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Amending act	Amendment type	Subdivision concerned	Date of effect
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► COMMISSION DELEGATED REGULATION (EU) 2021/1698

B 欧盟委员会委托法规（EU）2021/1698

of 13 July 2021 2021 年 7 月 13 日

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

补充欧洲议会和理事会法规（EU）2018/848 的程序要求，以承认有权对在第三国进行有机操作者和操作者群体以及有机产品进行控制的监管机构和监管机构，以及关于其监督和监管机构及监管机构应执行的控制和其他行动的规则

(Text with EEA relevance) （具有欧洲经济区相关性的文本）

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▼ B

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(Text with EEA relevance)

(与欧洲经济区相关的内容)

CHAPTER I 第一章

PROCEDURAL REQUIREMENTS FOR THE RECOGNITION OF CONTROL AUTHORITIES AND CONTROL BODIES

程序要求，以认可控制机构和控制机构

Article 1 条款 1

Requirements referred to in point (n) of Article 46(2) of Regulation (EU) 2018/848

《欧盟条例（EU）2018/848 第 46（2）款第（n）项所指的要求

1. A control authority or control body shall submit the request for recognition referred in Article 46(4) of Regulation (EU) 2018/848 using the model made available by the Commission. Only complete requests shall be taken into account.

1. 控制当局或控制机构应使用委员会提供的模板，提交关于《欧盟条例》（EU）2018/848 第 46(4)条所指的认可请求。只有完整的请求才会被考虑。

2. The technical dossier referred to in Article 46(4) of Regulation (EU) 2018/848 shall contain the following information in one of the official languages of the Union:
《欧盟条例（EU）2018/848 第 46(4)条所指的技术文件应包含以下信息，使用欧盟的官方语言之一：

(a)

the following information about the control authority or control body:

以下关于控制机构或控制主体的信息：

(i) name; 姓名;

(ii) mailing address; 邮寄地址

(iii) telephone number; 电话号码

(iv) email contact point; 电子邮件联系方式

(v) for control bodies, the name of their accreditation body;

对于监管机构，其认证机构的名称；

(b) an overview of the intended activities of the control authority or control body in the third country or third countries concerned, including an indication of the organic products, together with their Combined Nomenclature (CN) codes according to Council Regulation (EEC) No 2658/87 ([1](#)), distributed per category of products as set out in Article 35(7) of Regulation (EU) 2018/848, that are intended to be imported into the Union in accordance with point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 during the first year of activity following the recognition by the Commission;

对第三国或相关第三国控制机构或控制主体的预期活动概述，包括有机产品的指示，以及根据理事会法规（EEC）第 2658/87 号（1）的联合分类（CN）代码，按照《欧盟条例》2018/848 第 35 条第 7 款规定的产品类别进行分配，旨在根据《欧盟条例》2018/848 第 45 条第 1 款第 b 项第 i 点在委员会认可后的第一年内进口到联盟的产品

(c) a description of the control authority or control body as regards:

关于控制机构或控制主体的描述：

(i) its structure and size;

其结构和规模；

(ii) its IT management system;

其 IT 管理系统；

(iii) its branch offices, if any;

其分支机构（如有）；

(iv) its type of activities, including delegated activities, if any;

其活动类型，包括任何委托的活动；

(v) its organisational chart;

其组织结构图；

(vi) its quality management; 其质量管理；

(d) the certification procedures, in particular for granting or rejecting, suspension or withdrawal of the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848;

认证程序，特别是关于授予或拒绝、暂停或撤回第 45(1)条第(b)(i)点所指证书的程序；

(e) the translation of the production rules and control measures set out in Regulation (EU) 2018/848, and the delegated and implementing acts adopted pursuant to it in languages that are understandable for the contracted operators in the third countries for which the control authority or control body requests recognition;

《欧盟法规（EU）2018/848》中规定的生产规则和控制措施的翻译，以及根据该法规通过的委托和执行法案，以第三国合同运营商可理解的语言进行翻译；

(f) the documents proving that the criteria set out in Article 46(2) of Regulation (EU) 2018/848 are fulfilled, in particular a copy of the accreditation certificate granted by the accreditation body covering all categories of products for which recognition is requested;

证明《欧盟条例》（EU）2018/848 第 46(2)条规定的标准已得到满足的文件，特别是由认证机构颁发的涵盖所有请求认可的产品的认证证书副本；

(g) the procedures describing in detail the functioning and the implementation of the control measures to be set up in accordance with this Regulation, including, where relevant, control specificities for the group of operators;

详细描述根据本法规设立的控制措施的功能和实施的程序，包括（如有必要）针对运营商群体的控制特定性

(h) a catalogue of measures to be taken in cases of established non-compliance as laid down in Article 22 of this Regulation;

该法规第 22 条规定的在确定不遵守情况时应采取的措施目录；

(i) ►M1 a copy of the most recent assessment report referred to in Article 46(4), second subparagraph, of Regulation (EU) 2018/848, drawn up by the accreditation body or, as appropriate, by the competent authority, containing the information referred to in Part A of Annex I to this Regulation, including a witness audit report on a witness audit carried out within 2 years preceding the submission of the request for recognition. By way of derogation, for requests for recognition submitted before 31 December 2024, the witness audit report may be on a witness audit carried out within 3 years preceding the submission of the request for recognition. The assessment report shall give the following guarantees: ◀

►M1 一份关于《欧盟法规（EU）2018/848》第 46 条第 4 款第二段所指的最新评估报告副本，由认证机构或相应的主管当局编制，包含本法规附件 I 第 A 部分所指信息，包括对在提交认可请求前两年内进行的见证审计的见证审计报告。作为例外，对于在 2024 年 12 月 31 日之前提交的认可请求，见证审计报告可以是关于在提交认可请求前三年内进行的见证审计。评估报告应提供以下保证：◀

(i) that the control authority or control body has been satisfactorily assessed on its ability to ensure that products imported from third countries meet the conditions set out in points (a), (b)(i) and (c) of Article 45(1) and in Article 46(2) of Regulation (EU) 2018/848;

该控制当局或控制机构已对其确保从第三国进口的产品符合《第 45(1)条之(a)、(b)(i)和(c)点以及《欧盟条例》2018/848 第 46(2)条所规定的条件的能力进行了满意评估；

(ii) that the control authority or control body has the capacity and the competencies to implement effectively the control requirements and fulfil the criteria set out in Article 46(2) of Regulation (EU) 2018/848 and in this Regulation in each third country for which it requests recognition;

该控制当局或控制机构具有有效实施控制要求并满足《欧盟条例》（EU）2018/848

第 46(2)条以及本条例中规定的每个要求获得认可的第三国所设定的标准的资质和能力；

(j) proof that the control authority or control body has notified its activities to the relevant authorities of the third country concerned and its undertaking to respect the legal requirements imposed on it by the authorities of the third country concerned;
证明控制当局或控制机构已向相关第三国当局通知其活动，并承诺遵守相关第三国当局对其施加的法律要求；

(k) a website address, with a content available in at least one of the official languages of the Union and also understandable for the contracted operators, where the list referred to in point (a) of Article 17 of this Regulation can be found;
一个网站地址，其中包含至少一种欧盟官方语言的内容，并且对合同运营商来说是可理解的，其中可以找到本法规第 17 条第 (a) 点所指的清单；

(l) an undertaking by the control authority or control body to give access to all its offices and facilities to independent experts designated by the Commission and keep available and communicate all information related to its control activities in the third country concerned;

控制当局或控制机构承诺向由委员会指定的独立专家提供其所有办公室和设施的使用权，并保持相关所有信息可用并传达给相关第三国

(m) a statement by the control authority or control body that it has not been subject to withdrawal by the Commission, or withdrawn or suspended by any accreditation body, in the 24 months preceding their request for recognition for the third country and/or category of products they request a recognition for. This requirement does not apply in case of withdrawal pursuant to point (k) of Article 46(2a) of Regulation (EU) 2018/848;

控制当局或控制机构声明，在其请求承认第三国及其/或请求承认的产品类别之前 24 个月内，其未受到委员会的撤回，也未由任何认证机构撤回或暂停。本要求不适用于根据《欧盟条例》(EU) 2018/848 第 46 条第 2a 款第 (k) 项进行的撤回。

(n) any other information deemed relevant by the control authority or control body, or by the accreditation body.

任何控制机构或控制机构认为相关的其他信息，或认证机构认为相关的其他信息。

3. The control authority or control body shall provide any further information requested by the Commission for the purpose of its recognition.

控制当局或控制机构应向委员会提供其认可目的所需的任何进一步信息。

4. If the Commission finds that the information provided pursuant to paragraph 2 or 3 is incomplete, outdated or unsatisfactory, it shall reject the request for recognition.

如果委员会发现根据第 2 段或第 3 段提供的信息不完整、过时或令人不满意，它应拒绝认可请求。

Article 2 条款 2

Extension of the scope of the recognition

扩展认可范围

A control authority or control body recognised in accordance with Article 46 of Regulation (EU) 2018/848 may submit a request for extension of the scope of its recognition to an additional third country or to an additional category of products using the model made available by the Commission.

根据《欧盟条例》（EU）2018/848 第 46 条认可的监管机构或监管机构，可以提交请求，使用委员会提供的模板，将其认可的适用范围扩展至额外的第三国或额外的产品类别。

The request for extension of the scope of recognition shall consist of an update of the relevant parts of the technical dossier referred to in Article 1(2) with the appropriate information on the additional third country or the additional category of products subject to the scope extension.

请求扩大认可范围的申请应包括更新第 1(2)条所指技术档案的相关部分，并附上关于扩大范围所涉及额外第三国或额外产品类别的适当信息。

CHAPTER II 第二章

SUPERVISION OF THE CONTROL AUTHORITIES AND CONTROL BODIES BY THE COMMISSION

欧盟委员会对监管机构和监管机构的监督

Article 3 第 3 条

General requirements for the supervision of control authorities and control bodies

一般对监管机构和监管机构的监管要求

1.

The supervisory activities of the Commission in respect of control authorities and control bodies recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 shall focus on the evaluation of the operational performance of the control authorities and control bodies, taking into account the results of the work of the accreditation bodies referred in point (d) of Article 46(2) of that Regulation.

1. 根据欧盟条例（EU）2018/848 第 46（1）条认可的监管机构和监管机构的监管活动，应侧重于评估监管机构和监管机构的运营绩效，同时考虑该条例第 46（2）款第（d）项所指认证机构的工作结果。

2.

The intensity and frequency of the supervisory activities carried out by the Commission shall be adapted according to the risk of non-compliances in accordance with Article 46(6) of Regulation (EU) 2018/848.

2. 委员会进行的监管活动的强度和频率应根据《欧盟条例》（EU）2018/848 第 46(6)条规定的非遵守风险进行调整。

3.

Control authorities and control bodies recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 shall maintain the ability to meet the conditions and criteria set out in points (a), (b)(i) and (c) of Article 45(1) and Article 46(2) of that Regulation as set out in the technical dossier at the moment of their recognition. They shall also maintain the capacity and competencies to implement the control requirements, conditions and measures set out in Article 46(2) and (6) of Regulation (EU) 2018/848 and in this Regulation.

For that purpose, they shall demonstrate:

为此，他们应证明：

(a)

that they have effectively implemented their activities according to the conditions and criteria referred to in the first subparagraph; and

他们已有效实施了根据第一段所述的条件和标准进行的活动；

(b)

compliance with their operating procedures and the effectiveness of their control measures.

遵守其操作程序及其控制措施的有效性。

第 3 条根据《欧盟条例》（EU）2018/848 第 46(1)条认可的监管机构和监管机构应保持满足该条例第 45(1)款第（a）、（b）（i）和（c）项以及第 46(2)条规定的条件和标准的能力，这些条件和标准在技术文件中予以说明，并在其认可时予以确定。他们还应保持实施《欧盟条例》（EU）2018/848 第 46(2)条和（6）条以及本条例规定的控制要求、条件和措施的能力和资质。

[▼M1 ▲M1](#)

3a.

Within 2 years from the initial recognition or from the extension of the scope of recognition to a new category of products in accordance with Article 2, the control authority or control body shall provide a new witness audit report on a new witness audit carried out in accordance with Sections 1 and 2 of Part B of Annex I for the categories of products for which it has been recognised or for which the scope of recognition was extended.

3a. 自根据第 2 条对初始认可或认可范围扩展至新产品类别之日起 2 年内，控制机构或控制部门应就根据附件 I 第二部分第 1 节和第 2 节进行的新的见证审计，为已认可的产品类别或认可范围已扩展的产品类别提供新的见证审计报告。

[▼B](#)

4.

For the purpose of the annual report, the control bodies shall ensure that witness audits are carried out in accordance with Sections 1 and 2 of Part B of Annex I to this Regulation and the following rules:

[▼M1 ▲M1](#)

(a)

the period between two witness audits shall not exceed 4 years, starting from the date of the first witness audit carried out after the initial recognition or the initial extension of scope to a new category of products;

两次证人审计之间的期限不得超过 4 年，自首次进行证人审计的日期起算，该审计是在初始认可或初始扩展至新产品类别之后进行的

[▼B](#)

(b)

the number of witness audits carried out for the initial request for recognition shall not be considered for the calculation of the total number of witness audits to be carried out during the 4 years referred to in point (a);

证人审计的数量不应计入在(a)点所指的 4 年内应进行的总证人审计数量计算中

(c)

one additional witness audit shall be carried out:

应进行一次额外的证人审计:

(i)

every 2 years in those third countries where the high-risk product as referred to in Article 8 is produced or processed;

每两年在这些生产或加工第 8 条所述高风险产品的第三国

(ii)

for every 10 third countries recognised. This additional witness audit shall be carried out within 4 years;

对于每 10 个获认可的第三国, 这项额外的见证审计应在 4 年内进行;

(d)

more witness audits shall be performed at the request of the Commission or of the accreditation body based on a risk analysis of, in particular, the following factors:

应委员会或认证机构的要求, 根据以下因素的风险分析, 应进行更多见证审核:

(i)

the number of inspectors;

检查员数量;

(ii)

the number of operators;

操作员数量;

(iii)

the type of activities carried out by the operators;

运营商执行的活动类型;

(iv)

the number of witness audits carried out by the accreditation body;

该认证机构进行的见证审核数量

(v)

the irregularities concerning the control bodies;

关于监管机构的违规行为;

(vi)

the number of certified groups of operators and the size of them;
运营商认证小组的数量及其规模

(vii)

the critical findings for the control bodies or the specific inspector or inspectors;
控制机构或特定检查员或检查员的重大发现

(viii)

the nature of the products and the risk of fraud;
产品性质和欺诈风险;

(ix)

Commission feedback based on the previous annual report of the control body;
委员会根据控制机构上一年的报告反馈

(x)

suspicious of fraud by operators.
运营商涉嫌欺诈。

(xi)

the volume of products imported from a third country into the Union and the activity of
the control authority or control body in recognised third countries.
从第三国进口到欧盟的产品数量以及认可第三国控制机构的活动。

4. 为了编制年度报告，监管机构应确保人审计按照本法规附件 I 第二部分第 1 节
和第 2 节以及以下规则进行：

5.

Control authorities and control bodies shall submit documentation on their risk-
analysis procedure at the Commission's request.

5. 控制当局和控制机构应根据委员会的要求提交其风险评估程序文件。

6.

For the purpose of supervision of the control authorities and control bodies
recognised by the Commission, the latter may be assisted by two Member States to
act as co-reporters for the examination of technical dossiers submitted by control
authorities and control bodies for initial recognition or the extension of their scope of

recognition, the management and review of the list of recognised control authorities and control bodies and the evaluation of the operational performance, including annual reports, of the control authorities and control bodies.

6. 为了监督委员会认可的控制机构和控制部门，后者可由两个成员国协助，作为共同报告人审查控制机构和控制部门提交的技术档案，以进行初步认可或扩大认可范围，管理认可控制机构和控制部门的名单，以及评估控制机构和控制部门的运营绩效，包括年度报告。

7.

The Commission may divide the requests between the Member States proportionally with the number of votes of each Member State in the Committee on organic production.

7. 委员会将根据各成员国在有机生产委员会中的投票数，按比例将请求分配给成员国。

Article 4 第 4 条

Annual report 年度报告

By 28 February every year, the control authority or control body shall submit an annual report to the Commission.

截至每年 2 月 28 日，控制当局或控制机构应向委员会提交年度报告。

That annual report shall set out the activities of the control authority or control body in the previous year in accordance with Annex II

该年度报告应按照附件 II 列出控制机构或控制实体的上一年活动

It shall be submitted in one of the official languages of the Union and in English if the official language chosen is not English.

