materials listed hereunder 名稱 僅含有下列材料之複合物或產品	Description, specific conditions and limits 描述、特定條件和限制
Stone meal, sand of natural origin, clays and clay minerals 石粉、黏土及黏土礦物	e.g., perlite, sand and vermiculite, including when heat treated, perlite, sand and vermiculite, including when heat treated, may also be used for sprouted seeds production as an inert medium as referred to in Part I, point 1.3(a), of Annex II to Regulation (EU) 2018/848 例如，珍珠岩粉、沙子和蛭石，包括在熱處理時。 珍珠岩粉、沙子和蛭石，包括在熱處理時也可以作為幼芽種子的生產使用，作為(EU) 2018/848 附錄II第I部分第1.3(a)點中所提及的惰性介質。
Leonardite (Raw organic sediment rich in humic acids) 風化褐煤 (原始有機沉積物含豐富腐植酸)	only if obtained as a by-product of mining activities 限於取自採礦活動之副產品。
Humic and fulvic acids 腐殖酸和黃腐酸(富里酸)	only if obtained by inorganic salts/solutions excluding ammonium salts; or obtained from drinking water purification 限於取自無機鹽/溶液(銨鹽除外)；或取自飲用水淨化。
Xylite 木糖醇	only if obtained as a by-product of mining activities (e.g. by-product of brown coal mining) 僅限於採礦得到的副產物 (例如棕煤開採的副產物)
Chitin (Polysaccharide obtained from the shell of crustaceans) 幾丁質(取自甲殼類動物外殼之多醣)	obtained from organic aquaculture or from sustainable fisheries, in accordance with Article 2 of (EU) 1380/2013 取自有機水產或永續漁業，符合(EU) 1380/2013第2條規定。
Organic ⁽¹⁾ rich sediment from fresh water bodies formed under exclusion of oxygen (e.g. sapropel) 淡水中的有機體在缺氧情況下形成富含有機質的沉積物(如：腐泥)	only organic sediments that are by-products of fresh water body management or extracted from former freshwater areas 限淡水水體處理副產品或由原先淡水區抽取之有機沉積物。 when applicable, extraction should be done in a way to cause minimal impact on the aquatic system 適用時，抽取時應該以對水體系統造成影響最小化方式為之。 only sediments derived from sources free from contaminations of pesticides, persistent organic pollutants and petrol like substances 沉積物限其來源未受農藥、持久性有機污染物及石化物質污染。 until 15 July 2022: maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable 在2022年7月15日以前：乾燥物中元素之最高濃度(mg/kg)： 鎘：0.7；銅：70；鎳：25；鉛：45；鋅：200；汞：0.4；總鉻：70；鉻(六價鉻)：0。 from 16 July 2022, the relevant limits for contaminants set in (EU) 2019/1009 apply 自2022年7月16日起，適用(EU)2019/1009所載相關污染物限值。
Biochar - pyrolysis product made from a wide variety of organic materials of plant origin	only from plant materials, when treated after harvest only with products included in Annex I 限來自植物材料，收穫後僅使用附件1所含產品進行處理。

Name Compound products or products containing only materials listed hereunder 名稱 僅含有下列材料之複合物或產品	Description, specific conditions and limits 描述、特定條件和限制
and applied as a soil conditioner 生物碳 - 由多種植物源有機 材料製成之熱解產品，用作土 壤改良劑	until 15 July 2022: maximum value of 4 mg polycyclic aromatic hydro-carbons (PAHs) per kg dry matter (DM) 在2022年7月15日以前：每公斤乾燥物(dry matter, DM)中多環芳烴(PAH)最大 值為4毫克。 from 16 July 2022, the relevant limits for contaminants set in (EU) 2019/1009 apply 自2022年7月16日起，適用(EU)2019/1009所載相關污染物限值。
Recovered struvite and precipitated phosphate salts 回收的鳥糞石和沈澱磷酸鹽	products must meet the requirements laid down in Regulation (EU) 2019/1009 animal manure as source material cannot have factory farming origin 產品必須符合(EU)2019/1009要求 作為原料的動物糞便不得來自工廠化養殖
Sodium nitrate 硝酸鈉	only for algae production on land in closed systems 僅用於封閉系統中陸地藻類生產
Potassium chloride (muriate of potash) 氯化鉀	only of natural origin 僅用於天然來源
Carbon dioxide 二氧化碳	use for enrichment of water for algae production on land in closed systems; in this case, carbon dioxide shall be of food grade when available, carbon dioxide shall be obtained as a by-product of other processes or from renewable sources pursuant to Directive (EU) 2018/2001 of the European Parliament and of the Council may also be used in greenhouse production 用於在封閉系統中陸地藻類生產中富集水體；在這種情況下，二氧化碳應為 食品級。 如有二氧化碳，應根據 (EU) 2018/2001，取自其他流程的副產品或可再生來 源。 也可用於溫室生產
Calcium acetate 醋酸鈣	only for foliar application on vegetables in greenhouses and on apple trees to prevent deficiency in calcium obtained from calcium carbonate of natural origin 僅用於溫室蔬菜和蘋果樹的葉面噴施，以防止鈣缺乏。 由天然碳酸鈣獲得
Calcium phosphate 磷酸鈣	only when derived from sewage sludge ash only products complying with the requirements of Regulation (EU) 2019/1009 僅當其來自污水污泥灰時 僅限符合 (EU) 2019/1009 要求的產品
Plant fibre mats 植物纖維墊	plant-based fibres, such as hemp fibre, flax fibre, coconut fibre with no addition of any fertiliser, soil conditioner or nutrient nor additives or binders, only mechanically manufactured only for sprouted seeds production as an inert medium referred to in Part I, point 1.3(a), of Annex II to Regulation (EU) 2018/848 when available, materials from organic production shall be used 植物纖維，如：大麻纖維、亞麻纖維、椰子纖維。

Name Compound products or products containing only materials listed hereunder 名稱 僅含有下列材料之複合物或產品	Description, specific conditions and limits 描述、特定條件和限制
	不添加任何肥料、土壤改良劑、營養劑、添加劑或黏合劑，僅以機械方式生產。 僅用於作為 (EU) 2018/848 附件2第1部分第1.3(a)點所述的惰性培養基生產發芽種子。 如有有機生產材料，應使用。
Calcium and magnesium gluconate 葡萄糖酸鈣和葡萄糖酸鎂	derived from microbial fermentation 源自微生物發酵

- (1) Here 'organic' is used in the sense of organic chemistry, not organic farming.
 這裡的"有機"是指有機化學，而不是有機農業。





Annex VII-3. Authorised products and substances for use in the production of processed organic food and of yeast used as food 用於生產有機加工食品及用作食品的酵母的授權產品和物質

Part A. Authorised food additives and processing aids referred to in point (a) of Article 24(2) of Regulation (EU) 2018/848 針對 (EU)2018/848號規章第24(2)條第(a)點所指：授權的食品添加物和加工助劑

The organic foodstuffs to which food additives may be added are within the limit of authorisations given in accordance with Regulation (EC) 1333/2008.

有機食品可添加的食品添加物，應在法規 (EC) 1333/2008授予的授權範圍內。

The specific conditions and restrictions set out here are to be applied in addition to the conditions of the authorisations under Regulation (EC) 1333/2008.

除(EC)第1333/2008號規章下之授權條件外，此處列出之特定條件和限制亦適用。

The use as food additives or as processing aids shall be attributed on a case-by-case basis in accordance with Regulation (EC) No 1333/2008 and national legislation on processing aids.

作為食品添加劑或加工助劑的使用應根據 (EC) 1333/2008 和國家加工助劑法規逐案確定。

For the purpose of the calculation of the percentages referred to in Article 30(5) of Regulation (EU) 2018/848, food additives marked with an asterisk in the column of the code number shall be calculated as ingredients of agricultural origin.

為計算(EU) 2018/848號規章第30(5)條所指百分比，在代碼編號欄中標有星號之食品添加物，應作為農業源原料計算。

E-number or Eines (), or both E編號或Eines 或兩者	Name 名稱	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits 可以使用添加劑或加工輔助以及特定條件和限制的有機食品	
		Use as an additive 用作添加物	Use as a processing aid 用作加工助劑
E 153	Vegetable carbon 植物源碳	edible cheese rind of ashy goat cheese 灰山羊乾酪之可食用乾酪皮 Morbier cheese 莫爾比耶乾酪	
E 160b(i)*	Annatto bixin 胭脂樹紅紅木	Red Leicester cheese 紅列斯特乾酪 Double Gloucester cheese 雙格羅斯特乾酪 Cheddar 蘇格蘭切達乾酪 Mimolette cheese 美莫勒乾酪	
E 160b(ii)*	Annatto norbixin 胭脂樹紅降紅木	Red Leicester cheese 紅列斯特乳酪 Double Gloucester cheese 雙格羅斯特乳酪 Cheddar 蘇格蘭切達乳酪 Mimolette cheese 美莫勒乳酪	

E-number or Einecs (), or both E編號或Einecs 或兩者	Name 名稱	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits 可以使用添加劑或加工輔助以及特定條件和限制的有機食品	
		Use as an additive 用作添加物	Use as a processing aid 用作加工助劑
E 170/207-439-9 and 215-279-6	Calcium carbonate 碳酸鈣	products of plant and animal origin 植物源和動物源產品	products of plant origin 植物源產品
E 223	Sodium metabisulphite 焦亞硫酸鈉	Crustaceans 甲殼類動物	
E 267*	Buffered vinegar 緩衝醋	products of plant and animal origin 植物源和動物源產品 only from organic production 限取自有機生產者	
E 270/200-018-0	Lactic acid 乳酸	products of plant and animal origin 植物源和動物源產品	cheese乳酪 for the regulation of pH of the brine bath in cheese production 用於調節乳酪生產中鹽水浴pH值
E 290/204-696-9	Carbon dioxide 二氧化碳	products of plant and animal origin 植物源和動物源產品	products of plant and animal origin 植物源和動物源產品
E 296	Malic acid 蘋果酸	products of plant origin 植物源產品	
E 300	Ascorbic acid 抗壞血酸	products of plant origin 植物源產品	
E 306*	Tocopherol rich extract 富維生素E萃取物	products of plant and animal origin 植物源和動物源產品 only as antioxidant 僅用作抗氧化劑	
E 322*	Lecithins 卵磷脂	products of plant origin 植物源產品 milk products 乳製品	only from organic production 限取自有機生產者
E 325	Sodium lactate 乳酸鈉	products of plant origin 植物源產品 milk-based products 乳製品	
E 330	Citric acid 檸檬酸	products of plant and animal origin 植物源和動物源產品	
E 331	Sodium citrates 檸檬酸鈉	products of plant and animal origin 植物源和動物源產品	
E 333	Calcium citrates 檸檬酸鈣	products of plant origin 植物源產品	
E 334	Tartaric acid (L(+)-) 左旋酒石酸	products of plant origin 植物源產品	
E 335*	Sodium tartrates 酒石酸鈉	products of plant origin 植物源產品 from 1 January 2027, only from organic production	

E-number or Eines (), or both E編號或Eines 或兩者	Name 名稱	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits 可以使用添加劑或加工輔助以及特定條件和限制的有機食品	
		Use as an additive 用作添加物	Use as a processing aid 用作加工助劑
		自 2027 年 1 月 1 日起，限取自有機生產者	
E 336	Potassium tartrates 酒石酸鉀	products of plant origin 植物源產品 from 1 January 2027, only from organic production 自 2027 年 1 月 1 日起，限取自有機生產者	
E 337*	Potassium sodium tartrate	products of plant origin 植物源產品 from 1 January 2027, only from organic production 自 2027 年 1 月 1 日起，限取自有機生產者	
E 341(i)	Monocalcium phosphate 磷酸一鈣	self-raising flour 自發麵粉膨鬆劑 only as raising agent 僅用作膨鬆劑	
E 392*	Extracts of Rosemary 迷迭香萃取物	products of plant and animal origin 植物源和動物源產品 only from organic production 限取自有機生產者	
E 400	Alginic acid 海藻酸	products of plant origin 植物源產品 milk products 乳製品	
E 401	Sodium alginate 海藻酸鈉	products of plant origin 植物源產品 milk products 乳製品	
E 402	Potassium alginate 海藻酸鉀	products of plant origin 植物源產品 milk-based products 牛乳基產品	
E 406	Agar 瓊脂	products of plant origin 植物源產品 milk-based products 牛乳基產品	
E 407	Carrageenan 鹿角菜膠	products of plant origin 植物源產品 milk-based products 牛乳基產品	
E 410*	Locust bean gum 刺槐豆膠	products of plant and animal origin 植物源和動物源產品 only from organic production 限取自有機生產者	
E 412*	Guar gum	products of plant and animal origin	

E-number or Einecs (), or both E編號或Einecs 或兩者	Name 名稱	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits 可以使用添加劑或加工輔助以及特定條件和限制的有機食品	
		Use as an additive 用作添加物	Use as a processing aid 用作加工助劑
	關華豆膠	植物源和動物源產品 only from organic production 限取自有機生產者	
E 414*	Arabic gum 阿拉伯膠	products of plant and animal origin 植物源和動物源產品 only from organic production 限取自有機生產者	
E 415	Xanthan gum 玉米糖膠	products of plant and animal origin 植物源和動物源產品	
E 417	Tara gum 塔拉膠粉	products of plant and animal origin 植物源和動物源產品 only from organic production 限取自有機生產者 Only as thickener 僅用作增稠劑	
E 418*	Gellan gum 結蘭膠	products of plant and animal origin 植物源和動物源產品 only from organic production 限取自有機生產 only high-acyl form 僅限高鹽基形式	
E 422*	Glycerol 甘油	plant extracts and flavourings 植物萃取物及調味劑 only from plant origin 限植物來源 only from organic production 限取自有機生產者 as solvent and carrier 作為溶劑及載體 as humectant in gel capsules 作為凝膠膠囊中之保濕劑 as surface coating of tablets 作為錠劑表面包衣	
E 440(i)*	Pectin 果膠	products of plant origin 植物源產品 milk-based products 乳製品	
E 460/232- 674-9	Cellulose 纖維素	gelatine 明膠	gelatine明膠 products of plant origin植物源產品
E 464	Hydroxypropyl methylcellulose 羥丙基甲基纖 維素	products of plant and animal origin 植物源和動物源產品 only as encapsulation material for capsules 僅用作膠囊包覆物質	
E 500/207-	Sodium	products of plant and animal origin	products of plant and animal origin

E-number or Einecs (), or both E編號或Einecs 或兩者	Name 名稱	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits 可以使用添加劑或加工輔助以及特定條件和限制的有機食品	
		Use as an additive 用作添加物	Use as a processing aid 用作加工助劑
838-8, 205-633-8, 208-580-9	carbonates 碳酸鈉	植物源和動物源產品	植物源和動物源產品
E 501/209-529-3, 206-059-0	Potassium carbonates 碳酸鉀	products of plant origin 植物源產品	grapes 葡萄 only as drying agent to produce dried grapes 僅作為乾燥劑產生葡萄乾
E 503	Ammonium carbonates 碳酸銨	products of plant origin 植物源產品	
E 504	Magnesium carbonates 碳酸鎂	products of plant origin 植物源產品	
E 509/233-140-8	Calcium chloride 氯化鈣	products of plant origin 植物源產品 only to induce coagulation 僅用於誘發凝乳	products of plant origin 植物源產品 only as clarifying/flocculating agent 僅作為澄清/絮凝劑
		milk-based products 牛奶基底產品 only as stabilizer 僅作為穩定劑	
E 511/232-094-6	Magnesium chloride 氯化鎂	products of plant origin 植物源產品 only to induce coagulation 僅用於誘發凝乳	products of plant origin 植物源產品 only as clarifying/flocculating agent 僅作為澄清/絮凝劑
E 516/231-900-3	Calcium sulphate 硫酸鈣	products of plant origin 植物源產品 only as carrier or induce coagulation 僅作為載體或用於誘發凝乳	products of plant origin 植物源產品 only as clarifying/flocculating agent 僅作為澄清/絮凝劑
E 524/215-185-5	Sodium hydroxide 氫氧化鈉	surface-treated <i>Laugengebäck</i> 鹼水麵包表面處理 only as surface treatment 僅用作表面處理	sugar(s) 糖
		flavourings 調味劑 only as acidity regulator 僅作為酸度調節劑	oil from plant origin excluding olive oil 植物油不包括橄欖油
			plant protein extracts 植物蛋白萃取物
E 551/231-545-4	Silicon dioxide 二氧化矽	cocoa 可可 only as anticaking agent for use in automated dispensing machines 僅作為用於自動分配器的抗結塊劑	products of plant origin 植物源產品
		herbs and spices in dried powdered form 用於乾粉狀的香草和香料	
		flavourings 調味劑	
		propolis 蜂膠	
E 553b	Talc 滑石粉	products of plant origin 植物源產品	products of plant origin 植物源產品