应提交为欧盟的官方语言之一，如果选择的语言不是英语，则还需用英语提交。

Article 5 第五条

On-the-spot examinations and audits

现场检查和审计

1.

The Commission shall regularly organise risk-based on-the-spot examinations and/or audits of the control authorities and control bodies to evaluate the quality and effectiveness of the controls carried out by each control authority or control body. Those examinations and audits may be coordinated with the relevant accreditation body. The Commission may be accompanied by independent experts during these on-the-spot examinations and audits.

1. 委员会应定期组织基于风险的现场检查 and/或 对控制机构和控制部门的审计，以评估每个控制机构或控制部门所进行的控制的质量和有效性。这些检查和审计可以与相关认证机构协调。在这些现场检查 and 审计过程中，委员会可以由独立专家陪同。

2.

The Commission may request any further information, including the presentation of one or more ad-hoc on-the-spot examination reports established by independent experts that it designates.

2. 委员会可要求提供任何进一步的信息，包括指定独立专家编制的一个或多个临时现场检查报告的展示。

3.

On-the-spot examinations and audits may include:

(a)

a visit to the offices or premises of the control authorities and control bodies, their outsourced services and operators or groups of operators under their control, in the Union and in third countries;

对控制机构和控制机构的办公室或场所的访问，以及在其控制下的外包服务提供商或操作员群体，在联盟和第三国；

(b)

a document review of the relevant documents describing the structure, functioning and quality management of the control authorities or control bodies;

相关控制机构或控制部门的组织结构、运作和质量管理描述文件的文档审查

(c)

a document review of staff files, including evidence of their competencies, training records, conflict of interest statements and records of evaluation and supervision of staff;

员工文件审查文档，包括其能力证明、培训记录、利益冲突声明以及员工评估和监督记录；

(d)

a check of operators' or groups of operators' files in order to verify the treatment of non-compliances and complaints, the minimum control frequency, the use of a risk-based approach in the conduct of inspections, the implementation of follow-up visits and visits without prior notice, the sampling policy and the exchange of information with other control bodies and control authorities;

对运营商或运营商群体文件进行检查，以核实非合规和投诉的处理、最低控制频率、在检查过程中采用基于风险的策略、实施后续访问和无预先通知的访问、抽样政策和其他控制机构和控制当局的信息交换；

(e)

a review audit, which is the inspection of operators or groups of operators to verify compliance with the standard control and risk assessment procedures of the control authority or control body and to verify its effectiveness, taking into account the evolution of the operators' situation from the last inspection of the control authority or control body;

一次审查审计，即对操作员或操作员群体进行检查，以验证其是否符合控制机构或控制主体的标准控制程序和风险评估程序，并验证其有效性，同时考虑操作员自上次控制机构或控制主体检查以来的情况演变；

(f)

a witness audit, which is the evaluation of the performance of the physical on-the-spot inspection carried out by an inspector of the control authority or control body.

证人审计，即由控制当局或控制机构检查员进行的现场物理检查的性能评估。

3. 现场检查和审计可能包括：

Article 6 第六条

Traceability checks 可追溯性检查

The Commission may perform traceability checks on products or consignments covered by the scope of the recognition of a control authority or control body recognised in accordance with Article 46(1) of Regulation (EU) 2018/848.

委员会可以对根据《欧盟条例》（EU）2018/848 第 46(1)条认可的监管机构或监管机构认可范围内的产品或托运物进行追溯性检查。

For the purpose of tracing the ingredients or production phases of an organic product, the Commission may ask information from the competent authorities or from control authorities or control bodies involved in the control of those products falling under their supervision.

为了追踪有机产品的成分或生产阶段，委员会可要求从其监管下的相关产品控制的主管当局或控制当局或控制机构获取信息。

The Commission may perform traceability checks based on the annual risk assessment performed by it, complaints received by the Commission or Member States, or randomly.

委员会可以根据其进行的年度风险评估、委员会或成员国收到的投诉或随机进行追溯性检查。

The Commission shall perform traceability checks in a timeframe defined by it, which shall be communicated in time to the relevant competent authorities, control authorities and control bodies involved.

委员会应在它定义的时间内进行可追溯性检查，并及时向相关主管当局、控制当局和控制机构通报。

Article 7 第七条

Ad hoc request by the Commission

欧盟委员会的临时请求

The Commission may, at any time, based on a substantial analysis proving the necessity, make ad-hoc requests for information to a control authority or control body.

authority or control body.

Article 8 第八条

List of high-risk products

高风险产品清单

Control authorities and control bodies operating in respect of third countries shall apply Article 9(8), second subparagraph, and Articles 12(5) and 16(6) of this Regulation in respect of the high-risk products originating from third countries as listed in an implementing act adopted pursuant to Article 46(8) of Regulation (EU) 2018/848 on the basis of a selection made after major, critical or repetitive non-compliances affecting the integrity of organic or in-conversion products or production.

控制当局和第三国运营的控制机构应适用本法规第 9(8)条第二段以及第 12(5)条和第 16(6)条，针对根据《欧盟条例》（EU）2018/848 第 46(8)条通过的实施方案列出的、源自第三国的高风险产品，这些产品是在有机或转化产品或生产完整性受到重大、关键或重复性不符合规定后进行选择的。

CHAPTER III 第三章

CONTROLS IN RESPECT OF OPERATORS AND GROUPS OF OPERATORS BY THE CONTROL AUTHORITIES AND CONTROL BODIES

监管机构对运营商和运营商集团的控制

Article 9 第九条

General provisions 一般性规定

1. Controls performed by control authorities and control bodies for the verification of compliance with Regulation (EU) 2018/848 by operators and groups of operators in third countries shall include:

(a)

the verification of the application of preventive and precautionary measures, as referred to in Article 9(6) and in Article 28 of Regulation (EU) 2018/848, at every stage of production, preparation and distribution;

对预防性和预防措施应用的核实，如《条例》（EU）2018/848 第 9(6)条和第 28 条所述，在生产、准备和分销的每个阶段；

(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;

持有包括非有机或转换生产单位时，应核实记录以及确保有机、转换和非有机生产单位以及由这些单位生产的相应产品之间清晰有效分离的措施、程序或安排，以及用于有机、转换和非有机生产单位所使用的物质和产品。此类核实应包括对之前期间被追溯认可为转换期一部分的地块进行检查，以及对非有机生产单位的检查。

(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 measures to prevent substitution of products are implemented, that organic products and in-conversion products are identified at all times, that organic, in-conversion and non-organic products are stored, before and after the preparation operations, separated by place or time from each other, and that traceability of each lot from the individual land parcels to the collection centre has been ensured.

有机、转化中和非有机产品由操作员同时收集、在同一制备单元、区域或场所准备或储存，或运输到其他操作员或单位时，应核实记录和确保操作按地点或时间分离的措施、程序或安排，实施适当的清洁措施和防止产品替代的措施，确保有机产品和转化中产品始终得到识别，有机、转化中和非有机产品在制备操作前后按地点或时间相互分离储存，并确保从单个地块到收集中心的每个批次的可追溯性。

1. 控制机构和控制主体对第三方国家运营商和运营商群体遵守《欧盟条例》（EU）2018/848 的验证所进行的控制应包括：

2. Controls by control authorities and control bodies for the verification of compliance with Regulation (EU) 2018/848 shall be performed on all operators and groups of operators in third countries regularly, on a risk basis and with appropriate frequency, 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 Regulation (EU) 2018/848, which shall be determined taking into account the following elements:

(a)

the type, size, including newly added land parcels, and structure of the operators and groups of operators, as well as the number of new members joining the group of operators;

该运营商和运营商群体类型、规模（包括新增地块）、结构以及加入运营商群体的新成员数量；

(b)

location and complexity of the activities or operations of operators and groups of operators;

运营商和运营商群体的活动或运营的地点和复杂性

(c)

the length of time during which operators and groups of operators have been involved in organic production, preparation and distribution;
操作员和操作人员群体参与有机生产、准备和分销的时间长度;

(d)

the results of the controls performed in accordance with this Article, in particular as regards compliance with Regulation (EU) 2018/848;
根据本条款进行的控制结果，特别是关于符合欧盟法规（EU）2018/848 的情况;

(e)

in the case of a group of operators, the results of the internal inspections carried out in accordance with the documented procedures of the system for internal controls of the group of operators;
在运营商群体的情况下，根据运营商群体内部控制系统文件程序进行的内部检查结果;

(f)

whether the holding includes non-organic or in-conversion production units;
是否包括非有机或转换中的生产单位;

(g)

the type, quantity and value of products;
产品类型、数量和价值;

(h)

the risk of commingling of products or contamination with non-authorised products or substances;
产品混合或与非授权产品或物质污染的风险;

(i)

the application of derogations or exceptions to the rules by operators and groups of operators;
运营商和运营商群体对规则的豁免或例外应用;

(j)

the critical points for non-compliance at every stage of production, preparation and distribution;
生产、准备和分销每个阶段的非合规关键点

(k)

subcontracting activities;

分包活动

(l)

whether operators or groups of operators have changed their certifying control

authority or control body;

运营商或运营商群体是否已更改其认证控制机构或控制机构;

(m)

any information indicating the likelihood that consumers might be misled;

任何表明消费者可能被误导的信息

(n)

any information that might indicate non-compliance with Regulation (EU) 2018/848.

任何可能表明不符合（欧盟）2018/848 号法规的信息。

2. 对第三国所有运营商和运营商群体，应按照《欧盟条例》（EU）2018/848 第 3 条第 57 点定义的不合规可能性，基于风险和适当的频率，在整个生产、准备和分销过程中，定期进行符合《欧盟条例》（EU）2018/848 的监管机构和监管机构的控制。这些控制应考虑以下因素：

3.

Article 2 of Commission Delegated Regulation (EU) 2021/771 ([2](#)) and Articles 4, 5 and 6 of Commission Implementing Regulation (EU) 2021/279 ([3](#)) shall apply *mutatis mutandis* to controls in respect of groups of operators in third countries.

3. 委员会委托法规（EU）2021/771 的第二条（2）以及委员会执行法规（EU）2021/279 的第四、五、六条（3）应相应适用于对第三国运营商群体的控制。

4.

The control authority or control body 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.

4. 控制当局或控制机构应至少每年对所有运营商和运营商群体进行一次符合《欧盟条例》（EU）2018/848 的核查。符合性核查应包括现场实地检查。

5.

The control authority or control body 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.

5. 控制当局或控制机构应确保每年至少对第 4 段所述内容进行 10%的额外控制。控制当局或控制机构进行的所有现场物理检查中，至少 10%应无事先通知。

6.

Controls carried out as a follow-up on a suspected or established non-compliance shall not count towards the additional controls referred to in paragraph 5.

6. 对涉嫌或已确立的不合规行为进行的后续控制措施，不应计入第 5 段所述的额外控制措施中。

7.

Every year, the control authority or control body shall re-inspect at least 5 % of the members of a group of operators, but not less than 10 members. Where the group of operators has 10 members or less, all members shall be re-inspected.

每年，控制当局或控制机构应至少重新检查运营商群体中 5%的成员，但不少于 10 名成员。如果运营商群体有 10 名成员或更少，则所有成员都应重新检查。

8.

The physical on-the-spot inspection and the sampling shall be carried out by the control authority or control body at the most appropriate times in order to verify compliance on critical control points.

8. 物理现场检查和抽样应由监管机构或监管主体在最合适的时间进行，以便验证关键控制点的合规性。

For the high-risk products referred to in Article 8, the control authority or control body shall carry out, at least, two physical on-the-spot inspections per year of operators or groups of operators. One of these physical on-the-spot inspections shall be without prior notice.

对于第 8 条所述的高风险产品，控制机构或控制部门应至少每年对运营商或运营商群体进行两次现场检查。其中一次现场检查不得提前通知。

9.

Where operators or groups of operators run several production units or premises, including purchase and collection centres, all production units or premises, including purchase and collection centres, used for non-organic products shall also be subject to the control requirements set out in paragraph 4.

第九条 如果运营商或运营商群体运营多个生产单位或场所，包括采购和收集中心，所有用于非有机产品的生产单位或场所，包括采购和收集中心，也应遵守第四条规定的控制要求。

10.

The delivery or renewal of the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 shall be based on the results of the verification of compliance referred to in this Article.

第十条，关于《欧盟条例》（EU）2018/848 第 45(1)款第(b)(i)项所指证书的交付或续签，应基于本条款所指的合规性验证结果。

Article 10 第 10 条

Checks for the certification of operators or groups of operators

对运营商或运营商群体的认证检查

1.

Before accepting to certify operators or groups of operators, a control authority or control body shall ensure that the operators or groups of operators have provided the following:

(a)

a document in the form of a signed declaration, setting out:

一份签署声明的文件，载明：

(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;

有机和/或在转换生产单元的描述，以及相关情况下非有机生产单元和根据法规（EU）2018/848 应执行的活动描述；

(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;

相关措施，应在有机和/或在转换单位及/或场所及/或活动中采取，以确保符合（欧盟）2018/848 号法规；

(iii)

the precautionary measures to be taken in order to reduce the risk of contamination by non-authorised products or substances and the cleaning measures to be taken throughout the stages of production, preparation and distribution;

采取的预防措施以降低非授权产品或物质污染的风险，以及在生产的各个阶段、准备和分销过程中应采取的清洁措施；

(b)

a confirmation that the operators or groups of operators have not 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 groups of operators operate at different stages of production, preparation or distribution;

确认操作员或操作员群体未在相同第三国就同一类产品进行的活动中获得其他控制机构的认证，包括操作员或操作员群体在生产的不同阶段、准备或分销中进行操作的情况

(c)

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;

该组成员确认，他们未就同一产品（该产品受其所属运营商集团认证）的同一活动进行过个人认证

(d)

a signed undertaking by which the operators or groups of operators commit themselves:

一份由运营商或运营商群体签署的承诺书：

(i)

to give the control authority or control body access to all parts of all production units and all premises for control purposes, as well as to the accounts and relevant supporting documents;

为使控制当局或控制机构能够进入所有生产单元和所有场所的各个部分进行控制，以及查阅账户和相关支持文件；

(ii)

to provide the control authority or control body with any information necessary for the purposes of the controls;

为控制当局或控制机构提供为控制目的所需的任何信息；

(iii)

to submit, when requested by the control authority or control body, the results of its own quality assurance programmes;

提交，当控制当局或控制机构要求时，其自身质量保证计划的结果；

(iv)

to inform buyers of the products in writing and without undue delay, and to exchange relevant information with the control authority or control body, 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;

向买方以书面形式及时通知，并在怀疑不符合规定得到证实、怀疑不符合规定无法消除或已确定不符合规定影响相关产品完整性的情况下，与控制当局或控制机构交换相关信息；

(v)

to accept the transfer of the control file in case of a change of control authority or control body or, in the case of withdrawal from organic production, the keeping of the control file for 5 years by the last control authority or control body;

接受控制文件转让，在控制权或控制机构变更的情况下，或者在有机生产退出的情况下，由最后控制权或控制机构保留控制文件 5 年；

(vi)

to inform immediately the control authority or control body in the event of withdrawal from organic production;

立即通知控制当局或控制机构有关有机生产退出的情况；

(vii)

in the event that the subcontractors of the operators or of groups of operators are subject to controls by different control authorities or control bodies, to accept the exchange of information among those control authorities or control bodies;

在运营商或运营商群体的分包商受到不同控制当局或控制机构控制的情况下，接受这些控制当局或控制机构之间的信息交换；

(viii)

to perform the activities in accordance with the organic production rules;

按照有机生产规则执行活动；

(ix)

to accept the enforcement of the corrective measures established by the control authority or control body in the event of non-compliances.

接受控制机构或控制主体在不符合规定的情况下采取的纠正措施的执行。

1. 在接受认证运营商或运营商群体之前，监管机构或监管机构应确保运营商或运营商群体已提供以下内容：

2.

Before certifying operators or groups of operators, the control authority or control body shall verify:

(a)

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;

该运营商或运营商群体符合《欧盟条例》（EU）2018/848 的第 II、III 和 IV 章以及该条例的第 36 条。核查应至少包括一次现场实地检查。

(b)

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.