E-number or Eines (), or both E編號或Eines 或兩者	Name 名稱	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits 可以使用添加劑或加工輔助以及特定條件和限制的有機食品	
		Use as an additive 用作添加物	Use as a processing aid 用作加工助劑
E 901*/232-383-7	Beeswax 蜂蠟	confectionery 糖果 only from organic production 限取自有機生產者 only as glazing agent 僅作為光澤劑	confectionery 糖果 only from organic production 限取自有機生產者 only as releasing agent 僅作為脫模劑
E 903*/232-399-4	Carnauba wax 棕櫚蠟	confectionery 糖果 only from organic production 限取自有機生產者 only as glazing agent 僅作為光澤劑	products of plant origin 植物源產品 only from organic production 限取自有機生產者 only as releasing agent 僅作為脫模劑
		citrus fruit 柑橘 only from organic production 限取自有機生產者 only as mitigating method for mandatory extreme cold treatment of fruit as a mandatory quarantine measure against harmful organisms in accordance with (EU) 2017/1279 僅依(EU)2017/1279，對水果進行強制性極冷處理之緩解方法，作為防治有害生物之強制檢疫措施。	
E 938	Argon 氬	products of plant and animal origin 植物源和動物源產品	
E 939	Helium 氦	products of plant and animal origin 植物源和動物源產品	
E 941	Nitrogen 氮	products of plant and animal origin 植物源和動物源產品	
E 948	Oxygen 氧	products of plant and animal origin 植物源和動物源產品	
E 968	Erythritol 赤蘚糖醇	products of plant and animal origin 植物源和動物源產品	only from organic production without using ion exchange technology 僅當來自有機生產且未使用離子交換技術時
-/200-578-6	Ethanol 乙醇		products of plant and animal origin 植物源及動物源產品 only as solvent on crystallization primers for the production of sugar and/or extraction solvent 僅作為生產糖的結晶引子的溶劑和/或萃取溶劑
-/200-580-7	Acetic acid 醋酸		products of plant origin 植物源產品 from organic production, if available 來自有機生產，如有。

E-number or Eines (), or both E編號或Eines 或兩者	Name 名稱	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits 可以使用添加劑或加工輔助以及特定條件和限制的有機食品	
		Use as an additive 用作添加物	Use as a processing aid 用作加工助劑
-/215-108-5	Bentonite 膨潤土		products of plant origin 植物源產品
-/215-137-3	Calcium hydroxide 氫氧化鈣		products of plant origin 植物源產品
-/231-595-7	Hydrochloric acid 鹽酸		gelatine 明膠
			Gouda, Edam and Maasdammer cheeses, Boerenkaas, Friese and Leidse Nagelkaas 高達乾酪、艾登乾酪、馬斯丹乾酪、布爾安卡斯乾酪、弗裡斯蘭丁香乾酪 only as the regulation of the pH of the brine bath in the processing of cheeses 僅用於在乾酪加工過程中調節鹽水浴酸鹼值
-/231-639-5	Sulphuric acid 硫酸		gelatine 明膠
			sugar(s) 糖類
-/231-765-0	Hydrogen peroxide 過氧化氫		gelatine 明膠
-/232-554-6	Gelatin 明膠		products of plant origin 植物源產品
-/232-555-1	Casein 酪蛋白		products of plant origin 植物源產品
-/293-292-6	Isinglass 魚膠		products of plant origin 植物源產品
-/931-328-0	Activated carbon 活性碳		products of plant and animal origin 植物源及動物源產品
	Ammonium hydroxide 氫氧化銨		gelatine 明膠
	L(+) lactic acid from fermentation 左旋乳酸 (發酵來源)		plant protein extracts 植物蛋白萃取物
	Diatomaceous earth 矽藻土		products of plant origin 植物源產品
			gelatine 明膠
	Egg white albumin 蛋清蛋白		products of plant origin 植物源產品
	Hop extract	sugar 糖類	products of plant origin 植物源產品

E-number or Eines (), or both E編號或Eines 或兩者	Name 名稱	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits 可以使用添加劑或加工輔助以及特定條件和限制的有機食品	
		Use as an additive 用作添加物	Use as a processing aid 用作加工助劑
	啤酒花萃取物		from organic production, if available 來自有機生產，如有。 only for antimicrobial purposes 僅用於抗菌目的。
	Hazelnut shells 榛子殼		products of plant origin 植物源產品
	Perlite 珍珠岩粉		products of plant origin 植物源產品 gelatine 明膠
	Pine rosin extract 松香萃取物		products of plant origin 植物源產品 from organic production, if available 來自有機生產，如有。 only for antimicrobial purposes 僅用於抗菌目的。
	Rice meal 米粉		products of plant origin 植物源產品
	Tannic acid 單寧酸		products of plant origin 植物源產品 only as filtration aid 僅用作過濾助劑
	Vegetable oils 植物油		products of plant and animal origin 植物源及動物源產品 only from organic production 限取自有機生產者 only as greasing, releasing or antifoaming agent 僅用作油脂潤滑，釋放(離型、脫模)或消泡劑。
	Vinegar 醋		products of plant origin 植物源產品 only from organic production 限取自有機生產者
	Water 水		products of plant and animal origin 植物源和動物源產品 water intended for human consumption within the meaning of Directive (EU) 2020/2184 of the European Parliament and of the Council 歐洲議會和理事會的(EU) 2020/2184所定義的供人類飲用水
	Wood fibre 木材纖維		the source of timber should be restricted to certified, sustainably harvested wood products of plant and animal origin 植物源及動物源產品

E-number or Eines (), or both E編號或Eines 或兩者	Name 名稱	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits 可以使用添加劑或加工輔助以及特定條件和限制的有機食品	
		Use as an additive 用作添加物	Use as a processing aid 用作加工助劑
			the source of timber shall be restricted to certified, sustainably harvested wood 木材來源應該僅限於驗證合格、可永續採伐之木材 wood used shall not contain toxic components (post-harvest treatment, naturally occurring toxins or toxins from microorganisms) 所用木材不得含毒性成分 (採伐後處理、天然毒素或微生物毒素)

(+) European Inventory of Existing Commercial Chemical Substances (OJ C 146, 15.6.1990, p. 4).

現有商業化學物質的歐洲清單(OJ C 146, 15.6.1990, p. 4)。

Part B

Authorised non-organic agricultural ingredients to be used for the production of processed organic food referred to in point (b) of Article 24(2) of Regulation (EU) 2018/848

針對(EU)2018/848 號規章第 24(2)條第(b)點所指有機加工食品：在生產過程中所使用之經授權非有機農業原料

Name 名稱	Specific conditions and limits 特定條件和限制
Alga Arame (<i>Eisenia bicyclis</i>), unprocessed as well as products of first-stage processing directly related to this alga 昆布(海帶)，未加工及與該等產品直接相關的第一階段加工產品。	
Alga Hijiki (<i>Hizikia fusiforme</i>), unprocessed as well as products of first-stage processing directly related to this alga 鹿尾菜(羊棲菜)，未加工及與這些產品直接相關的第一階段加工產品。	
Bark of the Pau d'arco tree <i>Handroanthus impetiginosus</i> ("lapacho") 保哥果(內樹皮)、紫花風鈴木、(保哥茶)	only for use in Kombucha and tea mixtures 僅用於康普茶和茶混合物
Casings 腸衣	from natural raw materials of animal or from plant origin material 來自動物源或植物源材料之天然原材料。
Gelatin 明膠	from other sources than porcine 來自豬以外的其他來源
Milk mineral powder/liquid 乳礦物粉/液體	only when used for its sensory function to replace wholly or partly sodium chloride 僅當以其感官功能完全或部分替代氯化鈉時

Part C

Authorised processing aids and other products for the production of yeast and yeast products referred to in point (c) of Article 24(2) of Regulation (EU) 2018/848

針對(EU)2018/848 號規章第 24(2)條第(c)點所指酵母和酵母產品：在生產過程所使用之經授權加工助劑及其他產品

Name 名稱	Primary yeast 初生酵母	Yeast production/ confection/ formulation 酵母生產/甜點/配方	Specific conditions and limits 特定條件和限制
Calcium chloride 氯化鈣	×		
Carbon dioxide 二氧化碳	×	×	
Citric acid 檸檬酸	×		for the regulation of the pH in yeast production 酵母生產中調節pH值
Lactic acid 乳酸	×		for the regulation of the pH in yeast production 酵母生產中調節pH值
Nitrogen 氮	×	×	
Oxygen 氧	×	×	
Potato starch 馬鈴薯澱粉	×	×	for filtering 過濾用 only from organic production 僅限來自有機生產
Sodium carbonate 碳酸鈉	×	×	for the regulation of the pH 調節酸鹼用
Vegetable oils 植物油	×	×	greasing, releasing or antifoaming agent 油脂潤滑、脫模劑或消泡劑 only from organic production 僅限來自有機生產
Fermentation activators 發酵促進劑	×		nutrients from yeast extract or autolysate 來自酵母萃取物或自溶物的營養物質 up to 5 % of the substrate calculated in weight of dry matter 以乾物質重量計算，最高達基質5%

第二部分、驗證程序



Operating Procedure of Certification

驗證作業流程

I. Certification 驗證

- A. person seeking to receive or maintain organic certification must provide the following information: 欲取得或維持有機驗證者，必須提供下列資料：
- 1 the 'Organic System Plan' with the signed declaration. The 'Organic System Plan' should include the following contents: 填寫「有機驗證申請書」並簽署其中聲明文件，「有機驗證申請書」內容包含：
 - (i) a description of the organic and/or in-conversion production unit and, where relevant, of the non-organic production units and of the activities to be performed in accordance with Regulation (EU) 2018/848 號規章；對有機和/或有機轉型期生產單位的描述，及相關的非有機生產單位和根據(EU) 2018/848 號規章進行活動的描述；
 - (ii) the relevant measures to be taken at the level of the organic and/or in-conversion unit and/or premises and/or activities to ensure compliance with Regulation (EU) 2018/848; 在有機和/或有機轉型期單位和/或場所和/或活動層面採取的相關措施，以確保符合 (EU) 2018/848 號規章；
 - (iii) the precautionary measures to be taken in order to reduce the risk of contamination by non-authorized products or substances and the cleaning measures to be taken throughout the stages of production, preparation and distribution; 為降低非允用產品或物質污染風險，而採取的預防措施，及在生產、調製和流通的全階段採取的清潔措施；
 - (iv) Nature of operations and products. 作業與產品性質。
 - 2 a confirmation that the operators or groups of operators have not been certified by another certification body for activities in the same third country, pertaining to similar products, including different stages of production, preparation, or distribution. 農產品經營者或農產品經營者集團未獲得另一驗證機構關於同一第三國就同類產品開展的活動的驗證，包括其在生產、調製或流通的不同階段；
 - 3 a confirmation by the members of a group of operators that they have not been certified on an individual basis for the same activity for a given product covered by the certification of the group of operators to which they belong; 農產品經營者集團成員需確認他們沒有就其所屬集團驗證所涵蓋的特定產品的相同活動獲得單獨驗證；
 - 4 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「有機作物栽培集團申請附表」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。
 - 5 a signed 'Organic Certification Contract' by the operators or groups of operators. 農產品經營者

或農產品經營者集團應簽署「農產品驗證契約書 EU」。

- 6 Submit the applicable certification fees charged by TOC (Appendix I). 繳付驗證費用(如附錄 1)
- B. Prior to certification, the operators or groups of operators shall comply with: 農產品經營者或農產品經營者集團於進行驗證之前，應遵守：
 - 1 that the operators or groups of operators comply with Chapters II, III and IV of Regulation (EU) 2018/848 and Article 36 of that Regulation. The verification shall include at least one physical on-the-spot inspection; 農產品經營者或農產品經營者集團遵守 (EU) 2018/848 號規章第 II、III 和 IV 章及第 36 條。查證應至少包括一次現場實地稽查；
 - 2 that, where the operators or groups of operators subcontract any of its activities to third parties, both the operators or groups of operators and the third parties to whom those activities have been subcontracted, have been certified by recognised control authorities or control bodies confirming that they comply with Chapters II, III and IV of Regulation (EU) 2018/848 and Article 36 of that Regulation, unless the operators or groups of operators inform the relevant control authority or control body that they remain responsible as regards organic production and that they have not transferred that responsibility to the subcontractor. In such cases, the control authority or control body shall verify that the subcontracted activities comply with Chapters II, III and IV of Regulation (EU) 2018/848 and Article 36 of that Regulation in the context of the control activities it carries out in respect of the operators or groups of operators that have subcontracted their activities. 如果農產品經營者或經營者集團將其任何活動委外給第三方，且該等經營者或集團及承包這些活動的第三方均已獲得經認證的驗證機構驗證，確認其符合 (EU) 2018/848 號規章第 II、III 和 IV 章及第 36 條，除非農產品經營者或農產品經營者集團通知相關驗證機構仍對有機生產負責，且未將該責任轉移給分包商。在這種情況下，驗證機構應確認委外活動是否符合(EU) 2018/848 號規章第 II、III 和 IV 章及第 36 條規定，在其對已委外活動的農產品經營者或經營者集團進行的管控活動之內。
- C. Upon acceptance of an application, TOC must review the application to ensure completeness pursuant to “A、B” of this section. 收到申請資料，本公司應先審查資料是否完整符合「A、B」之要求。
- D. Determine by an initial review of the application materials whether the applicant appears to comply or may be able to comply with the Standard. 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. 由初步審查，判定該申請者是否符合或可能符合本標準規定。若審查申請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。
- E. Besides any other element that may be considered relevant by TOC, before certifying operators or groups of operators that were previously certified by another control authority or control body, TOC shall assess the following information to be transmitted by the previous control authority or control body: 除了本公司可能認為相關的任何其他事項外，在對原本由另一驗證機構驗證的農產品經營者或農產品經營者集團進行驗證之前，本公司應評估以下由前驗證機構傳送的資訊：

- 1 the status and validity of certification, including cases of scope reduction, suspension and withdrawal as referred to in International Organisation for Standardisation (ISO) standard ISO/IEC 17065; 驗證的狀態和有效性，包括 ISO/IEC 17065 提到的範圍縮小、暫停和撤銷的情況；
- 2 reports of inspection carried out in the preceding 3 years; 前三年的查驗報告；
- 3 the list of non-compliances and the measures put in place to address them, and the fact that all non-compliances were addressed; 不符合事項清單和為解決這些問題而採取措施，及所有不符合事項都得到解決的事實；
- 4 derogations granted or requests for derogation being processed by the previous control authority or control body; 前驗證機構核准的減免或要求減免；
- 5 information relating to any ongoing dispute relevant for the certification of the operators or groups of operators. 與農產品經營者或農產品經營者集團驗證有關的任何持續爭議的相關資訊。

If the previous control authority or control body does not transmit the information as required in Article 21(5) of this Regulation to the new control authority or control body or in case of doubts concerning the information transmitted, TOC shall not issue the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 to operators or groups of operators until this new control authority or control body has eliminated their doubts by other means of control. 如果前驗證機構未按照(EU) 2021/1698 第 21(5)條要求，將資訊傳達給新的驗證機構，或對傳達的資訊有疑問，本公司不得向農產品經營者或農產品經營者集團頒發(EU) 2018/848 號規章第 45(1)(b)(i)條中提到的證書，直到本公司通過其他管制手段消除疑慮。

- F. TOC shall not certify operators or groups of operators that have been withdrawn by their previous control authority or control body in the last 2 years, unless the recognition of the previous control authority or control body has been withdrawn by the Commission in accordance with Article 46(2a) of Regulation (EU) 2018/848 for the specific third country and category of products. 本公司不得對過去 2 年內被前驗證機構撤銷的農產品經營者或農產品經營者集團進行驗證，除非前驗證機構已被撤銷其根據 (EU) 2018/848 號規章第 46(2)(a)條針對特定第三國和產品類別的認可。
- G. TOC shall conduct the review of application materials and notification of its findings to the applicant within three months. 收到申請資料，本公司應於三個月內執行書面審查，並將審查結果告知申請者。
- H. Where the supplementary documents, correction activities, non-compliance with the regulation, or on-site audit cannot be conducted within six months after the document review due to reasons attributable to the applicant, the application shall be denied. 因可歸責申請人之事由致書面審查後六個月內未完成補件、改善或不符規定者或無法進行實地稽核，則駁回驗證申請。

II. Inspection procedure 查驗作業

- A. The auditor shall carry out the following tasks during the on-site inspection: 實地查驗時稽核員應作業內容如下：
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. 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 this Regulation;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規定。
 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。
 4. Verify that the information provided by the applicant 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. 確認申請者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。
 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。
 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. 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。
 7. Verify that ionizing radiation is not used for the treatment of organic food or of raw materials used in organic food. 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。
- B. 採樣
1. 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. 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。

2. TOC shall, on the basis of a risk assessment of non-conformity, annually conduct minimum 5 % of the number of operators, excluding operators exempted in accordance with Articles 34(2) of this Regulation shall be subject to sampling in accordance with Article 14(h) of Regulation (EU) 2017/625 every year; 本公司依據不符合性的風險評估，每年應至少對 5% 農產品經營者，不包括根據第 34(2) 條豁免者，根據 (EU) 2017/625 號規章第 14(h) 條進行取樣；
3. 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 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。
4. 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。

III. Granting certification 賦予驗證

- A. 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)，及任何向申請者要求或申請者提供的資料。
- B. The certification decisions includes “Granting Certification”, “Corrective action required”, “Suspension of certification”, “Denial of certification” and “Revocation of certification”. 驗證決定包含「驗證合格」、「限期改善」、「暫時終止」、「駁回」、「驗證終止」。
- C. When the certification decisions indicate "Corrective action required", the administration staff will make a Notice of Certification Decision for the issued non-compliance based on the results of the review meeting. The operator will be notified with the Notice to complete the necessary corrections within the specified time limit and respond to TOC. 當驗證決定為「限期改善」時，案件承辦人將依據審定會議之結果做成不符合通知書，以通知書通知業者於期限內完成矯正並回覆本公司。
- D. The reasons for “Suspension of certification”, “Denial of certification” and “Revocation of certification” should be stated in the Notice of Certification Decision and should refer to "Instruction Manual for Certification of Non-compliance". 有關「暫時終止」、「駁回」、「驗證終止」之事由應於驗證決定通知書中敘明，並參照「驗證不符合事項指導說明」。
- E. 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. 審定人員判斷申請者之「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

者有能力依照「有機驗證申請書」操作，則本公司將授與驗證。

IV. Various Certification Application 各式驗證申請

A. Initial Application 初次申請

1. The initial application is the first time an operator or a group of operators apply for certification.
初次申請案件係指農產品經營者首次向本公司提出驗證申請。

B. Annual Inspection and Renewal Inspection 追蹤查驗及展延查驗

1. For operators and groups of operators who have been certified by TOC, the administrator will determine the inspection quarter based on the expiration date of their certification. The application for annual and renewal inspection should be completed one month before the beginning of the quarter. TOC will conduct the annual and renewal inspection after receiving the required information.