该运营商或运营商群体以及将活动分包给第三方的第三方，已由认可的监管当局或监管机构认证，确认其符合《欧盟条例》（EU）2018/848 的第 II、III 和 IV 章以及该条例的第 36 条，除非运营商或运营商群体通知相关监管当局或监管机构，他们仍对有机生产负责，并且他们没有将责任转移给分包商。在这种情况下，监管当局或监管机构应核实分包活动是否符合《欧盟条例》（EU）2018/848 的第 II、III 和 IV 章以及该条例的第 36 条，在其实施针对分包活动的运营商或运营商群体的监管活动时。

2. 在认证运营商或运营商群体之前，控制当局或控制机构应核实：

3.

Besides any other element that may be considered relevant by the control authority or control body, before certifying operators or groups of operators that were previously certified by another control authority or control body, the new control authority or control body shall assess the following information to be transmitted by the previous control authority or control body:

(a)

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;

认证的状态和有效性，包括范围缩减、暂停和撤回等情况，如国际标准化组织（ISO）标准 ISO/IEC 17065 所述；

(b)

reports of inspection carried out in the preceding 3 years;

前三年进行的检查报告

(c)

the list of non-compliances and the measures put in place to address them, and the fact that all non-compliances were addressed;

不符合项清单及采取的措施，以及所有不符合项均已得到解决的事实

(d)

derogations granted or requests for derogation being processed by the previous control authority or control body;

被前控制机构或控制部门授予的豁免或正在处理中的豁免请求

(e)

information relating to any ongoing dispute relevant for the certification of the operators or groups of operators.

与任何正在进行的有关于运营商或运营商群体认证的相关争议信息。

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, the new control authority or control body 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.

如果前控制机构或控制部门未按照本法规第 21(5)条的要求向新控制机构或控制部门传输信息，或者在对传输的信息存在疑虑的情况下，新控制机构或控制部门不得在新的控制机构或控制部门通过其他控制手段消除疑虑之前，向运营商或运营商群体颁发《欧盟条例》（EU）2018/848 第 45(1)条 b)(i)点所指的证书。

3. 除了控制机构或控制主体可能认为相关的任何其他要素外，在认证之前由其他控制机构或控制主体认证的运营商或运营商群体，新的控制机构或控制主体应评估以下由先前控制机构或控制主体传输的信息：

4.

The control authority or control body 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.

4. 控制当局或控制机构不得对在过去两年内被其先前控制当局或控制机构撤回的运营商或运营商群体进行认证，除非根据《欧盟条例》（EU）2018/848 第 46(2a)条，委员会已撤回对特定第三国和产品类别的先前控制当局或控制机构的认可。

Article 11 第 11 条

Methods and techniques for controls

方法和控制技术

1.

Control methods and techniques applied by a control authority or control body shall include the following:

(a)

a check whether the maps or sketches with cardinal directions and geo-location of the production units and premises to be physically inspected, as provided by the operators or groups of operators, is up-to-date;

检查由操作员或操作员小组提供的生产单位和场所的地图或草图（包括方位和地理定位）是否最新；

(b)

an inspection of, as appropriate:

相应地进行检查：

(i)

the production units, equipment, means of transport, premises and other places under the control of the operator or group of operators;

生产单位、设备、运输工具、场所及其他受运营商或运营商群体控制的地方

(ii)

animals, plants and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals, and substances authorised for use in organic production;

动物、植物和商品，包括半成品、原材料、成分、加工助剂和其他用于商品制备和生产或用于饲养或处理动物的产品的物质，以及有机生产中允许使用的物质；

(iii)

traceability, labelling, presentation, advertising and relevant packaging materials;

可追溯性、标签、展示、广告以及相关包装材料；

(c)

an examination of documents, traceability records and other records and practices and procedures that are relevant for the assessment of compliance with Regulation

(EU) 2018/848. This includes documents accompanying food, feed and any substance or material entering or leaving an establishment;

对文件、追溯记录以及其他与评估是否符合欧盟法规（EU）2018/848 相关的记录和程序进行审查。这包括随食品、饲料进入或离开场所的任何物质或材料的文件。

(d)

interviews with operators and their staff;

与操作员及其员工的面谈

(e)

sampling and laboratory analysis;

采样和实验室分析;

(f)

the examination of the control system that operators and groups of operators have put in place, including an evaluation of its effectiveness;

对操作员和操作员群体实施的控制系统进行检查，包括对其有效性的评估;

(g)

the examination of non-compliances found during previous inspections and the measures taken by the operators or by the groups of operators to address them;

对之前检查中发现的不合规情况进行审查，以及操作员或操作员群体为解决这些问题所采取的措施;

(h)

any other action required to identify cases of non-compliance.

任何其他必要的行动以识别不合规案件。

1. 控制机构或控制主体应采用以下控制方法和技巧:

2.

The annual physical on-the-spot inspection referred to in Article 9(4) shall include a traceability check and a mass balance check of the operators or groups of operators, carried out by means of checks of documentary accounts and of any other relevant element deemed necessary by the control authority or control body.

第二，第九条（4）所述的年度现场检查应包括对操作员或操作员群体的可追溯性检查和质量平衡检查，通过检查文件账户和由控制当局或控制机构认为必要的任何其他相关要素进行。

3.

For the purpose of the traceability check and the mass balance check, the selection of products, groups of products and period under verification shall be based on a risk assessment by the control authority or control body.

3. 为了进行追溯性检查和质量平衡检查，所选择的产品、产品组和验证期间应基于控制机构或控制主体的风险评估。

4.

Besides any other relevant element deemed necessary by the control authority or control body, the traceability check shall cover the following elements justified by appropriate documents including stock and financial records:

(a)

the name and address of the supplier and, where different, of the owner or the seller, or the exporter of the products;

供应商的名称和地址，以及，如果不同，所有者或卖方，或产品的出口商；

(b)

the name and address of the consignee and, where different, of the buyer or importer of the products;

收货人名称和地址，以及产品购买者或进口商的名称和地址（如有不同）；

(c)

the certificate of the supplier in accordance with an implementing act adopted pursuant Article 45(4) of Regulation (EU) 2018/848;

供应商根据《欧盟条例》（EU）2018/848 第 45(4)条通过的执行条例颁发的证书；

(d)

the information referred to in the first paragraph of point 2.1 of Annex III to Regulation (EU) 2018/848;

关于《欧盟条例》（EU）2018/848 附件 III 第 2.1 点第一段所指的信息

(e)

the appropriate lot identification;

适当的批次标识

(f)

in the case of processors, the necessary information to allow internal traceability and guarantee the organic status of ingredients.

处理器的情况下，允许内部追溯和保证成分有机状态的必要信息。

4. 除了控制机构或控制主体认为必要的其他相关要素外，追溯性检查还应包括以下由适当文件证明的要素，包括库存和财务记录：

5.

The mass balance check shall cover the following elements justified by appropriate documents including stock and financial records, where relevant:

(a)

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;

交付给单位的产品性质和数量，以及相关情况下购买的材料和这些材料的使用，以及相关情况下产品的成分；

(b)

the nature and the quantities of products held in storage at the premises including at the time of the physical on-the-spot inspection;

该场所储存的产品性质和数量，包括在实物现场检查时的情况；

(c)

the nature and quantities of the products that have left the unit of the operators or groups of operators to the consignee's premises or storage facilities;

该产品从运营商或运营商群体单位离开至收货方场所或仓储设施的性质和数量；

(d)

in case of operators or groups of operators who buy or sell the product(s) without storing or physically handling the product(s), the nature and the quantities of products that have been bought and sold;

如操作员或操作员群体购买或销售产品而不存储或实际处理产品，所购买和销售的产品性质和数量；

(e)

the yield of the products obtained, collected or harvested over the previous year;

上一年度获得、收集或收获的产品产量；

(f)

the estimated or actual yield of the products obtained, collected or harvested over the current year;

当前年度获得、收集或收获的产品预计或实际产量；

(g)

the number and/or weight of livestock managed over the current and previous year;

当前及上一年度管理的牲畜数量和/或重量；

(h)

any losses, increase or decrease in quantity of products at any stage of production, preparation and distribution;

任何阶段的任何损失、产品数量增加或减少；

(i)

the total output of the holding in terms of organic and non-organic products.

该控股公司在有机和非有机产品方面的总产量。

5. 质量平衡检查应包括以下要素，并应由适当的文件证明，包括相关库存和财务记录：

Article 12 第 12 条

Sampling, methods used for sampling and selection of laboratories for sample analysis

采样，用于采样和选择实验室进行样品分析的方法

1.

The control authority or control body shall take and analyse samples for detecting the use of non-authorised products and substances for organic production, for checking production techniques not in compliance with the organic production rules or for detecting possible contamination by non-authorised products and substances for organic production.

1. 控制当局或控制机构应采取并分析样品，以检测有机生产中非授权产品和物质的使用，以检查不符合有机生产规则的生产技术，或以检测有机生产中非授权产品和物质的可能污染。

2.

The control authority or control body shall carry out sampling on at least 5 % of the number of individual operators under its control. For a group of operators, the control authority or control body carry out sampling on at least 2 % of the members of each group.

2. 控制当局或控制机构应对其控制下的至少 5%的个体操作员进行抽样。对于一组操作员，控制当局或控制机构应对每组至少 2%的成员进行抽样。

3.

The selection of the operators and groups of operators where samples have to be taken shall be based on risk assessment including the likelihood of non-compliance with the organic production rules, taking into account all stages of production, preparation and distribution.

3. 样品采集的运营商和运营商组的选择应基于风险评估，包括违反有机生产规则的可能性，考虑生产、准备和所有阶段的分布。

4.

In addition to the minimum sampling rate set in paragraph 2, the control authority or control body shall take and analyse samples in each case where the use of non- authorised products and substances or techniques for organic production is suspected, unless the control authority or control body considers that sufficient evidence is available without sampling.

4. 除第 2 段规定的最低抽样率外，控制机构或控制主体应针对涉嫌使用未经授权的产品和物质或有机生产技术的情况进行抽样和分析，除非控制机构或控制主体认为无需抽样即可获得充分证据。

5.

For the high-risk products referred to in Article 8, the control authority or control body shall take, in addition to the sampling rate set in paragraphs 2 and 3 of this Article, at least one field sample of the crop each year. That sample shall be taken from crops in the field, at the most appropriate moment to detect potential use of non- authorised substances according to the assessment of the control authority or control body. For operators not growing crops, a relevant sample of incoming raw material or intermediate product or processed product shall be taken.

第五条 对于第八条所指的高风险产品，控制当局或控制机构除应按照本条第二段和第三段设定的抽样率外，每年至少应从作物中采集一个田间样品。该样品应从田间作物中采集，在控制当局或控制机构评估的最合适时机进行，以检测非授权物质的可能使用。对于不种植作物的操作者，应采集相关原料或中间产品或加工产品的样品。

6.

The control authority and control body shall ensure that the laboratories used comply with the following:

(a)

they are accredited laboratories that meet the applicable requirements of ISO standard ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';

它们是符合 ISO 标准 ISO/IEC 17025 关于“测试和校准实验室能力的一般要求”适用要求的认可实验室；

(b)

their accreditation bodies are signatory of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;

他们的认证机构是国际实验室认可合作组织（ILAC）相互承认安排的签署方；

(c)

they have sufficient capacity for analysis and testing and they can ensure that samples are always tested with relevant methods included in the scope of their accreditation;

他们有足够的分析和测试能力，并确保样本始终使用其认证范围内的相关方法进行测试

(d)

as regards residue pesticide testing, they are accredited for gas and liquid spectrometry in order to be able to cover the list of pesticide residues monitored under the coordinated multi-annual control programme of the Union set out in Commission Implementing Regulation (EU) 2019/533 ([4](#)).

关于残留农药检测，它们获得了气体和液体光谱学的认证，以便能够覆盖欧盟委员会实施条例（EU）2019/533 中规定的协调多年度控制计划下监测的农药残留清单

(4) 。

6. 控制当局和控制机构应确保使用的实验室符合以下要求：

7.

The control authority or control body may delegate sampling tasks to other control authorities or control bodies recognised by the Commission or bodies accredited in accordance with ISO standard ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'.

7. 控制当局或控制机构可以将采样任务委托给委员会认可的其他控制当局或控制机构，或者根据 ISO 标准 ISO/IEC 17025 认证的机构。

Article 13 第 13 条

Documented control procedures

记录的控制程序

1.

Control authorities and control bodies shall perform controls on operators and groups of operators in accordance with documented procedures.

Those documented procedures shall cover:

那些记录的程序应包括：

(a)

a statement on the objectives to be achieved;

关于要实现的目标的声明；

(b)

tasks, responsibilities and duties of staff;

员工的任务、责任和职责

(c)

sampling strategy, procedures and methodology, control methods and techniques, including laboratory analysis, testing and interpretation and evaluation of results and consequent decisions;

抽样策略、程序和方法，包括实验室分析、测试、结果解释和评估以及后续决策的控制方法和技巧；

(d)

cooperation and communication with other control authorities, other control bodies and the Commission;

与其他控制机构、其他控制机构和委员会的合作与沟通

(e)

a procedure for assessing the risk linked to operators or groups of operators and for carrying out physical on-the-spot inspections and sampling;

评估与运营商或运营商群体相关的风险以及进行现场物理检查和采样的程序;

(f)

verification of the appropriateness of methods of sampling and of laboratory analysis, testing and diagnosis;

验证采样和实验室分析、测试和诊断方法的适宜性

(g)

any other activity or information required for the effective functioning of the controls, including in relation to training of inspectors and evaluation of their competencies;

任何其他对控制有效运作必要的行为或信息，包括与检查员培训及其能力评估相关的内容;

(h)

for groups of operators, the effectiveness of the system for internal controls.

对于操作员群体，内部控制的系统有效性。

1. 监管机构和监管机构应按照书面程序对运营商和运营商群体进行监管。

2.

Control authorities and control bodies shall:

(a)

take corrective measures in all cases where the procedures provided for in paragraph 1 identify shortcomings; and

采取纠正措施，在第一段规定的程序中识别出缺陷的所有情况下;

(b)

update the documented procedures provided for in paragraph 1 as appropriate.

更新第 1 段所述的文档程序，如有必要。

2. 监管机构和监管机构应：

Article 14 第 14 条

Written records of controls

书面控制记录

1.

Control authorities and control bodies shall draw up written records of each control they perform to verify compliance with Regulation (EU) 2018/848. Those records may be on paper or in electronic form. The control authorities and control bodies shall keep these records for 5 years from the day of the decision on certification by the control authority or control body.

Those records shall contain in particular:

这些记录应特别包含：

(a)

a description of the purpose of the controls;

控制目的的描述

(b)

the control methods and techniques applied;

所应用的控制方法和技术

(c)

the outcome of the controls, in particular the results of verifying the elements listed in Articles 11 and 12 of this Regulation; and

控制结果，特别是验证本法规第 11 条和第 12 条所列要素的结果；

(d)

actions that the operator or group of operators concerned is required to take as a result of the controls carried out by the control authority or control body, with an indication of the deadline to take action.

相关运营商或运营商群体必须采取的行动，以及采取行动的截止日期。

1. 监管机构和监管组织应制定书面记录，以验证其执行的每项监管是否符合《欧盟条例》（EU）2018/848。这些记录可以是纸质或电子形式。监管机构和监管组织应自监管机构或监管组织作出认证决定之日起保存这些记录 5 年。

2.

The written records shall be countersigned by the operator or the inspected member of the group of operators as confirmation of their receipt of that written record. A copy of that record shall be kept by the operator or the inspected member of the group of operators either on paper or in electronic form.

2. 书面记录应由操作员或检查员小组的受检成员副署，以确认他们已收到该书面记录。操作员或检查员小组的受检成员应保留该记录的副本，可以是纸质形式或电子形式。

Article 15 第 15 条

Specific control requirements for algae and aquaculture animal production

特定藻类和水产动物生产的控制要求

1.

For the purpose of determining the start of the conversion period provided in Article 10(2) of Regulation (EU) 2018/848, the control authority or control body shall ensure that operators or groups of operators producing algae or aquaculture animals notify the control authority or control body of the relevant activity.

1. 为了确定《欧盟条例》（EU）2018/848 第 10（2）条规定的转换期开始，控制机构或控制部门应确保生产藻类或水产养殖动物的运营商或运营商群体通知控制机构或控制部门相关活动。

2.

The control authority or control body shall ensure that organic production of algae or aquaculture animals takes place in a location with no risk of contamination in accordance with point 1.1 of Part III of Annex II to Regulation (EU) 2018/848. In particular, the control authority or control body shall ensure that adequate separation measures have been taken in accordance with point 1.2 of that Part III.