凡取得本公司有機驗證資格者，承辦人將根據驗證證書到期日決定查驗季別，並於當季別開始前一個月1號完成追蹤或展延查驗申請收件，本公司於資料收件完成後執行追蹤查驗及展延查驗作業；

2. The certified operators or groups of operators may submit an application for an renewal inspection three months before the expiration of their organic certification certificates, and late applications will not be accepted. 有機驗證證書效期屆滿三個月前，驗證合格者得提出展延查驗申請，逾期申請者不予受理。
3. TOC shall carry out a verification of compliance with Regulation (EU) 2018/848 for all operators and groups of operators at least once a year. The verification of compliance shall include a physical on-the-spot inspection. However, in exceptional situations, TOC may, at its discretion, conduct additional on-site inspections, including unannounced inspections. 本公司應至少每年一次對所有農產品經營者和農產品經營者集團進行(EU) 2018/848規定的符合性查證，此應包括現場實地查驗；但情況特殊者，經本公司評估得酌予增加不定期追蹤查驗，包含不通知查驗。

- C. TOC shall ensure that it carries out every year at least 10 % of additional controls to those referred to in paragraph 4. Of all physical on-the-spot inspections carried out by the control authority or control body, at least 10 % shall be without prior notice. 本公司應確保其每年至少執行(EU)2021/1698 規章第 9(4)條中提到的額外管制之 10%。在執行的實地稽查中至少 10%應不事先通知。

V. Withdrawal of certification 自願撤回驗證

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

2. TOC shall make an approval of the applicant's withdrawal, and reply with "Notice of Withdraw". 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，並以“自願撤回驗證通知書”回覆。已繳交之費用概不退還，且應繳清相關費用。
3. 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。
4. 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。
5. If the applicant wants to reapply after Withdraw, a time interval evaluation by TOC is required, but no more than six months from. 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。

VI. Surrender of certification 結束驗證

1. The operation may surrender its certification along with a written notice of surrender to TOC at any time. 經營者有權隨時向本公司敘明理由，提出申請結束驗證。
2. TOC shall make an approval of the operation's surrender, and reply with surrender notice. An operation who surrenders its certification shall be liable for the costs of services provided up to the time of surrender of its application. 本公司應依經營者提出之申請，核准其結束驗證，並以“自願結束驗證通知書”回覆。已繳交之費用概不退還，且應繳清相關費用。
3. Upon surrender of EU organic certificate, the operation may not produce, process, sell, market or represent as organic, products previously under certification. The operation must complete a new application for certification if the operation wishes to obtain organic certification in the future. 提出結束驗證後，該經營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。未來該經營者必須完成一個新的驗證申請，以取得有機驗證。

VII. Change 異動

- A. In the following cases, operators or groups of operators should promptly notify TOC of any change requests and complete the 'Application for Change' with the relevant information for TOC to review: 有下列情況應提出異動申請即時通知本公司，並請填列「異動表」附上相關資料供本公司審核：
 1. Application, including drift, of a non-authorised substance to any field, production units, site, facility, livestock or product that is part of an operation. 施用(包括漂移)非授權物質於作業內的田區、生產單位、場地、設施、禽畜或產品。

2. Change in a certified operation or any portion of a certified operation that may affect its compliance with regulations of this Regulation or the content of the certification application.
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或影響到驗證申請書之內容。
3. 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。



Operating Procedure of Export

出口作業程序

I. Import of organic and in-conversion products to Union 有機和有機轉型期產品進口至歐盟市場 ((EU) 2018/848 Art. 45(1), (5))

A. A product may be imported from a third country for the purpose of placing that product on the market within the Union as an organic product or as an in-conversion product, provided that the following three conditions are met: 產品得從第三國進口，目的是將該產品作為有機產品或有機轉型期產品，投放歐盟市場，惟須先滿足以下三個條件：

1 the product is a product as referred to in Article 2(1) of Regulation (EU)2018/848; 該產品是 (EU)2018/848 規章第 2(1)條所指產品；

2 one of the following applies: 下列情況之一適用：

2.1 the product complies with Chapters II, III and IV of Regulation (EU)2018/848, and all operators and groups of operators referred to in Article 36 of that Regulation, including exporters in the third country concerned, have been subject to controls by TOC, and TOC has provided all such operators, groups of operators and exporters with a certificate confirming that they comply with this Standard; 產品符合(EU)2018/848 規章第 2、3、4 章規定，又該規章第 36 條所指所有農產品經營者和農產品經營者集團，包括有關第三國之出口商，都已受到本公司管制，本公司已向所有該等農產品經營者、農產品經營者集團及出口商，提供其符合本標準之證書；

The certificate shall: 此證書應：

2.1.1 be issued in electronic form, in accordance with the model set out in Annex VI, and by using the electronic Trade Control and Expert System (TRACES) referred to in point (36) of Article 2 of Commission Implementing Regulation (EU) 2019/1715; 按照證書範本，並使用 (EU) 2019/1715 號規章第 2(36)條所述電子貿易管制專家系統(TRACES)，以電子形式發出；

2.1.2 allow the identification of: 可識別以下內容：

(1) the operator, group of operators or exporter covered by the certificate, including the list of members of a group of operators; 證書所涵蓋的農產品經營者、農產品經營者集團或出口商，包括農產品經營者集團成員列表；

(2) the category of products covered by the certificate, classified in the same way as provided for in Article 35(7) of Regulation (EU) 2018/848; and 證書所涵蓋的產品類別，同(EU) 2018/848 號規章第 35(7)條規定的方式分類；及

(3) its period of validity; 證書效期

2.1.3 certify that the activity of the operator, group of operators or exporter complies with this Standard; and 證明農產品經營者、農產品經營者集團或出口商的活動符合本標準

2.1.4 be updated whenever changes occur concerning the data included in it. 每當其中所含資料

發生異動時進行更新。

- 2.2 in cases where the product comes from a third country which is recognised in accordance with Article 48 of Regulation (EU) 2018/848, that product complies with the equivalent production and control rules of that third country and is imported with a certificate of inspection confirming this compliance that was issued by TOC. 若產品來自依(EU) 2018/848 號規章第 48 條被認可之第三國，則該產品符合該第三國同等生產和管制規則，又進口時檢附本公司頒發之確認符合性查驗證書。

- 3 the operators in third countries are able at any time to provide the importers and the national authorities in the Union and in those third countries with information allowing the identification of the operators that are their suppliers and the control authorities or control bodies of those suppliers, with a view to ensuring the traceability of the organic or in-conversion product concerned. That information shall also be made available to the control authorities or control bodies of the importers. 第三國農產品經營者為歐盟和第三國進口商和國家機關之供應商，前者可以隨時提供資訊給後者，一方面能夠辨識前者為後者之供應商，另一方面能夠辨識該等供應商之管制機關或驗證機構，以確保有關有機產品或有機轉型期產品之可追溯性。該等資訊亦應提供給進口商之管制機關或驗證機構。

- B. Compliance with the conditions and measures for the import of organic products and in-conversion products referred to in paragraph 1 into the Union shall be ascertained at border control posts, in accordance with Article 47(1) of Regulation (EU) 2017/625. The frequency of the physical checks referred to in Article 49(2) of that Regulation shall depend on the likelihood of non-compliance as defined in point (57) of Article 3 of Regulation (EU) 2018/848. 依 (EU) 2017/625 號規章第 47(1)條規定，進口第 A 項所指有機產品和有機轉型期產品進入歐盟，應在邊境管制站查明是否符合條件及措施。該規章第 49(2)條所指實體查核頻率，應視 (EU) 2018/848 號規章第 3 條第(57)點針對不符合可能性之定義而定。

II. Verification of consignments intended for import into the Union 查證進口到歐盟的貨物 ((EU) 2021/1698 Art. 16)

- A. TOC shall verify consignments intended for import into the Union with regard to the compliance with Regulation (EU) 2018/848 and Regulation (EU) 2021/1698. This 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. 本公司應查證擬進口到歐盟的貨物是否符合(EU) 2018/848 號規章和(EU) 2021/1698 號規章。這種查證應包括系統的文件檢查，並在貨物離開第三出口國或原產國之前，適用時根據風險評估，進行現場查驗。

- B. For the purposes of this Article, the relevant control authority or control body shall be: 就本條而言，相關管制機關或驗證機構應為：
- 1 the control authority or control body of the producer or the processor of the product concerned; or 有關產品的生產者或調製者的管制機關或驗證機構；或
 - 2 where the operator or group of operators carrying out the last operation for the purpose of preparation is different from the producer or processor of the product, the control authority or control body of the operator or group of operators carrying out the last operation for the purpose of preparation as defined in point (44) of Article 3 of Regulation (EU) 2018/848. 如果為調製目的而進行最後操作的農產品經營者或農產品經營者集團，不同於產品的生產者或加工者，則根據(EU) 2018/848 號規章第 3(44)條定義的調製目的所進行最後一道加工的農產品經營者或農產品經營者集團的管制機關或驗證機構。

TOC shall be recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 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. 本公司應根據 (EU) 2018/848 號規章第 46(1)條被歐盟認證，於第三國(如適用)做最後處理作業的產品(包含原產地)。

- C. The documentary checks referred to in paragraph A shall aim at verifying: 第 A 項所述紀錄檢查應旨在查證：
- 1 the traceability of the products and ingredients; 產品和成分的可追溯性；
 - 2 that the volume of the products included in the consignment is in line with the mass balance checks of the respective operators or groups of operators according to the assessment carried out by TOC; 根據本公司進行的評估，托運貨物中包含的產品數量符合相應農產品經營者或農產品經營者集團的進出平衡查核；
 - 3 the relevant transport documents and commercial documents (including invoices) of the products; 產品相關運輸單據和商業單據(包括發票)
 - 4 in case of processed products, that all organic ingredients of such products have been produced by operators or groups of operators certified in a third country by TOC recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 or by a third country recognised in accordance with Articles 47 and 48 of Regulation (EU) 2018/848, or have been produced and certified in the Union in accordance with that Regulation. 如為加工產品，此類產品的所有有機成分由在根據(EU) 2018/848 號規章第 47 和 48 條認可的第三國，或由根據(EU) 2018/848 號規章第 46(1)條認可的本公司驗證的農產品經營者或農產品經營者集團生產，或已根據(EU) 2018/848 號規章於歐盟生產和驗證。

Those documentary checks shall be based on all relevant documents, including the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848, the latest record of the inspections, the production plan for the product concerned and records kept by the

operators or groups of operators, available transport documents, commercial and financial documents and any other documents deemed relevant by TOC. 這些文件檢查應基於所有相關文件，包括(EU) 2018/848 號規章第 45(1)(b)(i)條提到的證書、最新查驗記錄、相關產品的生產計劃和農產品經營者或農產品經營者集團保存的記錄、有效的運輸文件、商業和財務文件和本公司認為相關的任何其他文件。

- D. For consignments made out of bulk organic products, TOC shall draw up a travel plan in the Trade Control and Expert System (TRACES), including all the premises to be used during the travel from the third country of origin or export to the Union. 對於由散裝有機產品組成的貨物，本公司應在貿易管制專家系統(TRACES)中制定行程計劃，包括從第三國原產地或出口歐盟旅行期間使用的所有場所。
- E. For consignments of high-risk products referred to in Article 8, TOC shall carry out systematic physical checks and take at least one representative sample of each consignment. Moreover, TOC shall have complete documentation of the traceability of the operators or groups of operators and the product, including transport and commercial documents, including invoices. At the request of the Commission or the competent authority of a Member State, TOC shall send this traceability documentation as well as the results of the sampling analysis to the control authority or control body of the importer and to the competent authority of the Member State where the consignment is verified. 對於第 8 條所述高風險產品的托運，本公司應當進行系統性實物檢查，每批托運貨物至少抽取一份具有代表性的樣品。此外，本公司應有完整的記錄，說明農產品經營者或農產品經營者集團和產品可追溯性，包括運輸和商業文件，包括發票。應歐盟執委會或會員國主管機關要求，本公司應將此可追溯性文件及抽樣分析的結果，發送給進口商的管制機關或驗證機構、及貨物被核實的會員國主管機關。

In case of suspicion of non-compliance, the Commission or the competent authority of a Member State may request the TOC to make available without delay the list of all operators and all groups of operators in the organic production chain of which the consignment is part, and of their control authorities or control bodies. 如果懷疑不符合，歐盟執委會或會員國主管機關可要求本公司立即提供有機生產鏈中(貨物為其一部分)的所有農產品經營者和所有農產品經營者集團的名單及其管制機關或驗證機構。

Instruction Manual for Certification of Non-compliance

驗證不符合事項指導說明

I. Denial of Certification 駁回

TOC will deny the application with written notification, in any of the following circumstance:
有下列情形之一者，本公司以書面敘明理由駁回申請，逕予結案。

A. Identification principal 認定原則

1. The product applied for organic certification does not compliant with (EU) 2018/848 Regulation at any stage of production, preparation or distribution, and the circumstances are serious. 申請驗證農產品之生產、調製和流通任何階段未符合 (EU)2018/848之規定，且情節重大。
2. The agricultural ingredient of the product applied for organic certification is less than 95 % by weight are organic 申請驗證之有機加工食品，其產品的有機農業原料含量，按重量計，少於95%。
3. Where the on-site audit cannot be conducted within six months after the document review due to reasons attributable to the applicant. 因可歸責申請人之事由致書面審查後六個月內無法進行實地稽核。
4. Where the applicant, without good cause shown, fails to make corrections or improvements within a specific period notified by TOC. 經通知補正或限期改善，無正當理由屆期未補正或改善。
5. Where the product analysis results indicate the presence of residues of non-authorised substances. 產品檢驗結果含有禁用物質。
6. False documents or information is provided that can result in serious consequences. 提供不實文件或資訊，且情節重大。
7. Where the certification procedure cannot be completed within a one-year period after the date of accepting the application for reasons attributable to the applicant. 自申請案受理之次日起，因可歸責申請人之事由逾一年未結案。
8. Within two year after the certified status is terminated by the certification body due to the violation of (EU)2018/848. 違反(EU)2018/848規定，經其他驗證機構終止驗證資格未滿二年。
9. The product applied for certification does not included in the category of certification accepted by TOC 申請驗證產品不符合本公司受理驗證範圍。
10. The operator does not pay any fees they due within 15 days after they received the notification of reminder for payment. 通知繳交各項驗證費用，經催繳超過十五天未繳交者。
11. Failure to comply with the undertaking stated in the organic system plan statement,

the circumstances are serious, or the corrective action has not been completed as scheduled after being notified by TOC. 未遵守有機驗證申請書聲明中之義務，其情節重大或經本公司通知，仍未如期完成改善者。

12. When the operator or group of operator has obvious reasons, such as participation in illegal activities, history of repeated non-compliance with certification/ product requirements, etc., or the application has been denied by TOC, and the reasons of the denial been identified has not been addressed, then TOC may refuse to accept the certification application and deny it directly. 當農產品經營者或農產品經營者集團存在明顯的理由，如參加非法活動、有屢次不符合驗證／產品要求之歷史等相關問題、或曾遭本公司駁回申請，其駁回理由經本公司認定並未消除者，本公司可拒絕受理驗證申請而逕予駁回。

- B. When submitting a new application after denial of certification, TOC will evaluate whether the reason for the previous denial has corrected or disappeared, and then decide whether to accept it. 駁回後再提申請時，將由本公司評估之前遭駁回之原因是否已改善或消失，再決定是否受理。

II. Suspension of Certification 暫時終止

TOC shall suspend all or part of the certification scope, under the following circumstance: 有下列情形之一者，本公司得暫時終止其全部或部份驗證範圍。

A. Identification principal 認定原則

1. Fail to correct the critical or major non-compliance issued during the surveillance inspections, additional inspections, or renewal inspections, or been required by certification decision within a specified period or fail to provide corrective action required within a specified period for 3 times and pass the certification review. 追蹤查驗、增列查驗或展延查驗，開立次要不符合或經驗證決定須限期改善之事項，未於期限內改善，或經限期改善三次仍未通過審查者。
2. Fail to pass the certification review within six months after the inspection due to delay of providing corrective action of non-compliance or improvement required within a specified period. 因延遲矯正或經限期改善未完成，致查驗後六個月內無法通過審查者。
3. The operator does not pay any fees they due within 15 days after they received the notification of reminder for payment. 通知繳交各項驗證費用，經催繳超過十五天未繳交者。
4. Failure to comply with the undertaking stated in the organic system plan statement, or the content of contract. 未遵守申請書之確認聲明或契約書之所述內容。