2. 控制机构或控制部门应确保藻类或水产养殖动物的有机生产在无污染风险的地点进行，符合《欧盟条例》（EU）2018/848 附件 II 第三部分第 1.1 点的规定。特别是，控制机构或控制部门应确保已采取适当的隔离措施，符合该部分第 1.2 点的规定。

3.

For the purposes of point 3.1.3.1(c) of Part III of Annex II to Regulation (EU) 2018/848, the control authority or control body shall ensure that the plant fraction of feed is organic and the feed fraction derived from aquatic animals originates from organic aquaculture or from fisheries that have been certified as sustainable in line with the 2009 FAO's Guidelines for the ecolabelling of fish and fisheries products from marine capture fisheries.

3. 根据欧盟法规（EU）2018/848 附件 II 第三部分 3.1.3.1(c)的规定，控制机构或控制部门应确保饲料的植物部分是有机的，以及从水生动物中提取的饲料部分来源于有机水产养殖或根据 2009 年 FAO 关于海洋捕捞渔业鱼类和水产产品生态标签指南认证的可持续渔业。

4.

For the purposes of point 3.1.4.2(e) of Part III of Annex II to Regulation (EU) 2018/848, the control authority or control body shall ensure that they have information on all treatments, and they shall check that these treatments are carried out in accordance with the requirements of that Regulation.

4. 根据《欧盟法规》（EU）2018/848 附件 II 第三部分 3.1.4.2(e)的规定，控制机构或控制部门应确保他们拥有所有处理方式的信息，并应检查这些处理方式是否符合该法规的要求。

5.

For the purpose of authorising the use of wild seed within the meaning of point 3.2.1 of Part III of Annex II to Regulation (EU) 2018/848, the control authority or control body shall ensure that points (a), (b) and (c) of that point are respected.

5. 为了授权在《欧盟法规（EU）2018/848》附件 II 第三部分第 3.2.1 点意义上的使用野生种子，控制当局或控制机构应确保遵守该点的(a)、(b)和(c)项。

Article 16 第 16 条

Verification of consignments intended for import into the Union **货物进口到联盟的验证**

1.

The relevant control authority or control body shall verify consignments intended for import into the Union with regard to the compliance with Regulation (EU) 2018/848

and this Regulation. 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.

1. 相关控制当局或控制机构应核实拟进口到联盟的货物是否符合《欧盟条例》（EU）2018/848 和本法规。此核实应包括系统性的文件检查，并根据风险评估，在货物离开出口国或原产国第三国之前，进行适当的实物检查。

2.

For the purposes of this Article, the relevant control authority or control body shall be:

(a)

the control authority or control body of the producer or the processor of the product concerned; or

相关产品的生产者或加工者的控制当局或控制机构；或

(b)

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.

在执行最后操作以进行准备的目的下，运营商或运营商群体与产品的生产商或加工商不同时，根据《欧盟条例》（EU）2018/848 第 3 条第 44 点定义的控制当局或控制机构。

The relevant control authority or control body 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.

相关控制当局或控制机构应根据《欧盟条例》（EU）2018/848 第 46(1)条，承认与相关产品及其原产国（或，如适用，进行最后操作以备使用的国家）相关的控制机构。

2. 本条款的目的在于，相关监管机构或监管机构应为：

3. The documentary checks referred to in paragraph 1 shall aim at verifying:

(a)

the traceability of the products and ingredients;
产品及成分的可追溯性;

(b)

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 the control authority or control body;
该批货物中产品的体积与控制机构或控制机构群体根据评估进行的质量平衡检查相符;

(c)

the relevant transport documents and commercial documents (including invoices) of the products;
相关运输文件和商业文件（包括发票）的产品;

(d)

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 a control authority or control body recognised in accordance with Article 46(1) or referred to in Article 57 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.

如涉及加工产品，则此类产品的所有有机成分均应由根据《欧盟条例》（EU）2018/848 第 46(1)条或第 57 条认可的或参照该条例的第三国控制机构或控制机构认证的运营商或运营商群体生产，或者根据该条例在联盟内生产和认证。

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 the control authority or control body.

这些文件审核应基于所有相关文件，包括《欧盟条例》（EU）2018/848 第 45(1)款第(b)(i)点所指的证书、最新检查记录、相关产品的生产计划、操作员或操作员群体保存的记录、可用的运输文件、商业和财务文件以及控制当局或控制机构认为相关的任何其他文件。

3. 第 1 段中提到的纪录片审查应旨在核实：

4.

In relation to the risk assessment preceding physical checks as referred to in paragraph 1, the relevant control authority or control body shall take into account the following criteria:

(a)

the relevant criteria listed in Article 9(2);

第 9(2)条列出的相关标准;

(b)

whether there are several operators involved in the distribution chain of the products who do not store or physically handle organic products;

是否涉及多个在产品分销链中不储存或实际处理有机产品的运营商;

(c)

high-risk products referred to in Article 8;

第八条所指的高风险产品

(d)

any criteria deemed relevant by the control authority or control body.

任何由控制机构或控制部门认为相关的标准。

4. 关于第 1 段所述的物理检查前的风险评估, 相关控制机构或控制部门应考虑以下标准:

5.

For consignments made out of bulk organic products, the relevant control authority or control body 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.

5. 对于由散装有机产品组成的货物, 相关控制当局或控制机构应在贸易控制和专家系统 (TRACES) 中制定旅行计划, 包括从原产国或出口国到联盟旅行期间使用的所有场所。

6.

For consignments of high-risk products referred to in Article 8, the relevant control authority or control body shall carry out systematic physical checks and take at least

one representative sample of each consignment. Moreover, the control authority or control body 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, the control authority or control body 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.

第六条 对于第八条所指的高风险产品，相关控制机构或控制主体应进行系统性的物理检查，并从每批货物中至少抽取一个代表性样品。此外，控制机构或控制主体应保存操作员或操作员群体以及产品的可追溯性完整记录，包括运输和商业文件，包括发票。应委员会或成员国主管当局的要求，控制机构或控制主体应将此可追溯性文件以及抽样分析结果发送给进口国的控制机构或控制主体以及验证货物的成员国主管当局。

7.

In case of suspicion of non-compliance, the Commission or the competent authority of a Member State may request the relevant control authority or control body 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.

7. 如怀疑存在不合规情况，委员会或成员国的主管当局可要求相关控制当局或控制机构立即提供所有运营商和所有运营商群体的名单，以及其控制当局或控制机构，这些运营商和运营商群体构成了该批货物所属的有机生产链的一部分。

CHAPTER IV 第四章

OTHER ACTIONS TO BE CARRIED OUT BY THE CONTROL AUTHORITIES AND CONTROL BODIES

其他控制机构和控制部门应采取的措施

Article 17 第十七条

List of operators and other relevant information to be publicly available

运营商及其他相关信息公开列表

The control authority or control body shall make the following information available on its website, in at least one official language of the Union:

控制当局或控制机构应在其网站上提供以下信息，至少使用联盟的一种官方语言：

(a)

a list of certified operators and certified groups of operators, containing:

一份经认证的运营商和经认证的运营商团体名单，包括：

(i)

for operators, their name and address;

对于运营商，其名称和地址；

(ii)

for groups of operators, the name and address of the group and the number of its members;

对于操作员群体，群体的名称和地址以及其成员数量；

(iii)

information relating to the certificates, in particular, the certificate number, category of products covered by the certification, status and validity of certification, including cases of scope reduction, suspension and withdrawal as referred to in ISO standard ISO/IEC 17065;

与证书相关的信息，特别是证书编号、认证覆盖的产品类别、认证状态和有效期，包括根据 ISO 标准 ISO/IEC 17065 所述的范围缩减、暂停和撤回的情况；

(b)

in the case of control bodies, updated information on their accreditation, including a link to the latest accreditation certificate issued by its accreditation body.

关于控制机构，包括其认证机构签发的最新认证证书链接的认证更新信息。

The list referred to in point (a) shall be immediately updated after any change of the status of the certification. In case of withdrawal, the information referred to in point (a)(iii) shall be kept in the list for 5 years after the withdrawal;

该点(a)所指的清单应在认证状态发生任何变更后立即更新。在撤回的情况下，该点(a)(iii)所指的信息应在撤回后保留 5 年。

Article 18 第十八条

Database of operators and groups of operators

运营商和运营商群体数据库

The control authority or control body shall keep an updated electronic database of operators and groups of operators. That database shall include the following information:

控制当局或控制机构应保持一个更新后的操作员和操作员群体的电子数据库。该数据库应包括以下信息：

(a)

name and address of the operators or groups of operators. In case of a group of operators, the size of the group, name and address of each member of the group;
运营商或运营商群体的名称和地址。如为运营商群体，则需提供群体规模、每位成员的名称和地址。

(b)

information concerning the scope of the certification, certificate number, status and validity of the certificate;

关于认证范围、证书编号、证书状态和有效性的信息；

(c)

status of the operators or groups of operators, whether in conversion (including period of conversion) or organic;

运营商或运营商群体状态，无论是否在转换中（包括转换期）或有机状态；

(d)

risk level of the operators or groups of operators in accordance with Article 9;

运营商或运营商群体根据第 9 条的风险等级

(e)

in case of subcontracting activities that are under the control of the certified operators or groups of operators, name and address of the subcontracted third party or third parties;

如涉及受认证操作员或操作员团体控制的分包活动，分包第三方或第三方的名称和地址；

(f)

the geographical coordinates and surface area of all the production units and premises;

所有生产单位和场所的地理坐标和面积；

(g)

inspection reports and the results of sampling analysis, as well as the results of any other controls performed, including the controls carried out on consignments;
检验报告和采样分析结果，以及进行的任何其他控制措施的结果，包括对货物的控制措施；

(h)

non-compliances and measures applied;
不符合项及采取的措施

(i)

notifications via the system referred to in Article 20(1);
系统指称的第 20(1)条中的通知

(j)

derogations granted and relevant supporting documents in accordance with the requirements of this Regulation; and
根据本法规要求授予的豁免和相关的支持文件；

(k)

any other information deemed relevant by the control body or the control authority.
任何控制机构或控制当局认为相关的其他信息。

The information shall be kept by the control authority or control body for 5 years. The control authority or control body shall make that information available to the Commission upon request.

该信息应由控制机构或控制部门保存 5 年。控制机构或控制部门应根据要求将该信息提供给委员会。

Article 19 第 19 条

Information requirements

信息需求

[▼M1 ▲M1](#)

1.

After its recognition, the control authority or control body shall notify the Commission in due time, and not later than within 30 calendar days, of the occurrence of changes to the content of its technical dossier, including the new witness audit reports referred to in Article 3(3a).

1. 在其获得认可后，控制当局或控制机构应在不迟于 30 个日历日内及时通知委员会其技术档案内容变更的情况，包括第 3(3a)条所指的新证人审计报告。

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2.

The control authority or control body shall keep available and communicate at the request of the Commission or the competent authorities of the Member States all information related to its control activities in the third country.

2. 控制当局或控制机构应根据委员会或成员国主管当局的要求，保持所有与其在第三国控制活动相关的信息可用并予以沟通。

3.

The supporting documents relating to the request for recognition under Article 46 of Regulation (EU) 2018/848 and those required under this Regulation shall be kept by the control authorities or control bodies at the disposal of the Commission and the Member States for 5 years following the year in which the controls took place or the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 and documentary evidence were delivered.

3. 根据欧盟条例（EU）2018/848 第 46 条提出的认可请求的相关文件以及本条例要求的文件，应由控制当局或控制机构保留，供委员会和成员国使用，保留期限为 5 年，自控制发生或根据欧盟条例（EU）2018/848 第 45 条第 1 款第（b）（i）点所述证书和文件证据交付的年份起计算。

Article 20 第 20 条

Systems and procedures for the exchange of information

系统和信息交换的程序

1.

The control authority or control body shall use the Organic Farming Information System (OFIS) for the exchange of information with the Commission, with other control authorities and other control bodies, and with the competent authorities of the Member States and of the third countries concerned.

1. 控制当局或控制机构应使用有机农业信息系统（OFIS）与委员会、其他控制当局和其他控制机构，以及成员国和有关第三国的主管部门交换信息。

2.

The control authority or control body shall take the appropriate measures and establish documented procedures to ensure timely exchanges of information with the Commission and with other control authorities and control bodies.

2. 控制当局或控制机构应采取适当措施，并建立书面程序，以确保与委员会以及其他控制当局和控制机构及时交换信息。

3.

Where a document or procedure provided for in Article 46 of Regulation (EU) 2018/848 or in the delegated and implementing acts adopted pursuant to that Article requires the signature of an authorised person or the approval by a person at one or more of the stages of that procedure, the computer systems set up for the communication of those documents shall make it possible to identify each person and guarantee that the integrity of the content of the documents, including as regards the stages of the procedure, cannot be altered, in accordance with Union law, and in particular with Commission Decision 2004/563/EC, Euratom ([5](#)).

第三条 如根据《欧盟条例》（EU）2018/848 第 46 条或根据该条款通过的委托和实施方案规定的文件或程序需要授权人员的签名或该程序一个或多个阶段的批准，为这些文件的通信而建立的计算机系统应使能够识别每个人员，并保证文档内容的完整性，包括程序阶段，根据联盟法律，特别是根据委员会决定 2004/563/EC，Euratom（5），不得更改。

Article 21 条款 21

Exchange of information between the Commission, control authorities, control bodies and competent authorities

欧盟委员会、监管机构、监管机构和有权机构之间的信息交流

1.

The control authority or control body shall immediately share information with the Commission, with other control authorities and control bodies, and with the competent authorities of the Member States and of the third countries concerned on

any suspicion of non-compliance that affects the integrity of organic or in-conversion products.

1. 控制当局或控制机构应立即与委员会、其他控制当局和机构以及相关成员国和第三国的有权当局分享任何涉嫌违反有机或转化产品完整性的怀疑信息。

2.

Where a control authority or control body is notified by the Commission, after the Commission has received a notification from a Member State in accordance with Article 9 of Implementing Regulation (EU) 2021/279 as regards suspected or established non-compliance affecting the integrity of imported organic or in-conversion products, it shall carry out an investigation in accordance with Article 22 of this Regulation. The control authority or control body shall inform the Commission and the Member State that sent the initial notification (notifying Member State), using the template set out in Annex III to this Regulation. The control authority or control body shall reply within 30 calendar days from the date of receiving that notification and shall inform about the actions and measures taken, including the results of the investigation and provide any other information when available and/or required by the notifying Member State.

2. 当控制机构或控制机构收到委员会的通知，且委员会已根据《实施条例》（EU）2021/279 的第 9 条从成员国收到通知，关于涉嫌或已确认的违反进口有机或转化产品完整性的情况时，它应按照本规定的第 22 条进行调查。控制机构或控制机构应使用本规定的附件 III 中规定的模板，通知委员会和发出初始通知的成员国（通知成员国）。控制机构或控制机构应在收到该通知之日起 30 个日历日内回复，并告知采取的行动和措施，包括调查结果，并在有可用信息或根据通知成员国的要求时提供其他信息。

3.

The notified control authority or control body shall provide further necessary information if requested by the notifying Member State.

3. 如果通知成员国要求，通知的控制当局或控制机构应提供进一步必要的信息。

4.

Where operators or groups of operators and/or their subcontractors are subject to controls by different control authorities or control bodies, those control authorities or

control bodies shall exchange the relevant information on the operations covered by their control activities.

4. 当运营商或运营商群体及其分包商受到不同控制当局或控制机构的控制时，这些控制当局或控制机构应交换其控制活动所涵盖的运营的相关信息。

5.

Where operators or groups of operators and/or their subcontractors change their control authority or control body, the new control authority or control body shall request the control file of the operator or group of operators concerned from the previous control authority or control body. The previous control authority or control body shall, within 30 days, provide to the new control authority or control body the control file of the operator or group of operators concerned and the written records referred to in Article 14, the status of the certification, the list of non-compliances and the corresponding measures taken by the previous control authority or control body.

5. 当操作员或操作员群体及其分包商更改其控制权限或控制机构时，新的控制权限或控制机构应从先前控制权限或控制机构请求相关操作员或操作员群体的控制文件。先前控制权限或控制机构应在 30 天内向新的控制权限或控制机构提供相关操作员或操作员群体的控制文件、第 14 条所指的书面记录、认证状态、不合格清单以及先前控制权限或控制机构采取的相应措施。

The new control authority or control body shall ensure that non-compliances noted in the report of the previous control authority or control body have been addressed by the operators or groups of operators.