5. The product uses or is found to contain genetically modified products, non-authorised products, substances, or commingling with non-organic products, or those that do not meet the standards of food-related laws and regulations. 產品使用或檢出含有基因改造產品，非授權產品、物質，或混用非有機產品，或不符合食品相關法規之標準者。
6. The use of certification certificates and logo of European Union or TOC does not comply with (EU) 2018/848 Regulations, and the improvement has not been completed within the notified specified period. 使用驗證證書及驗證標章不符合本公司規定，經通知限期改善仍未完成改善者。
7. Labelling, advertising, displaying or place on the market non-certified products as organic products. 販賣、展示或廣告非驗證之產品而聲稱為已驗證產品。
8. Other violations without reaching the revocation of certification. 其他違規而未達驗證終止者。

B. Operation contents 作業內容

1. When certified operators or group of operators of organic or in-conversion agricultural are suspended, TOC will publish relevant information on the website and provisionally delete all or part of the certification scope information of the operator or group of operators. However, during the investigation period, the relevant information will not be published before the certification decision has not been approved. 有機農產品、有機轉型期農產品經營者驗證資格暫時終止時，本公司將於網站公告相關訊息，並暫時刪除該農產品經營者之全部或部分驗證範圍資料。惟調查期間未經審定決議前不需公告。
2. In cases of suspension of certification, the administration staff shall notify the operator or group of operator the followings: 暫時終止之案件，承辦人通知農產品經營者下列事項：
 - (1) Measures required for reinstatement the certification in accordance with relevant certification regulations. 依據驗證相關規定結束暫時終止與恢復產品驗證所需之措施。
 - (2) Any other measures required by relevant certification regulations. 驗證相關規定要求的任何其他措施。
3. When the operator or group of operators received the notification of suspension of all or part of certification scope, shall immediately stop claim to organic production in the advertising and using logo of organic on the entire or part of products. Recall the products that have been put on the market with the certification logo and make a record report to TOC. 農產品經營者收到本公司暫時終止全部/部分驗證範圍通知時，應立即停止驗證宣傳及再使用全部或部分驗證範圍標章，並視情況回收已上市貼(印)有驗證標章之產品等，並作成紀錄回報本公司。

4. The period of suspension of certification shall be determined by TOC according to the circumstances of each case, and the maximum is one year; the operator or group of operators shall submit a request with relevant documents for reinstatement of certification to TOC before the expiration of the period, and the application beyond the time limit will not be accepted. 驗證暫時終止之期限由本公司依個案情形定之，最長以一年為限；農產品經營者須於期滿前備妥相關文件向本公司提出恢復驗證申請，超過期限不予受理。
5. Certification procedures for reinstatement, such as on-site inspection, sample analysis, certification review or decision required shall comply with the provisions of "Operation Procedures of Certification (TOC-EU-QP01)". 結束暫時終止所需之實地查驗、產品測試、審查或決定等驗證程序應符合「驗證作業程序(TOC-EU-QP01)」之規定。
6. After the reinstatement of certification, TOC shall make necessary update for the certification certificate, TOC's website, and the authorization for using the logo to show that the product is still continuously certified. 在暫時終止後恢復驗證，本公司應對驗證證書、本公司網站、標章使用之授權做必要之修訂，以顯示該產品仍持續獲得驗證。
7. If the reduction of the certification scope is used as the corrective action for reinstatement of certification, the certification certificate, TOC's website, and the authorization of using logo shall be updated to ensure that the operator or group of operator is informed of the reduction of the certification scope. 如以減列驗證範圍做為恢復驗證資格之條件時，則驗證證書、本公司網站、標章使用之授權應做必要之修訂，以確保農產品經營者獲知驗證範圍減列之情況。

III. Revocation of certification (Including all or part of revocation) 驗證終止：含全部終止或部分終止兩種

A. Identification principal 認定原則

1. Revocation of all certification: The operator or group of operator has one of the following circumstances, TOC will inform in writing to revoke the certification and withdraw the certification certificate. 全部終止：經驗證合格之農產品經營者有下列情形之一，本公司以書面通知終止驗證，並收回驗證證書。
 - (1) Fails to continue conforming to the relevant provisions of (EU)2018/848 or certification contract in a serious manner or fails to make correction within the specific period required by TOC. 未持續符合(EU)2018/848或驗證契約相關規定，經要求限期改正而未改正或情節重大。

- (2) Refuses, evades, or impedes the surveillance inspection by TOC. 拒絕、規避或妨礙本公司之追蹤查驗。
- (3) Provides false documents or information that has serious consequences. 提供不實文件或資訊，且情節重大。
- (4) The contents of an advertisement published are inconsistent with the certified contents in a serious manner. 刊登廣告內容與驗證合格內容不一致，且情節重大。
- (5) Cannot reinstated the certification after the expiry of all or part of certification scope were suspended. 經暫時終止其全部或部分驗證範圍期滿後，無法恢復驗證者。
- (6) Critical non-compliance exists during the on-inspection, and the certification decision is made after review. 查驗發現有主要不符合事項，經審查並作成驗證決定者。
- (7) The product uses or is found to contain genetically modified products, non-authorized products, substances, or commingling with non-organic products, or those that do not meet the standards of food-related laws and regulations. 產品使用或檢出含有基因改造產品，非授權產品、物質，或混用非有機產品，或不符合食品相關法規之標準者。
- (8) The use of certification certificates, contract and logo of European Union or TOC does not comply with (EU) 2018/848 Regulations. 未依規定使用驗證證書、契約書及驗證標章者。
- (9) The operator or group of operators have been certified by another control body in relation to activities carried out in the same third country regarding the same category of products, including in cases in which operators or group of operators operate at different stages of production, preparation of distribution. 相同驗證範圍另取得其他驗證機構之有機驗證資格者。
- (10) Those who have been found to be false. 經查有虛偽不實者。
- (11) The products cause serious harm to consumers due to willful or negligent, which is verified by TOC. 因故意或過失致其產品對消費者造成嚴重傷害，經本公司查證屬實者。
- (12) Does not submit the application for surveillance or renewal inspection within 15 days after they received the notification of reminder. 應提出定期追蹤查驗或展延查驗之申請，經催辦超過十五天未提出申請者。
- (13) Other violations without reaching the revocation of all certifications. 其他違規而情節重大者。

2. Revocation of part of certification: The operator' or group of operators' products or premise has one of the following circumstances, TOC will inform in writing to revoke part of the certification scope and renew the certification certificate. 部分終止：經驗證合格之場區或產品，有下列情形之一，本公司以書面終止其部分驗證範圍並視需要辦理換證。
 - (1) The product is found to contain genetically modified products, non-authorised products, substances, or commingling with non-organic products, or those that do not meet the standards of food-related laws and regulations, the certification of the product or premise shall be revoked. 產品檢出含有基因改造產品，非授權產品、物質，或混用非有機產品，或不符合食品相關法規之標準者，則該場區或產品應終止驗證。
 - (2) The organic production area is close to the conventional production pollution sources, and the buffer zone or barriers established cannot prevent the pollution. 有機生產區緊鄰慣行生產污染源，所設立之緩衝帶或障礙物無法阻絕污染者。
 - (3) The substances or food additives used do not comply with the provisions of Annex VII of (EU) 2018/848 "Authorising Certain Products and Substances for Using in Organic Production and Establishing their Lists". 所使用之物質或食品添加物不符 (EU)2018/848附件 VII「授權用於有機生產的產品和物質清單」之規定。
 - (4) Other violations without reaching the revocation of all of certifications. 其他違規而未達全部終止者。

B. Operation contents 作業內容

1. In the situation of revocation, TOC will publish relevant information on the website and delete all or part of the certification scope information of the operator or group of operators and announce the invalidation of the certificate and logo of certification. 驗證終止者，本公司將於網站刪除該驗證者之全部或部分場區之資料，並公告終止驗證者之證書、標章失效等訊息。
2. Inform the operator or group of operators to recall the products produced by the revoked certification scope. 通知驗證者需回收經終止驗證範圍所生產之產品。
3. When the operator or group of operators received the notification of revocation of all certification scope, shall immediately stop claim to organic production in the advertising and the using of organic logo, and return the certification certificate within 15 days from the next day. If it is not returned, the certificate will automatically become invalid. 農產品

經營者收到本公司終止全部驗證範圍通知時，應立即停止驗證宣傳、驗證標章之使用，並於次日起十五日內繳回驗證證書，若未繳回，證書亦自動失效。

Those who were revoked all certifications scope shall not apply for certification again within two years from the day after the certification decision. 終止全部驗證者，於驗證決定終止之次日起未滿二年，不得重新申請驗證。



Operating Procedure of Compliant and Appeal process

抱怨及申訴作業程序

I. 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來往通訊，皆須以書面(包含電子郵件或一般郵件)送至收件人通訊地址。
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。

II. 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 EU organic regulations) and its claims. 對抱怨的原因提出充分的說明(例如：具體說明違反歐盟有機法規中那一項規定)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 B 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B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動無關，本公司得視情況不予受理。
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。

III. 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時，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，以新資訊作為提出申訴的理由，否則本公司不予受理。
6. Investigation and a 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。
8. The investigation of appeals: 申訴案件調查：
 - 8.1 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。
 - 8.2 During the period of investigation, the effect of original decision would not be affected; Provided, if necessary, the implementation of relevant decision may suspend. 在調查期間，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。

8.3 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。

9. 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。



第三部分、附件



Appendix I. Certification Fees 驗證費用表

A. Taiwan 台灣

1. New Application 新申請費用

Item 項目	Fees (New Taiwan Dollars) 費用 (新台幣元)	Description 說明
Application Fees 資料審查費	NTD 30,000	Document review, evaluation and report. 申請文件審查、評估、報告
Administrative Fees 驗證管理費	<ul style="list-style-type: none"> First activity 第一條生產線 NTD 30,000 / 件 Each additional activity 每增加一條生產線 NTD 20,000 / 件 Section C displays the grower group certification fee 集團驗證依 C 所示收費 	Document review, report evaluation, and recordkeeping 文件審查、報告評估、紀錄保存
Inspection Fees 現場稽核費	NTD 10,000 per person / per day for one site 人/日/場次	Review, on-site inspection (annual and unnoticed), inspection report 審查、現場查驗、查驗報告
Travel Fees 旅費	<ul style="list-style-type: none"> North of Taichung, NTD 1,500/person day. 台中以北：NTD 1,500/人天 South of Taichung and Hualien, Taitung, NTD 3,000/person day. 台中以南及花東：NTD 3,000/人天 If it exceeds the actual cost, the actual cost shall prevail. 若超出以實際費用為準。 	Includes transportation, accommodation, meals and miscellaneous expenses necessary to perform your inspection 含交通、住宿、膳食等執行現場稽核所需費用

2. Regular Surveillance 定期追蹤查驗

Item 項目	Fees (New Taiwan Dollars) 費用 (新台幣元)	Description 說明
Application Fees 資料審查費	NTD 20,000	Document review, evaluation and report. 申請文件審查、評估、 報告
Administrative Fees 驗證管理費	<ul style="list-style-type: none"> ● First activity 第一條生產線 NTD 30,000 / 件 ● Each additional activity 每增加一條生產線 NTD 20,000 / 件 ● Section C displays the grower group certification fee 集團驗證依 C 所示收費 	Document review, report evaluation, and recordkeeping 文件審查、報告評估、 紀錄保存
Inspection Fees 現場稽核費	NTD 10,000 per person / per day for one site 人/日/場次	Review, on-site inspection (annual and unnoticed), inspection report 審查、現場查驗、查驗 報告
Travel Fees 旅費	<ul style="list-style-type: none"> ● North of Taichung, NTD 1,500/person day. 台中以北：NTD 1,500/人天 ● South of Taichung and Hualien, Taitung, NTD3,000/person day. 台中以南及花東：NTD 3,000/人天 ● If it exceeds the actual cost, the actual cost shall prevail.若超出以實際費用為準。 	Includes transportation, accommodation, meals and miscellaneous expenses necessary to perform your inspection 含交通、住宿、膳食等 執行現場稽核所需費用

3. Seal Fee Schedule 標章費用表 (Taiwan 台灣)

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 million (500 萬以下)	20 thousands (2 萬)
5million~10 million (500~1,000 萬)	30 thousands (3 萬)
10million~30 million (1,000~3,000 萬)	60 thousands (6 萬)
30million~50 million (3,000~5,000 萬)	90 thousands (9 萬)
50million~80 million (5,000~8,000 萬)	140 thousands (14 萬)
80 million~110 million (8,000 萬~1 億 1000 萬)	190 thousands (19 萬)
Above 110 million (1 億 1000 萬以上)	260 thousands (26 萬)

B. Area outside Taiwan 海外

1. New Application 新申請費用

Item 項目	Fees (US Dollars) 費用 (美金)	Description 說明
Application Fees 資料審查費	<ul style="list-style-type: none"> ● Individual 個別: USD 1,000 ● Grower group 生產者集團: USD 1,000 	Document review, evaluation and report. 申請文件審查、評估、報告
Administrative Fees 驗證管理費	<ul style="list-style-type: none"> ● First activity 第一條生產線 USD 1,000 ● Section C displays the grower group certification fee. 集團驗證依 C 所示收費 ● Each additional scope (crop/ wild crop/ handling) 每增加一項範圍(作物/野採/加工) USD 700 ● Each additional activity 每增加一基地/產線 USD 500 	Document review, report evaluation, and recordkeeping 文件審查、報告評估、紀錄保存
Inspection Fees 現場稽核費	USD 350 per person / per day for one site 人/日/場次	Review, on-site inspection (annual and unnoticed), inspection report 審查、現場查驗、查驗報告
Travel Fees 旅費	The expenses required for the on-site audit, including transportation, accommodation, meals, etc., shall be borne by the applicant. 含交通、住宿、膳食等執行現場稽核所需費用，由申請者負擔。	

2. Regular Surveillance 定期追蹤查驗

Item 項目	Fees (US Dollars) 費用 (美金)	Description 說明
Application Fees 資料審查費	<ul style="list-style-type: none"> ● Individual 個別: USD 500 ● Producer group 生產者集團: USD 500 	Document review, evaluation and report. 申請文件審查、評估、報告
Administrative Fees 驗證管理費	<ul style="list-style-type: none"> ● First activity 第一條生產線 USD 1,000 ● Section C displays the grower group certification fee. 集團驗證依 C 所示收費 ● Each additional scope (crop/ wild crop/ handling) 每增加一項範圍(作物/野採/加工) USD 700 ● Each additional activity 每增加一基地/產線 USD 500 	Document review, report evaluation, and recordkeeping 文件審查、報告評估、紀錄保存
Inspection Fees 現場稽核費	USD 350 per person / per day for one site 人/日/場次	Review, on-site inspection (annual and unnoticed), inspection report 審查、現場查驗、查驗報告
Travel Fees 旅費	The expenses required for the on-site audit, including transportation, accommodation, meals, etc., shall be borne by the applicant. 含交通、住宿、膳食等執行現場稽核所需費用，由申請者負擔。	

3. Seal Fee Schedule 標章費用表(Area outside Taiwan 海外)

Organic product sales amount / year (USD) 有機產品銷售金額/年 (美金)	Seal fee/year (USD) 標章費/年 (美金)
Below 170 Thousand (17 萬以下)	700
170 Thousand ~350 Thousand (17~35 萬)	1,000
350 Thousand ~1 million (35~100 萬)	2,000
1million~1 million 700 Thousand (100~170 萬)	3,000
1 million 700 Thousand ~2 million 700 Thousand (170~270 萬)	4,700
1 million 700 Thousand ~3 million 700 Thousand (270 萬~370 萬)	6,400
Above 3 million 700 Thousand (370 萬以上)	8,700

C. Crops/ Producer group operation administrative fees schedule 作物/集團驗證驗證管理費收費表

Producer group members 成員數	Administrative Fees 驗證管理費	
	TW 台灣(NTD)	Area outside Taiwan 海外(USD)
1-25	30,000	2,000
26-50	50,000	3,400
51-100	70,000	4,200
101-150	100,000	5,000

D. Other 其他

Change fees: Certification accounts in Taiwan are charged in NTD; Certification accounts in overseas areas are charged in US dollars. 異動費用：台灣驗證戶依台幣所示收費；海外地區驗證戶依美金所示收費		
Administrative Fees 驗證管理費	USD 500 / activity NTD 20,000 / 件	For new field, or processing line 適用於增加田區、廠區或生產線
New Item Fees 增項費	USD 35 / item NTD 1,000 / 項	For new items within one processing line 適用於同一生產線增加品項
Review fee for labelling change 標示異動審查費	USD 20 / Label NTD 600/ 個標示	If the initial application passes the first review of product labeling, there will be no charge. 初次申請通過產品標示第一次審查不收費
Non-organic changes in input materials 非有機投入資材異動	USD 10 / item NTD 300 / 支	Including "Disease, pest, or weed control material Change" and "Application for the use of non-organic ingredients" 包含「病蟲草害防治資材使用」以及「非有機原料審查申請」
Pest Management Change in Processing Units 驗證廠區有害生物防治變更	USD 20 / time NTD 600/ 次	
TRANSACTION Certificate 交易證明：		
USD 55 / Copy NTD 1,500 / 每份		
CERTIFICATE FEE 證書費：		
USD 35 / Copy NTD 1,000 / 每份		Not Applicable for New Application and Continuation of Certification 適用於非年度查驗換證
Remark 備註	The above charges: 4 to 7 working days for normal documents; 2 to 3 working days for urgent documents, double the charge 上述收費：正常件 4~7 個工作天；如需趕急件 2~3 工作天皆以雙倍收費	

E. Instructions for refunding fees 退還費用說明

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.
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，實地查驗後不退資料審查費、現場稽核費及交通費，案件進入審定後，全數不退費