新的控制当局或控制机构应确保之前控制当局或控制机构报告中指出的不符合规定的问题已由运营商或运营商群体解决。

6.

Where operators or groups of operators are subject to a traceability check and a mass balance check, control authorities and control bodies shall exchange the relevant information allowing finalisation of these checks.

6. 当操作员或操作员群体需要接受可追溯性检查和质量平衡检查时，控制当局和控制机构应交换相关信息，以便完成这些检查。

Article 22 条款 22

Additional rules on actions to be taken in case of non-compliance

额外关于不遵守情况下的行动规则

1.

In addition to the measures referred to in Article 29(1), (2) and (3) of Regulation (EU) 2018/848 and Article 2 of Implementing Regulation (EU) 2021/279, where a control authority or control body suspects or receives substantiated information, including information from other control authorities or control bodies, that a product, which may not be in compliance with Regulation (EU) 2018/848, is intended to be imported from a third country for the purpose of placing that product on the market within the Union, but which bears terms referring to the organic production, or where such a control authority or control body has been informed by an operator of a suspicion of non-compliance in accordance with Article 27 of that Regulation:

(a)

it shall immediately carry out an investigation with a view to verifying compliance with Regulation (EU) 2018/848 or with the delegated or implementing acts adopted pursuant to that 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;

应立即进行调查，以核实是否符合《欧盟条例》（EU）2018/848 或根据该条例通过的委托或实施法案；此类调查应尽快完成，在合理期限内完成，并应考虑产品的耐用性和案件复杂性；

(b)

it shall prohibit the import from that third country for the purpose of placing the product concerned on the market within the Union as organic or in-conversion product pending the results of the investigation referred to in point (a). Before taking such a provisional decision, the control authority or control body, shall give the operator or group of operators an opportunity to comment.

应禁止从该第三国进口，目的是在调查（a）点所述的调查结果出来之前，将相关产品作为有机产品或转换产品投放欧盟市场。在作出此类临时决定之前，控制当局或控制机构应给予操作员或操作员群体发表意见的机会。

1. 除《欧盟条例》（EU）2018/848 第 29（1）、（2）和（3）条及《实施条例》（EU）2021/279 第 2 条所指的措施外，当监管机构或监管机构收到包括来自其他监管机构或监管机构的信息在内的充分信息，怀疑或得知一个可能不符合《欧盟条例》

(EU) 2018/848 的产品打算从第三国进口，以便在联盟内投放市场，或者当此类监管机构或监管机构根据该条例第 27 条被操作者告知存在不合规的怀疑时：

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, those products shall be allowed to be used and labelled as organic or in-conversion products.

2. 如果第 1 段第 (a) 点所指调查的结果未显示任何影响有机或转化产品完整性的不合规情况，则允许使用并标注这些产品为有机或转化产品。

3.

The control authority or control body shall develop a catalogue of measures to be taken in case of established non-compliance. That catalogue of measures shall be based on the elements specified in Annex IV to this Regulation and shall cover at least:

(a)

a list of non-compliances with reference to the specific rules of Regulation (EU) 2018/848 or of the delegated or implementing acts adopted pursuant to that Regulation. That list shall include, at least the non-compliances listed in Part B of Annex IV to this Regulation;

不符合《欧盟条例》(EU) 2018/848 的具体规则或根据该条例通过的委托或执行性法规的清单。该清单至少应包括本条例附件 IV 第二部分列出的不符合规定的情况。

(b)

the classification of the non-compliances into three categories: minor, major and critical as set out in Part A of Annex IV to this Regulation, taking into account at least the following criteria:

该法规附件 IV A 部分规定的非合规性分为三类：轻微、主要和严重，至少考虑以下标准：

(i)

the application of precautionary measures referred to in Article 28(1) of Regulation (EU) 2018/848, the practical measures referred in point (a)(ii) of Article 10(1) of this Regulation and the reliability of own controls carried out by the operator or group of operators in line with point (f) of Article 11(1) of this Regulation;

关于《欧盟条例》（EU）2018/848 第 28(1)条所指预防措施的适用，本条例第 10(1)条第(a)(ii)点所指的实际行动，以及运营商或运营商集团根据本条例第 11(1)条第(f)点实施的自身控制的可靠性；

(ii)

the impact on the integrity of the organic or in-conversion of products;
对产品有机或转化完整性的影响；

(iii)

the ability of the traceability system to locate the affected product(s) in the supply chain and prohibition of importing from a third country for the purpose of placing the product(s) on the market within the Union with reference to organic production;
追溯系统定位受影响产品（们）在供应链中的能力以及禁止从第三国进口以在联盟市场投放产品（们）的有机生产相关禁令

(iv)

the response of the operator or group of operators to previous requests from the control authority or control body;
操作员或操作员群体的对控制当局或控制机构的先前请求的回应

(c)

the measures to be applied for each non-compliance.
各项不合规应采取的措施。

3. 控制当局或控制机构应制定一份在确定存在不合规情况时应采取的措施清单。该措施清单应基于本法规附件 IV 中规定的要素，并至少包括：

4.

The control authority or control body shall document the results of the investigations referred to in point (a) of Article 29(1) of Regulation (EU) 2018/848.

4. 控制当局或控制机构应记录《欧盟条例》（EU）2018/848 第 29(1)款第(a)项所指调查的结果。

Article 23 条款 23

Additional rules on measures in the event of non-compliance

关于不遵守情况下的额外措施规则

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 a result of the use of non-authorised products, substances or techniques, or commingling with non-organic products, the control authority or control body shall ensure, in addition to the measures to be taken in accordance with paragraphs 2 and 3 of this Article, that no reference is made to organic production as set out in Chapter IV of Regulation (EU) 2018/848, in the labelling and advertising of the entire lot or production run of the product intended to be imported from a third country for the purpose of placing that product on the market within the Union.

1. 在生产、准备和分销的任何阶段，如果不符合规定影响了有机或转换产品的一致性，例如由于使用未经授权的产品、物质或技术，或与非有机产品混合，控制机构或控制机构应确保，除按照本条第二款和第三款采取的措施外，在标签和广告中不得提及根据《欧盟条例》（EU）2018/848 第 IV 章规定的有机生产，对于打算在联盟市场上市的产品，不得提及从第三国进口的整个批次或生产批次。

2.

Where the non-compliance is established, the control authority or control body shall:

(a)

take any action necessary to determine the origin and extent of the non-compliance and to establish the responsibilities of the operator or group of operators; and
采取任何必要措施，以确定不合规的来源和范围，并确立运营商或运营商群体的责任；

(b)

take appropriate measures to ensure that the operator or group of operators remedies the non-compliance and prevents further occurrences of such non-compliance.

采取适当措施确保运营商或运营商群体纠正违规行为并防止此类违规行为再次发生。

When deciding which measures to take, the control authority or control body shall take account of the nature of that non-compliance and the past record of the operator or of the group of operators with regard to compliance.

在决定采取哪些措施时，控制当局或控制机构应考虑该不合规的性质以及操作员或操作员群体在合规方面的过往记录。

2. 在非合规性得到确认的情况下，控制当局或控制机构应：

3.

When acting in accordance with paragraph 2 of this Article, the control authority or control body shall take any measure it deems appropriate to ensure compliance with Regulation (EU) 2018/848 and the delegated and implementing acts adopted pursuant that Regulation, including:

(a)

applying the catalogue of measures referred to in Article 22(3) of this Regulation;
适用本法规第 22(3)条所指的措施目录;

(b)

ensuring that the operator or group of operators increases the frequency of own controls;
确保操作员或操作员群体增加自身控制的频率;

(c)

ensuring that certain activities of the operator or of the group of operators are subject to increased or systematic controls by the control authority or control body.
确保运营商或运营商群体的某些活动受到控制机构或控制机构的增加或系统控制的约束。

3. 在根据本条第二款行事时，控制当局或控制机构应采取其认为适当的任何措施，以确保遵守条例（EU）2018/848 以及根据该条例通过的委托和实施法案，包括：

4.

In the event of serious, or repetitive or continued non-compliance, the control authority or control body shall ensure that the operator or group of operators, in addition to the measures laid down in paragraphs 2 and 3, is prohibited from placing on the market within the Union for a given period products which refer to organic production, and that its certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 be suspended or withdrawn, as appropriate.

4. 在发生严重、重复或持续不遵守规定的情况下，控制当局或控制机构应确保操作员或操作员群体，除第 2 段和第 3 段规定的措施外，在一定期限内不得将指明有机生产的产品投放欧盟市场，并且应根据《欧盟条例》（EU）2018/848 第 45(1)条(b)(i)点，暂停或撤销其证书。

5.

The control authority or control body shall provide the operator or group of operators with a written notification of its decision concerning the action or measure to be taken in accordance with this Article, together with the reasons for that decision.

第五条 控制当局或控制机构应向运营商或运营商群体提供书面通知，说明根据本条采取的行动或措施及其决定理由。

Article 24 第 24 条

Checks to be carried out for the purpose of the retroactive recognition of a previous period

进行追溯承认先前期间的检查

1.

Before granting retroactive recognition of a previous period as part of the conversion period for the purposes of point (b) of Article 10(3) of Regulation (EU) 2018/848, the control authority or control body shall ensure that the operator submits the following documents proving that the land parcels were natural or agricultural areas that, for a period of at least 3 years, have not been treated or have not been contaminated with products or substances that are not authorised for use in organic production in accordance with Regulation (EU) 2018/848:

(a)

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 ongoing production and their geolocation coordinates;

地图清晰标识出请求追溯认可覆盖的每一块土地，以及这些土地的总面积，如适用，还包括正在生产的生产性质和数量及其地理坐标；

(b)

any other relevant documents deemed necessary by the control authority or control body to assess the request for retroactive recognition.

任何控制当局或控制机构认为必要的其他相关文件，以评估对追溯承认的请求。

1. 在根据《欧盟条例》（EU）2018/848 第 10(3)条 b 项的目的，将先前时期作为转换期的一部分进行追溯认可之前，控制机构或控制机构应确保运营商提交以下文件，以证明地块为自然或农业区域，且至少 3 年内未进行过处理或未受到《欧盟条例》（EU）2018/848 未授权用于有机生产的物质或产品的污染：

2.

In addition, the control authority or control body shall take the following steps:

(a)

it shall carry out a detailed risk analysis based on documentary evidence 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 3 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. The control authority or control body shall keep documents on the risk analysis;

应基于文件证据进行详细的风险分析，以评估请求追溯认可的土地地块是否在至少 3 年的期限内使用过未经授权用于有机生产的物质或产品，特别是考虑到与请求相关的总面积以及在该期间内每个受请求地块上实施的农艺实践。控制当局或控制机构应保留风险分析的相关文件。

(b)

it shall take samples on soil and/or plant from each land parcel in line with the results of the risk analysis referred to in point (a), including those land parcels identified as presenting the risk of being contaminated;

应对每个地块的土壤和/或植物进行采样，符合关于（a）点所述的风险分析结果，包括那些被认定为存在污染风险的地块

(c)

it shall draw up an inspection report in one of the official languages of the Union, including photographs of the parcels, following a physical inspection of the operator, including the land parcels covered by the request for retroactive recognition for the purpose of verifying the consistency of the information collected, but before any cultivation measures have been taken by the operator.

应使用联盟的官方语言之一编制一份检查报告，包括包裹的照片，在对运营商进行物理检查后进行，包括请求追溯认可的土地地块，以验证收集到的信息的准确性，但在运营商采取任何耕作措施之前。

2. 此外，控制当局或控制机构应采取以下措施：

3.

Based on the information provided by the operator in accordance with paragraph 1 and after having completed the steps set out in paragraph 2, the control authority or

control body shall draw up a final written report. The final written report shall include a justification why the previous period can be recognised retroactively as part of the conversion period. This final written report shall also indicate the starting period considered as organic for each land parcel concerned as well as the total surface of the land parcels benefiting from this retroactive recognition of a period.

3. 根据操作员根据第 1 段提供的信息，并在完成第 2 段规定的步骤后，控制当局或控制机构应编制一份最终书面报告。最终书面报告应包括说明为什么前一时期可以追溯性地认定为转换期的一部分的理由。这份最终书面报告还应指明每个相关地块被视为有机的起始期，以及从这一追溯性认定的时期中受益的土地地块的总面积。

4.

The control authority or control body shall immediately notify the Commission, the Member States and in case of a control body its accreditation body of any retroactive recognition granted. For each retroactive recognition granted, the control authority or control body shall provide the final written report referred to in paragraph 3.

4. 控制当局或控制机构应立即通知委员会、成员国，并在控制机构的情况下，通知其认证机构任何给予的追溯性认可。对于每个给予的追溯性认可，控制当局或控制机构应提供第 3 段中提到的最终书面报告。

5.

The control authority or control body shall ensure that the operator to whom the granted retroactive recognition applies keeps documentary evidence relating to that recognition, as well as documentary evidence on the use of the land parcels covered by that recognition, for 3 years.

5. 控制当局或控制机构应确保获得追溯承认的运营商保存与该承认相关的文件证据，以及与该承认覆盖的土地地块使用相关的文件证据，保存期限为 3 年。

Article 25 第 25 条

Authorisations for the use of non-organic plant reproductive material

非有机植物繁殖材料的使用许可

1.

Before granting authorisations for the use of non-organic plant reproductive material as set out in point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848, the

control authority or control body shall assess the following information and draw up a justification for each derogation granted:

(a)

scientific and common name (common and Latin name);

科学名和普通名（普通名和拉丁名）；

(b)

variety; 多样性

(c)

total weight of seeds or number of plants concerned;

种子总重量或相关植物数量

(d)

the availability of organic or in-conversion plant reproductive material;

有机或转化植物繁殖材料的可获得性；

(e)

documentation or a statement from the operator proving that the requirements set out in point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848 have been fulfilled.

文件或运营商的声明，证明已满足《欧盟法规（EU）2018/848》附件 II 第一部分第 1.8.5.2 点规定的各项要求。

1. 在根据《欧盟条例》（EU）2018/848 附件 II 第一部分第 1.8.5.2 点规定授权使用非有机植物繁殖材料之前，控制机构或控制部门应评估以下信息，并为每个批准的豁免制定理由：

2.

For each authorisation for the use of non-organic plant reproductive material as set out in point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848, the control authority or control body shall include the relevant information in the annual report referred to in Article 4 of this Regulation.

2. 对于《欧盟法规（EU）2018/848》附件 II 第一部分第 1.8.5.2 点规定的非有机植物繁殖材料使用许可，控制机构或控制部门应将相关信息纳入本法规第 4 条所指的年度报告中。

Article 26 条款 26

Derogations as regards the use of non-organic animals and aquaculture juveniles

关于非有机动物和水产养殖幼体的使用豁免

1.

Before granting derogations as regards the use of non-organic livestock species (bovine, equine, ovine, caprine, porcine and cervine animals, rabbits, and poultry) in accordance with points 1.3.4.3 and 1.3.4.4 of Part II of Annex II to Regulation (EU) 2018/848, the control authority or control body shall assess the following information and draw up a justification for each derogation:

(a)

scientific and common name (common and Latin name, i.e. species and genus);
科学名和普通名（普通名和拉丁名，即物种和属名）；

(b)

breeds and strains; 品种和品系

(c)

production purposes: meat, milk, eggs, dual purpose or breeding;
生产目的：肉类、牛奶、蛋类、双重用途或繁殖

(d)

total number of animals;
动物总数

(e)

availability of the relevant organic livestock species;
相关有机畜禽物种的可用性

(f)

documentation or a statement from the operator proving that the requirements set out in point 1.3.4.3 and 1.3.4.4 of Part II of Annex II to Regulation (EU) 2018/848 have been fulfilled.

文件或运营商的声明，证明已满足《欧盟法规（EU）2018/848》附件 II 第二部分第 1.3.4.3 点和 1.3.4.4 点规定的各项要求。

1. 在根据《欧盟条例》（EU）2018/848 附件 II 第二部分第 1.3.4.3 点和第 1.3.4.4

点授予非有机牲畜物种（牛、马、羊、山羊、猪、鹿类动物、兔子和小型家禽）使用豁免之前，控制机构或控制部门应评估以下信息并为每个豁免制定理由：

2.

For each non-organic livestock species (bovine, equine, ovine, caprine, porcine and cervine animals, rabbits, and poultry), the control authority or control body shall include the relevant information on the derogations granted in accordance with points 1.3.4.3 and 1.3.4.4 of Part II of Annex II to Regulation (EU) 2018/848 in the annual report referred to in Article 4 of this Regulation.

2. 对于每种非有机牲畜物种（牛、马、羊、山羊、猪、鹿类动物、兔子以及家禽），控制当局或控制机构应在其年度报告中包含根据《欧盟条例》（EU）2018/848 附件 II 第二部分第 1.3.4.3 点和第 1.3.4.4 点授予的豁免的相关信息，该报告如本法规第 4 条所述。

3.

Before granting derogations as regards the use of non-organic aquaculture juveniles in accordance with point 3.1.2.1 of Part III of Annex II to Regulation (EU) 2018/848, the control authority or control body shall assess the following information and draw up a justification for each derogation:

(a)

species and genus (common and Latin name);

物种和属（普通名和拉丁名）

(b)

breeds and strains when applicable;

品种和品系（如适用）；

(c)

life stage (such as eggs, fry, juveniles) as available for sale as organic;

生命阶段（如卵、鱼苗、幼鱼）可作为有机产品销售

(d)

quantity available as estimated by the operator;

可供操作员估算的数量；

(e)

total number of juveniles;

总幼仔数量

(f)

availability of the relevant organic aquaculture species;

相关有机水产养殖物种的可用性

(g)

documentation or a statement from the operator proving that the requirements set out in point 3.1.2.1 of Part III of Annex II to Regulation (EU) 2018/848 have been fulfilled.

文件或运营商的声明，证明已满足《欧盟条例》（EU）2018/848 附件 II 第三部分第 3.1.2.1 点规定的各项要求。

3. 在根据《欧盟条例》（EU）2018/848 附件 II 第三部分第 3.1.2.1 点授予非有机水产养殖幼体使用豁免之前，控制机构或控制部门应评估以下信息并为每个豁免制定理由：

4.

For each derogation granted as regards the use of non-organic aquaculture juveniles in accordance with point 3.1.2.1 of Part III of Annex II to Regulation (EU) 2018/848, the control authority or control body shall include the relevant information in the annual report referred to in Article 4 of this Regulation.

4. 对于根据《欧盟条例》（EU）2018/848 附件 II 第三部分第 3.1.2.1 点授予的关于使用非有机水产养殖幼体的每一项豁免，控制机构或控制部门应将相关信息纳入本法规第 4 条所指的年度报告中。

Article 27 条款 27

Reporting on provisional authorisation for the use of non-organic agricultural ingredients for processed organic food

关于使用非有机农业成分加工有机食品的临时授权报告

The control authority or control body shall immediately notify the Commission, the Member States, accreditation bodies and other control authorities and control bodies recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 of any provisional authorisation granted for the use of non-organic agricultural ingredients for processed organic food in accordance with Article 25(4) of that Regulation. That notification shall include the justification, presented in the dedicated form made

available by the Commission, that such authorisation has been granted in accordance with Article 25(1) of Regulation (EU) 2018/848.

控制当局或控制机构应立即通知委员会、成员国、认证机构和根据《欧盟条例》

(EU) 2018/848 第 46(1)条认可的任何其他控制当局和控制机构，关于根据该条例第 25(4)条授予的用于加工有机食品的非有机农业成分的临时授权。该通知应包括由委员会提供的专用表格中呈现的理由，即根据《欧盟条例》(EU) 2018/848 第 25(1)条已授予此类授权。

CHAPTER V 第五章

DEROGATIONS FROM REGULATION (EU) 2018/848 IN CATASTROPHIC CIRCUMSTANCES

《在灾难性情况下对（欧盟）2018/848 号法规的豁免》

Article 28 条款 28

Recognition of catastrophic circumstances

承认灾难性情况

For the purposes of the exceptional production rules referred to in Articles 22(1) and 45(3) of Regulation (EU) 2018/848, in order for a situation to qualify as catastrophic circumstances deriving from an ‘adverse climatic event’, ‘animal diseases’, an ‘environmental incident’, a ‘natural disaster’ or a ‘catastrophic event’, as well as any comparable situation, the control authority or control body may recognise a situation as catastrophic circumstances based on a statement issued by the relevant authorities of the third country in which the situation occurs, where available. If such a statement is not available, any such recognition by the control authority or control body shall be based on data provided by official organisations justifying the catastrophic circumstances.

为了适用《欧盟条例》(EU) 2018/848 第 22(1)条和第 45(3)条所述的特别生产规则，如果一个情况符合由“不利气候事件”、“动物疾病”、“环境事件”、“自然灾害”或“灾难性事件”引起的“灾难性情况”，以及任何类似情况，控制机构或控制机构可以根据发生该情况第三国相关当局发布的声明，如果有的话，将该情况认定为灾难性情况。如果此类声明不可用，控制机构或控制机构对该情况的任何此类认定应基于官方组织提供的数据，以证明灾难性情况。

Article 29 条款 29

Conditions for derogations

豁免条件

1.

Following the recognition referred to in Article 28, a control authority or control body may, upon identification of the operators affected in the area concerned or upon request from the individual operator or the member of the group of operators concerned, grant the relevant derogations set out in Article 3 of Delegated Regulation (EU) 2020/2146 and the conditions related thereto, provided that those derogations and conditions apply:

(a)

for a limited period and no longer than necessary, and in no case longer than 12 months, to continue or recommence organic production as carried out before the date of application of those derogations;

在有限的时间内，且不超过必要的期限，在任何情况下不超过 12 个月，继续或恢复在那些豁免措施申请日期之前进行的有机生产；

(b)

in relation to specifically affected types of production or, where relevant, land parcels; and

关于具体受影响的生产品类或，如适用，土地地块；

(c)

to the individual operator or the member of the group of operators concerned.

致相关运营商个人或运营商组成员。

1. 根据第 28 条所指的认可，控制当局或控制机构在确定受影响区域内的运营商或应相关运营商或运营商群体成员的请求后，可授予《欧盟委托法规（EU）2020/2146》第 3 条规定的相关豁免以及相关的条件，前提是这些豁免和条件适用：

2.

The application of the derogations referred to in paragraph 1 shall be without prejudice to the validity of the certificates referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848 during the period where the derogations apply, provided that the operator or operators concerned fulfil the conditions under which derogations were granted.

2. 在适用豁免期间，对第 1 段所述豁免的应用，不应损害《欧盟条例》（EU）2018/848 第 45(1)条(b)(i)点所述证书的有效性，前提是相关运营商满足授予豁免的条件。

3.

Control authorities and control bodies shall immediately notify the Commission, the Member States and, in case of a control body their accreditation body, of the derogations granted by them pursuant to this Regulation via the system referred to in Article 20(1). In particular, the control authority or control body shall indicate the name of the operator or operators concerned, the time period for the derogation, the type of production or, where relevant, land parcels, the justification for the derogation and include a statement from the relevant authority of the third country as referred to in Article 28. Where such a statement is not available, the control authority or control body shall justify the non-inclusion of such a statement and provide the relevant data on which the recognition is based.

3. 控制当局和控制机构应立即通过第 20(1)条所述系统通知委员会、成员国以及，在控制机构的情况下，其认证机构，根据本法规授予的豁免。特别是，控制当局或控制机构应指明相关运营商或运营商的姓名、豁免的时间段、生产类型或相关情况下，土地地块、豁免的正当理由，并包括第 28 条所述第三国相关当局的声明。如果此类声明不可用，控制当局或控制机构应说明不包含此类声明的理由，并提供基于该认可的相关数据。

4.

The control authority or control body shall ensure that any operator to whom the granted derogations apply keep documentary evidence relating to the granted derogations as well as documentary evidence on the use of those derogations during the period where those derogations apply. The control authority or control body shall verify the compliance of the operator or operators with the conditions of the granted derogations.

4. 控制当局或控制机构应确保任何受授予豁免的运营商在豁免期间保存有关授予豁免的文件证据以及使用这些豁免的文件证据。控制当局或控制机构应核实运营商或运营商是否符合授予豁免的条件。

CHAPTER VI 第六章

GENERAL AND FINAL PROVISIONS

一般和最终条款

Article 30 条款 30

References to competent authorities and Member States in Annex II to Regulation (EU) 2018/848

参考文献中提及的合格当局和成员国，在欧盟法规（EU）2018/848 的附件 II 中

1.

References to competent authorities in the following points of Annex II to Regulation (EU) 2018/848 shall be read as referring to control authorities and control bodies recognised in accordance with Article 46(1) of that Regulation:

(a)

point 1.7.2 and the first paragraph of point 1.7.3 of Part I;
第 1.7.2 点以及第一段第 1.7.3 点（第一部分）；

(b)

points 1.3.4.3, 1.3.4.4.3, 1.6.7, 1.7.5, 1.7.8, 1.9.3.1, 1.9.4.1 and 1.9.4.2 of Part II;
第 II 部分第 1.3.4.3 点、第 1.3.4.4.3 点、第 1.6.7 点、第 1.7.5 点、第 1.7.8 点、第 1.9.3.1 点、第 1.9.4.1 点和第 1.9.4.2 点；

(c)

points 3.1.2.1 and 3.1.3.1 of Part III.
第 3.1.2.1 和 3.1.3.1 点（第三部分）。

The information referred to in point 1.9.4.1 of Part II shall be sent to the Commission only.

相关信息仅应发送至委员会。

1. 在《欧盟条例》（EU）2018/848 附件 II 的以下各点中，对有权机构的提及应理解为指根据该条例第 46(1)条认可的监管机构和监管机构。

2.

The reference to Member States in point 1.9.4.4(c) of Part II of Annex II to Regulation (EU) 2018/848 shall be read as referring to control authorities and control bodies recognised in accordance with Article 46(1) of that Regulation.

2. 应将《欧盟条例》（EU）2018/848 附件 II 第二部分第 1.9.4.4(c) 点中提到的成员国理解为根据该条例第 46(1)条认可的监管机构和监管机构。

Article 31 条款 31

Entry into force and application

生效和适用

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

本法规自公布于欧盟官方公报之日起第二十天生效。

It shall apply from 1 January 2022.

自 2022 年 1 月 1 日起适用。

This Regulation shall be binding in its entirety and directly applicable in all Member States.

本法规应在其全部内容上对所有成员国具有约束力，并直接适用于所有成员国。

ANNEX I 附件 I

Content of the assessment report referred to in Article 1(2)(i)

评估报告的内容，如第 1(2)(i)条所述

PART A 第一部分

An assessment report referred to in point (i) of Article 1(2) shall consist of a document and record review report, an on-site assessment report and a witness audit report, and may contain any other information deemed necessary by the accreditation body or competent authority.

第 1 条第 2 款第(i)项所指的评估报告应包括一份文件和记录审查报告、现场评估报告和见证审计报告，并可包含认证机构或主管当局认为必要的任何其他信息。

1. *Document and record review report*

1. 文档和记录审查报告

The document and record review report shall contain the following elements:

文件和记录审查报告应包含以下要素：

1.1.

Assessment of the following:

以下评估：

(a)

the structure and size;

结构和尺寸；

(b)

IT management system; IT 管理系统

(c)

branch offices; 分支机构

(d)

type of activities, including subcontracting activities other than inspection and sampling;

活动类型，包括除检验和抽样外的分包活动；

(e)

organisational chart; 组织结构图

(f)

quality management; 质量管理;

1.2.

Assessment of the procedures for the exchanges of information between headquarter and branch offices, and subcontracted laboratories, as well as with the Commission, Member States, other control authorities and other control bodies;
对总部与分支机构、分包实验室以及与委员会、成员国、其他监管机构和其他监管机构之间信息交换程序的评估;

1.3.

Assessment of the knowledge and qualification of the staff as regards Union legislation on organic production rules and controls;
对员工关于欧盟有机生产规则和控制立法的知识和资格的评估

1.4.

Verification that the language regime chosen and the documents issued by the control authority or control body are understandable for the contracted operators or groups of operators, in particular internal procedures for the staff involved in the certification process or in the controls;
验证所选的语言制度以及控制当局或控制机构发布的文件对合同运营商或运营商群体是可理解的，特别是涉及认证过程或控制的员工内部程序

1.5.

Assessment of the continuous training programmes, and effective monitoring by the control authority or control body of the competencies acquired during the trainings;
对持续培训计划的评估，以及控制机构或控制主体对培训期间获得的能力的有效监控

1.6.

Assessment of the experience and the competency of the staff on the category(ies) of products as set out in Article 35(7) of Regulation (EU) 2018/848 subject to the controls and in each third country covered by the recognition, including the employment status of inspectors concerned and their contractual relationship with the control body;
对根据《欧盟条例》（EU）2018/848 第 35(7)条规定的产品类别（类别）中工作人员的经验 and 能力进行评估，受控制措施和每个受认可第三国的影响，包括相关检查员的就业状况及其与控制机构的合同关系；

1.7.

Assessment of the internal procedures related to the control activities in respect of operators and groups of operators, if any, and the specific skills and training required for the inspectors of the control authority or control body controlling the system for internal controls of groups of operators;

评估与操作员和操作员群体相关的控制活动内部程序（如有），以及控制当局或控制该系统内部控制的操作员群体的检查员所需的具体技能和培训

1.8.

A description and an evaluation of the performance of the control system to be put in place for each third country, including where relevant, control specificities for groups of operators;

对每个第三国将要实施的控制系统性能的描述和评估，包括相关情况下针对运营商群体的控制具体性

1.9.

Any other information deemed necessary by the accreditation body.

任何认证机构认为必要的其他信息。

2. *On-site assessment report*

2. 现场评估报告

An on-site assessment report by the accreditation body or, as appropriate, by the competent authority, shall contain the following elements:

现场评估报告应由认证机构或，如适用，由主管当局编制，应包含以下要素：

2.1.

An assessment report of the office(s) where certification decisions are taken, containing the following information:

办公室（们）进行认证决策的评估报告，包含以下信息：

(a)

result of the checking of files of all categories of products as set out in Article 35(7) of Regulation (EU) 2018/848 for which recognition is requested, and confirmation that the control body has correctly implemented the requirements on controls in respect of operators and groups of operators as set out in Chapter III of this Regulation and in particular Articles 9 and 10;

检查所有类别产品文件的结果，这些产品文件如《欧盟条例》（EU）2018/848 第

35(7)条所述，且请求承认，以及确认监管机构已正确实施本法规第三章所述，特别是第 9 条和第 10 条关于操作者和操作者群体控制要求

(b)

evaluation of the catalogue of measures to be taken in case of established non-compliance;

对已确立的不合规情况下应采取的措施目录进行评估

(c)

evaluation of the risk analysis procedures for the purpose of the inspections, including inspections without prior notice;

风险评估程序的评估，包括无事先通知的检查

(d)

evaluation of the sampling strategy, procedure and methodology;

评估抽样策略、程序和方法

(e)

evaluation of the communication with the Commission and other control authorities and other control bodies;

对与委员会和其他监管机构以及其他监管机构的沟通进行评估；

(f)

conclusions from interviews with control and certification staff regarding their performance and competency on certification and control tasks;

结论来自对控制和认证人员关于他们在认证和控制任务中的表现和能力的访谈

(g)

confirmation that the control authority or control body has the means to implement the control system in line with this Regulation in each third country for which it requests recognition, in particular sufficient inspectors to carry out any physical checks at any stage of production, preparation and distribution, as appropriate, based on their risk assessment, additional inspections or samplings and documents in languages that are understandable by the contracted operators, when these documents are intended for operators or groups of operators;

确认控制当局或控制机构有实施本法规所要求的控制系统的手段，针对其请求承认的每个第三国，特别是有足够的检查员在任何生产、准备和分销阶段进行适当的物理检查，基于其风险评估，进行额外检查或抽样，以及以合同运营商可理解的语言编写的文件，当这些文件是为运营商或运营商群体准备的时；

(h)

confirmation of the capacity and competencies of the control authority or control body to perform its tasks for each third country for which it requests recognition, taking into account, in particular, the expected number of operators or members of the group of operators, volume of exported products, nature and origin of products, including evaluation of operators and inspectors files.

确认控制机构或控制主体执行其任务的能力和资质，针对其请求承认的每个第三国，特别是考虑到操作员或操作员群体的预期数量、出口产品量、产品性质和来源，包括对操作员和检查员档案的评估。

2.2.

A witness audit report, resulting from a witness audit carried out in accordance with Part B, containing the following elements:

证人审计报告，根据 B 部分进行的证人审计结果，包含以下要素：

(a)

the name of the operator, the audited inspector and the accreditation body's assessor;

运营商名称、审核检查员和认证机构评估员；

(b)

general information about the witness audit such as venue, time, audit plan or parties, and the operator's or group of operators' experience with regard to organic production rules;

关于证人审计的一般信息，例如地点、时间、审计计划或各方，以及操作员或操作员组的有机生产规则经验；

(c)

scope of inspection; 检查范围

(d)

inspector preparation and knowledge, such as planning of work, working instructions, documents and material made available to the inspector, knowledge of the inspector on the relevant category of products, evaluation of the robustness of the organic system plan of the operator or the system of internal control of the group of operators, checking of conflicts of interest, knowledge on Regulation (EU) 2018/848, knowledge of the internal procedures of its control body as regard the functioning or the implementation of the control system and certification process;

检查员准备和知识，例如工作计划、工作指导、提供给检查员的文件和材料，检查员对相关产品类别的了解，评估运营商或运营商群体的有机系统计划或内部控制系统的稳健性，检查利益冲突，对法规（EU）2018/848 的了解，对其控制机构内部程序的了解，关于控制系统的运作或实施以及认证程序的知识；

(e)

inspector performance, such as relevance of the duration of the inspection, evaluation of the interview, verification of previous non-compliances, collection of relevant information, authority and analytical skills, conversation and questioning technique, effective language skills, knowledge of the local agricultural conditions and agricultural practices, processing practices in that country and social skills;
检查员表现，例如检查持续时间的相关性、面试评估、以前不合规的核实、收集相关信息、权威性和分析技能、对话和提问技巧、有效的语言技能、对当地农业条件和农业实践的了解、该国加工实践和社会技能；

(f)

quality of the physical inspection of the facility/holding/unit such as methodology and quality of the inspection check list used, information provided by the operator in the organic system plan, robustness of the mass balance and traceability checks, the methodology used for the sampling and the inspection of critical areas;
设施/养殖场/单元的物理检查质量，例如检查清单的方法和质量，有机系统计划中操作员提供的信息，质量平衡和可追溯性检查的稳健性，采样和关键区域检查所采用的方法；

(g)

findings, status of the non-compliances detected and corrective measures applied;
发现结果、未遵守状况及采取的纠正措施

(h)

evaluation of the non-compliances identified by the accreditation body's assessor but not detected by the inspector;
对认证机构评估员识别但未由检查员发现的非合规性进行评估；

(i)

quality and completeness of the exit interview conducted;
离职面谈的质量和完整性

(j)

overall assessment of the effectiveness of the inspection;

总体评估检查的有效性

(k)

list of non-compliances detected, description and time line for the corrective measures to be carried out by the control authority or control body to solve them;

检测到的非合规清单，控制机构或控制主体为解决这些问题而采取的纠正措施描述和时间表；

(l)

in the case of a group of operators, a specific section providing a description and evaluation of the effectiveness of the system for internal controls; and

在运营商群体的情况下，一个特定部分提供对内部控制系统有效性的描述和评估；

(m)

an overall assessment of the capacity and reliability of the control authority or control body for performing the certification activities, taking into account the outcome of the assessment performed in accordance with section 2.1. Any other information deemed necessary by the accreditation body or competent authority, including for instance, reports and conclusions of additional witness audits.

对控制机构或控制主体执行认证活动的能力和可靠性的总体评估，考虑到根据第 2.1 节进行的评估结果。包括认证机构或有权机构认为必要的任何其他信息，例如额外见证审计的报告和结论。

PART B 第二部分

1. The witness audit referred to in point 2.2 of Part A shall be:

1. 本部分 A 第 2.2 点所指的见证审核应：

(a)

carried out by the accreditation body or, as appropriate, the competent authority;

由认证机构或，如适用，主管当局执行；

(b)

based on a risk analysis and shall document the whole activity under witness;

基于风险评估，并应在见证人面前记录整个活动

(c)

carried out physically and may only be carried out remotely if so decided by the Commission.

执行物理操作，并且只有在委员会决定的情况下才能远程执行。

2. In addition to Section 1, the witness audit shall be carried out:

2. 除了第 1 节外，还应进行证人审计：

(a)

for each category of products as set out in Article 35(7) of Regulation (EU) 2018/848 for which the recognition is requested. All non-compliances detected by the accreditation body or competent authority shall be fully addressed by the control authority or control body respectively, and confirmed by the accreditation body or competent authority;

对于根据《欧盟条例》（EU）2018/848 第 35(7)条规定的每一类产品，对于其认可请求。认证机构或主管当局发现的全部不符合项应由控制机构或控制部门分别全面解决，并由认证机构或主管当局确认。

(b)

for each category of products in a different third country, if the control authority or control body requests or is already recognised for more than one third country; and 对于不同第三国的每个产品类别，如果控制机构或控制实体要求或已被多个第三国认可；

(c)

as a matter of priority in groups of operators, in case the control authority or control body certifies groups of operators.

作为操作员群体的优先事项，在控制当局或控制机构认证操作员群体的情况下。

3. For a control authority or control body recognised under Article 33(3) of Council Regulation (EC) No 834/2007 ([6](#)) and included in the list established in accordance with Article 57(2) of Regulation (EU) 2018/848, the information referred to in point 2.2 of Part A of this Annex shall result from witness audits carried out:

3. 对于根据理事会条例（EC）第 834/2007 号第 33（3）条认可的监管机构或监管机构，并列入根据条例（EU）2018/848 号第 57（2）条建立的名单中的，本附件 A 第 2.2 点所指信息应源自进行的见证审计：

[▼M1 ▲M1](#)

(a)

during the last 3 years by their accreditation body or competent authority for the purpose of their recognition under Regulation (EC) No 834/2007 for each category of products for which the control authority or control body requests recognition in accordance with Article 46 of Regulation (EU) 2018/848; and

在过去 3 年内，由其认证机构或主管当局根据《欧盟条例》（EC）第 834/2007 号的规定，为每个产品类别申请认可，控制机构或控制主体根据《欧盟条例》（EU）2018/848 号第 46 条请求认可；

VB

(b)

in a third country for which the control authority or control body is recognised under Article 33(3) of Regulation (EC) No 834/2007.

在第三国，其控制机构或控制主体根据《欧盟条例》（EC）第 834/2007 号第 33（3）条获得认可。

However, for each of these witness audits, the accreditation body or competent authority shall confirm that all non-compliances have been fully addressed by the control authority or control body.

然而，对于每次的证人审计，认证机构或主管当局应确认所有不符合规定的问题都已完全由控制当局或控制机构解决。

ANNEX II 附件二

General and specific requirements for the annual report referred to in Article 4 一般和具体要求，适用于第 4 条所指的年度报告

1. The annual report shall update all the elements contained in the technical dossier as set out in Article 1(2).

1. 年度报告应更新第 1 条第 2 款规定的技术档案中包含的所有要素。

2. The annual report shall contain the information of the control authority or control body to be updated for the purpose of the annual report and shall include the name and code number of the control authority or control body, mailing address, telephone number, email contact point and website address, which shall include a direct link, with an easy access from the home webpage, to the up-to-date list of operators or groups of operators.

2. 年度报告应包含为编制年度报告而需更新的监管机构或监管实体的信息，并应包括监管机构或监管实体的名称和代码编号、邮寄地址、电话号码、电子邮件联系方式和网站地址，其中应包括一个直接链接，从主页轻松访问最新的运营商或运营商群体列表。

3. For the purposes of the annual report, the technical dossier shall be completed with the following:

3. 为了编制年度报告，技术档案应包含以下内容：

(a)

the control activities of the control authority or control body in the third country or third countries in the previous year, per category of products, as set out in Article 35(7) of Regulation (EU) 2018/848, including the information about the number of operators and groups of operators as well as the number of their members (including subcontractors, if the operators or groups of operators do not remain responsible for the subcontractors) which were subject to their controls on 31 December of the previous year, broken down by third country and category of products;

上一年度第三国或第三国控制当局或控制机构的控制活动，按产品类别划分，如《欧盟条例》（EU）2018/848 第 35(7)条所述，包括关于运营商和运营商群体数量及其成员数量（包括分包商，如果运营商或运营商群体不对分包商承担责任）的信息，这些信息是在上一年 12 月 31 日受其控制，按第三国和产品类别细分；

(b)

an undertaking that the control authority or control body has performed the required updates of the translation of the production rules according to Article 1(2)(e) of this Regulation or any other relevant documents required for the purposes of Article 46(2) of Regulation (EU) 2018/848 or this Regulation;

一项承诺，即控制当局或控制机构已根据本法规第 1(2)(e)条或任何其他根据欧盟法规 (EU) 2018/848 第 46(2)条或本法规目的所需的相关文件，对生产规则翻译的必要更新已完成；

(c)

any update of the internal procedures, including the certification and control system set up by the control authority or control body in compliance with this Regulation;

任何关于内部程序的更新，包括根据本法规建立的由控制当局或控制机构设置的认证和控制系统；

(d)

a link to the website of the control authority or control body, with the information required in accordance with Article 17;

一个链接到监管机构或监管实体的网站，包含根据第 17 条所需的信息

(e)

an annual assessment report of the office(s) where certification decisions are taken, as referred to in point 2.1 of Part A of Annex I:

办公室（们）的年度评估报告，如附件 I A 部分第 2.1 点所述，在这些办公室（们）做出认证决定

(i)

ensuring that the control authority or control body has been satisfactorily assessed by the accreditation body or competent authority in the previous year on its ability to ensure that products imported from third countries comply with Regulation (EU) 2018/848;

确保在上一年评估中，认证机构或有权机构已对控制机构或控制主体确保从第三国进口的产品符合《欧盟条例》(EU) 2018/848 的能力进行了满意评估；

(ii)

confirming that the control authority or control body still has the capacity and the competencies to implement the control requirements, conditions and measures set out in Article 46(2) and (6) of Regulation (EU) 2018/848 and in this Regulation, in each third country for which it is recognised;

确认控制当局或控制机构仍具备实施《欧盟条例》（EU）2018/848 第 46(2)和(6)条以及本条例规定的控制要求、条件和措施的能力和资质，对于其被认可的每个第三国

(iii)

including any updated information of the annual assessment report as regards the results and an evaluation of:

包括关于评估结果和评估的年度评估报告的任何更新信息：

—

the checks of the files of the operators or groups of operators;

操作员或操作员组的文件检查

—

the list of non-compliances, as well as the number of non-compliances in relation to the number of certified operators or groups of operators;

不符合项清单，以及与获认证操作员或操作员团体数量相关的非合规数量

—

the handling of non-compliances and complaints, if any, with an explanation on the corrective measures implemented by the operators or groups of operators for the lasting closure of its non-compliances;

非合规和投诉的处理（如有），并说明运营商或运营商群体为永久关闭其非合规行为所采取的纠正措施；

—

the catalogue of measures and its implementation;

措施目录及其实施；

—

the risk analysis procedure;

风险评估程序

—

the annual risk plan;

年度风险计划

—

the sampling strategy, procedure and methodology;

采样策略、程序和方法；

—
the changes to any of the procedures;
任何程序的变更;

—
the exchange of information with other control authorities, control bodies and the Commission;
与其他控制当局、控制机构和委员会之间的信息交流;

—
the competence of the staff involved in the inspection and certification process;
涉及检验和认证流程的员工能力;

—
the training programmes;
培训计划;

—
the knowledge and competence of new staff;
新员工的知识和能力

—
the effectiveness and reliability of the activity witnessed and an overall assessment of the performance of the control authority or control body;
该活动的有效性和可靠性以及控制机构或控制主体的整体绩效评估

—
other elements that the accreditation body or competent authority considers relevant for the purposes of Regulation (EU) 2018/848;
其他认证机构或主管当局认为与《欧盟条例》（EU）2018/848 目的相关的其他要素;

(iv) (iv)

confirming as regards the extensions of the scope of recognition to additional third countries or categories of products in the previous year, the capacity and competencies of the control authority or control body to perform controls in accordance with this Regulation in each new third country or for each new category of products concerned, if there are active operators or groups of operators.
确认关于上一年的范围扩展至额外的第三国或产品类别，控制机构或控制主体在每个

新的第三国或针对每个相关的新产品类别执行本法规规定的控制的能力和资质，如果存在活跃的运营商或运营商群体。

4. The annual report shall include the following information with regard to cases of non-compliance and the measures taken:

4. 年度报告应包括以下关于违规案件及采取的措施的信息：

(a)

the number of physical on-the-spot inspections with and without prior notice;
现场检查（事先通知与否）的数量

(b)

the number of the samples collected in inspections with and without prior notice and where applicable, the actions taken;
收集的样本数量，包括事先通知和未通知的检查，以及适用的情况下采取的措施

(c)

the number of samples collected due to suspicion, complaints or during an investigation as referred to point (a) of Article 22(1) notified through OFIS as referred to in Article 21(2) (OFIS case);
因怀疑、投诉或在进行调查期间根据第 22(1)条(a)款所述收集的样本数量，通过 OFIS 通知，如第 21(2)条所述（OFIS 案件）

(d)

the number of OFIS cases of suspected or established non-compliance;
涉嫌或已确立的不合规 OFIS 案件数量；

(e)

the number of non-compliances found, broken down into minor, major and critical according to the classifications of non-compliances of organic or in-conversion products laid down in Annex IV;
发现的不合规数量，根据附件 IV 中规定的有机或转换产品不合规分类，细分为轻微、主要和严重不合规

(f)

measures referred to Annex IV taken in respect of operators or groups of operators in cases of non-compliances.

针对不符合规定的情况，针对运营商或运营商群体采取的、参照附件 IV 的措施。

5. When the control authority or control body has certified operators or groups of operators from another control authority or control body, the annual report of the receiving control authority or control body shall indicate for each transferred operator or group of operators:

5. 当控制当局或控制机构已认证来自另一控制当局或控制机构的操作员或操作员群体时，接收控制当局或控制机构的年度报告应针对每个转移的操作员或操作员群体指出：

(a)

the name of the operator or group of operators, its geographical location and its previous certificate number;

运营商或运营商组的名称、其地理位置及其之前的证书编号；

(b)

the name of its previous control authority or control body;

其之前控制机构或控制主体的名称；

(c)

the date of transfer of the control file;

控制文件转移日期

(d)

the list and nature of open non-compliances and measures required by the previous control authority or control body, if any;

该开放非合规清单及其性质，以及前控制机构或控制机构如有的话所需采取的措施；

(e)

the measures put in place by the operator or group of operators to ensure that the non-compliances will not occur again, and the date(s) of the inspection(s) carried out by the new control authority or control body to verify that corrective measures have been correctly implemented;

该运营商或运营商群体采取的措施，以确保不再发生违规行为，以及新控制机构或控制机构进行检验的日期，以核实纠正措施是否已正确实施；

(f)

the indication whether the operator or group of operators was involved in any OFIS case.

操作员或操作员团体是否参与过任何 OFIS 案件。

6. Concerning high-risk products referred to in Article 8, the following information shall be provided:

6. 关于第 8 条所述的高风险产品，应提供以下信息：

(a)

the list of the operators or groups of operators responsible for the high-risk products;
负责高风险产品的操作员或操作员群体的名单；

(b)

for each operator or group of operators:
对于每个运营商或运营商组：

(i)

the inspections carried out, indicating the date of each inspection;
该次检查执行情况，指明每次检查的日期；

(ii)

the sampling and analyses carried out;
所进行的采样和分析

(iii)

non-compliances found; 发现违规情况

(iv)

the measures applied; 实施的措施；

(v)

for each operator or group of operators that changed its control authority or control body, the corrective measures and/or sanctions applied if non-compliances were noted in the report of the previous control authority or control body;
对于每个改变其控制权限或控制机构的运营商或运营商群体，如果在先前控制机构或控制机构的报告中发现不合规，则采取的纠正措施和/或处罚；

(c)

for each consignment showing a non-compliance:
对于每批显示不合规的货物：

(i)

reference to the certificate of inspection for imported consignments;
参考进口货物的检验证书

(ii)

overview of sampling analysis results that indicate the presence of residues of non-authorised substances;
概述表明存在未经授权物质残留的采样分析结果

(iii)

investigations and follow-up measures taken by the control authority or control body in case of commingling or residues of non-authorised substances found in the consignment, including the decision concerning the consignment as well as confirmation that operators have taken corrective measures.

对控制当局或控制机构在发现货物中存在非授权物质混合或残留物时采取的调查和后续措施，包括关于货物的决定以及确认操作员已采取纠正措施。

7. For authorisations for the use of non-organic plant reproductive material in accordance with point 1.8.5.2 of Part I of Annex II to Regulation (EU) 2018/848, the following information shall be provided:

7. 根据欧盟法规（EU）2018/848 附件 II 第一部分第 1.8.5.2 点关于非有机植物繁殖材料使用的授权，应提供以下信息：

(a)

scientific and common name (common and Latin name);
科学名和普通名（普通名和拉丁名）；

(b)

variety; 多样性

(c)

number of derogations and total weight of seeds or number of plants derogated;
违规数量和种子或植物的总重量；

(d)

number of operators and groups of operators which have been granted an authorisation.
已授权的运营商和运营商组数量。

8. For derogations granted in accordance with points 1.3.4.3 and 1.3.4.4 of Part II of Annex II to Regulation (EU) 2018/848 for each non-organic livestock species (bovine,

equine, ovine, caprine, porcine and cervine animals, rabbits, poultry), the following information shall be provided:

第 8 条：对于根据《欧盟条例》（EU）2018/848 附件 II 第二部分第 1.3.4.3 点和第 1.3.4.4 点授予的豁免，针对每种非有机牲畜物种（牛、马、羊、山羊、猪、鹿、兔子、家禽），应提供以下信息：

(a)

scientific and common name (common and Latin name i.e. species and genus);
科学名和普通名（即物种和属的普通名和拉丁名）；

(b)

breeds and strains; 品种和品系

(c)

production purposes: meat, milk, eggs, dual purpose or breeding;
生产目的：肉类、牛奶、蛋类、双重用途或繁殖

(d)

number of derogations and total number of animals derogated;
违规数量和被违规动物总数

(e)

number of operators and groups of operators, which have been granted a derogation.
已获授权宽限的运营商和运营商群体数量。

9. For authorisations granted for the use of non-organic aquaculture juveniles in accordance with point 3.1.2.1 of Part III of Annex II to Regulation (EU) 2018/848, the following information shall be provided:

第九条：根据《欧盟条例》（EU）2018/848 附件 II 第三部分第 3.1.2.1 点授予的非有机水产养殖幼体使用许可，应提供以下信息：

(a)

species and genus (common and Latin name);
物种和属（普通名和拉丁名）

(b)

breeds and strains when applicable;
品种和品系（如适用）；

(c)

total number of derogations and number of juveniles for each species;
总豁免数量和每种物种的未成年人数量

(d)

number of operators and groups of operators, which have been granted an
authorisation.

运营商和已授权的运营商组数量。

10. The annual report shall contain any other information deemed relevant to satisfy
a specific requirement of Regulation (EU) 2018/848 by the control authority, the
control body or the accreditation body.

第十条 年度报告应包含控制机构、控制机构或认证机构认为与满足（欧盟）2018/848
号法规的特定要求相关的任何其他信息。

ANNEX III 附件三

OFIS template as referred to in Article 21(2)

《EUR-Lex - 02021R1698-20230908 - EN - EUR-Lex》 本文第 21(2)条所指 OFIS 模板

Template for a standard reply to a standard international notification on suspected or established non-compliance

模板：针对疑似或已确立的不合规的国际通知的标准回复

A. Investigation A. 调查
1) Which control authority(-ies) and/or control body(-ies) are/were in charge of the investigation?: 1) 哪个监管机构（们）和/或监管机构（们）负责调查？
2) Describe cooperation between the different operators and competent authority(-ies) or, where appropriate, control authority(-ies) and/or control body(-ies) involved, in the different countries involved (if any)?: 2) 描述不同运营商和主管部门或，如适用，监管机构或监管机构之间在涉及的不同国家（如有）的合作情况？
3) Which investigation methods/procedures have been used?: 3) 使用了哪些调查方法/程序？
For instance, have the operators concerned been submitted to a specific control?: 例如，相关运营商是否已接受过特定控制？
Have samples been taken and analysed?: 已采集并分析过样本了吗？
4) What is the outcome of the investigation?: 4) 调查结果是什么？
What are the results of the inspections/analyses (if any)?: 检查/分析结果（如有）是什么？
Has the origin of the non-compliance/suspicion of non-compliance/other problem raised been cleared up?: 已查明不合规/涉嫌不合规/其他问题的起源了吗？

<p>What is your assessment of the seriousness of the non-compliance/suspicion of non-compliance/other problem raised?:</p> <p>您对外合规/涉嫌不合规/其他问题的严重性有何评估？</p>
<p>5) Has the origin of the contamination/non-compliance/suspicion of non-compliance/other problem raised and the responsibility of the actors been clearly identified and established?:</p> <p>5) 污染/不合规/涉嫌不合规/其他问题是否已查明起源，相关行为者的责任是否已明确界定和确立？</p>
<p>Comment on the origin of the contamination/non-compliance/other problem raised and the responsibility of the actors:</p> <p>对提出的污染/不合规/其他问题的起源和参与者的责任进行评论：</p>
<p>6) Have the operators identified been involved in other non-compliance/suspicion of non-compliance/other problem raised cases in the last 3 years?</p> <p>6) 在过去 3 年中，这些运营商是否在其他不合规/涉嫌不合规/其他问题案例中有所涉及？</p>
<p>Comment on the operators identified in other non-compliance/suspicion of non-compliance/other problems in the last 3 years:</p> <p>对过去 3 年内其他非合规/涉嫌非合规/其他问题中确定的操作员进行评论：</p>
<p>B. Measures and penalties:</p> <p>B. 措施和处罚：</p>
<p>*1) What preventive and corrective measures have been taken (e.g. as regards the distribution/circulation of the product on the Union market and third-country markets)?:</p> <p>1) 已采取了哪些预防措施和纠正措施（例如，关于产品在欧盟市场和第三国市场的分销/流通）？</p>
<p>*2) What actions in case of non-compliance/suspicion of non-compliance/other problem raised were taken on the operators and/or the products concerned? (1):</p> <p>2) 在出现不合规/疑似不合规/其他问题时，对相关运营商和/或产品采取了哪些行动？ (1)：</p>
<p>(1) Mode of actions (written form, warning, etc.):</p> <p>(*1) 行动方式（书面形式、警告等）？</p>

Was the certification of the producer/processor limited, suspended or withdrawn?: 生产者/加工者的认证是否受到限制、暂停或撤回?
Date of entry into force of the actions (if any) (DD/MM/YYYY): 生效日期 (如有) (DD/MM/YYYY) :
Duration of the actions (if any) (in months): 行动期限 (如有) (月) :
Control authority and/or control body which adopted and applied the actions (if any): 控制当局和/或采取并实施行动 (如有) 的机构:
3) Are additional inspections planned at the operators concerned?: 3) 是否计划对相关运营商进行额外检查?
4) What other measures are the control authority or control body planning to prevent the occurrence of similar cases?: 4) 控制当局或控制机构计划采取哪些其他措施来防止类似情况的发生?
C. Other information C. 其他信息
D. Annexes D. 附件
Reply comments: 回复评论:
Contact point 联系方式
(^{*1}) <i>Mandatory fields. 必填字段。</i> (¹) Measure pursuant to Article 29(1) and (2) of Regulation (EU) 2018/848 and Article 22(1), (2) and (3) and Article 23(1) and (4) of this Regulation. 根据《欧盟条例》(EU) 2018/848 第 29 条第 1 款和第 2 款以及本条例第 22 条第 1 款、第 2 款和第 3 款, 以及第 23 条第 1 款和第 4 款的规定采取的措施。

ANNEX IV 附件四

Catalogue of measures referred to in Article 22(3)

措施目录，参见第 22(3)条

PART A 第一部分

Elements for the development and application of the catalogue of measures

措施目录的开发和应用要素

1. Subject to Part B, the control authority or control body may classify cases of non-compliance as minor, major or critical, on the basis of the classification criteria in point (b) of Article 22(3) when one or more of the following situations apply:

1. 在 B 部分的规定下，控制当局或控制机构可以根据第 22(3)条(b)点中的分类标准，将不符合规定的情况划分为轻微、重大或严重，当出现以下一种或多种情况时：

(a)

the case of non-compliance is minor when:

不合规案件在以下情况下较少：

(i)

the precautionary measures put in place by the operator are proportionate and appropriate, and the controls that the operator has put in place are efficient according to the assessment by the control authority or control body;

采取的操作者的预防措施是成比例且适当的，操作者实施的管控措施根据管控机构或管控主体的评估是有效的

(ii)

the non-compliance does not affect the integrity of the organic or in-conversion product;

不合规不影响有机或转化产品的完整性；

(iii)

the traceability system can locate the affected product(s) in the supply chain and the product can be prevented from being imported from a third country for the purpose of placing that product on the market within the Union with reference to organic production;

追溯系统可以定位供应链中受影响的产品，并且可以防止该产品从第三国进口，目的在于将该产品在联盟市场上销售，参照有机生产

(b)

the case of non-compliance is major when:

不合规案件在以下情况下较为严重:

(i)

the precautionary measures are not proportionate and appropriate and the controls that the operator has put in place are inefficient according to the assessment by the control authority or control body;

预防措施不适当且不成比例, 运营商实施的管控措施根据管控机构或管控主体的评估效率低下

(ii)

the non-compliance affects the integrity of the organic or in-conversion product;

违反行为影响有机或转化产品的完整性;

(iii)

the operator did not correct in a timely manner a minor non-compliance;

操作员未及时纠正轻微的不合规行为

(iv)

the traceability can locate the affected product(s) in the supply chain and the product can be prevented from being imported from a third country for the purpose of placing that product on the market within the Union with reference to organic production;

可追溯性可以定位供应链中受影响的产品(们), 并且可以防止该产品从第三国进口, 目的在于将该产品在联盟市场上销售, 参照有机生产;

(c)

the case of non-compliance is critical when:

不合规案件在以下情况下至关重要:

(i)

the precautionary measures are not proportionate and appropriate and the controls that the operator has put in place are inefficient according to the assessment by the control authority or control body;

预防措施不适当且不成比例, 运营商实施的管控措施根据管控机构或管控主体的评估效率低下

(ii)

the non-compliance affects the integrity of the organic or in-conversion product;
违反行为影响有机或转化产品的完整性；

(iii)

the operator fails to correct previous major non-compliances or repeatedly fails to correct other categories of non-compliances; and
操作员未能纠正之前的重大不合规或反复未能纠正其他类别的非合规行为；

(iv)

there is no information from the traceability system to locate the affected product(s) in the supply and the products cannot be prevented from being imported from a third country for the purpose of placing that product on the market within the Union with reference to organic production.

没有可追溯性系统提供的信息来定位供应链中受影响的产品，且无法阻止这些产品从第三国进口，以在联盟内将产品投入有机生产市场。

2. **Measures** 2. 措施

Control authorities or control bodies may apply one or more of the following measures in a proportionate manner to the listed categories of cases of non-compliance:

监管部门或监管机构可以按照比例原则，对列出的违规案件类别采取一项或多项以下措施：

Category of non-compliance 不合规类别	Measure 测量
Minor 较小	Submission by the operator of an action plan within a time limit setting on the correction of the non-compliance(s) 行动计划操作者在规定时间内提交纠正（不合规）的申请
Major 主要	No reference to organic production in the labelling and advertising of the entire lot or production run concerned (crop(s) or animal(s) affected) according to Article 42(1) of Regulation (EU) 2018/848 无关于有机生产在相关批次或生产批次（受影响的作物或动物）的标签和广告中的提及（根据欧盟法规（EU）2018/848 第 42（1）条）

	<p>Prohibition of import from a third country for the purpose of placing that product on the market within the Union as organic production for a given period according to Article 42(2) of Regulation (EU) 2018/848</p> <p>禁止从第三国进口，目的在于将该产品作为有机生产在联盟市场内销售，根据《欧盟条例》（EU）2018/848 第 42 条第 2 款规定，在一定期限内禁止进口</p> <p>New conversion period required 新转换期要求</p> <p>Limitation of the certificate's scope 证书范围的限制</p> <p>Improvement of the implementation of the precautionary measures and the controls that the operator has put in place to ensure compliance 改进实施预防措施和运营商为确保合规而采取的控制措施</p>
Critical 关键	<p>No reference to organic production in the labelling and advertising of the entire lot or production concerned (crop(s) or animal(s) affected) according to Article 42(1) of Regulation (EU) 2018/848 无关于有机生产在相关批次或生产（受影响的作物或动物）的标签和广告中的提及（根据欧盟法规（EU）2018/848 第 42（1）条）</p> <p>Prohibition of import from a third country for the purpose of placing that product on the market within the Union as organic production for a given period according to Article 42(2) of Regulation (EU) 2018/848 禁止从第三国进口，目的在于将该产品作为有机生产在联盟市场内销售，根据《欧盟条例》（EU）2018/848 第 42 条第 2 款规定，在一定期限内禁止进口</p> <p>New conversion period required 新转换期要求</p> <p>Limitation of the certificate's scope 证书范围的限制</p> <p>Suspension of the certificate 证书暂停</p>

	Withdrawal of the certificate 撤销证书
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PART B 第二部分

List of cases of non-compliance and the corresponding classification mandatory to be included in the catalogue of measures

不符合案例清单及其在措施目录中必须包含的相应分类

Non-compliance 不合规	Category 类别
Significant deviation between input and output calculation (mass balance) 输入和输出计算（质量平衡）之间存在显著偏差	Major 主要
Absence of records and financial records showing the compliance with Regulation (EU) 2018/848 记录和财务记录显示符合（欧盟）2018/848 号法规的情况缺失	Critical 关键
Intentional omission of information leading to incomplete records 故意遗漏导致记录不完整的信息	Critical 关键
Falsification of documents connected with the certification of organic products 伪造与有机产品认证相关的文件	Critical 关键
Intentional re-labelling of downgraded products as organic 故意将降级产品重新标记为有机	Critical 关键
Intentional mixing organic with in-conversion or non-organic products 故意将有机产品与转化中或非有机产品混合	Critical 关键
Intentional use of non-authorized substances or products within the scope of the Regulation (EU) 2018/848 故意使用《欧盟法规（EU）2018/848》范围内的非授权物质或产品	Critical 关键
Intentional use of GMOs 故意使用转基因生物	Critical 关键
The operator refuses the control authority or the control body access to premises subject to controls, or to its book keepings, including	Critical 关键

financial records, or refuses to allow the control authority or control body to take samples 操作员拒绝控制当局或控制机构进入受控场所，或进入其账簿，包括财务记录，或拒绝允许控制当局或控制机构取样	
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([1](#)) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

(1) 1987 年 7 月 23 日理事会法规 (EEC) 第 2658/87 号关于关税和统计分类以及共同海关关税 (官方公报 L 256, 1987 年 9 月 7 日, 第 1 页)。

([2](#)) 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 (OJ L 165, 11.5.2021, p. 25).

(2) 欧盟委员会委托法规 (EU) 2021/771, 2021 年 1 月 21 日, 补充欧洲议会和理事会法规 (EU) 2018/848, 规定在有机生产官方控制和操作者群体官方控制框架内对文件账户进行检查的具体标准和条件 (官方公报 L 165, 2021 年 5 月 11 日, 第 25 页)。

([3](#)) 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 (OJ L 62, 23.2.2021, p. 6).

(3) 欧盟委员会实施条例 (EU) 2021/279, 于 2021 年 2 月 22 日制定, 规定了欧洲议会和理事会关于有机生产和有机产品标签的可追溯性和合规性控制及其他措施的条例 (EU) 2018/848 的实施细则 (官方公报 L 62, 2021 年 2 月 23 日, 第 6 页)。

([4](#)) Commission Implementing Regulation (EU) 2019/533 of 28 March 2019 concerning a coordinated multiannual control programme of the Union for 2020, 2021 and 2022 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin (OJ L 88, 29.3.2019, p. 28).

(4) 欧盟委员会 2019 年 3 月 28 日颁布的执行条例 (EU) 2019/533, 关于确保符合农药最大残留限量并评估消费者接触植物和动物源性食品中农药残留的风险的联盟

2020 年、2021 年和 2022 年协调多年度控制计划（官方公报 L 88, 2019 年 3 月 29 日, 第 28 页）。

(⁵) Commission Decision 2004/563/EC, Euratom of 7 July 2004 amending its Rules of Procedure (OJ L 251, 27.7.2004, p. 9).

(5) 欧盟委员会 2004/563/EC, 欧洲原子能共同体 2004 年 7 月 7 日决定修改其程序规则（官方公报 L 251, 2004 年 7 月 27 日, 第 9 页）。

(⁶) Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

(6) 欧盟理事会法规（EC）第 834/2007 号, 2007 年 6 月 28 日关于有机生产和有机产品标签, 并废除法规（EEC）第 2092/91 号（官方公报 L 189, 2007 年 7 月 20 日, 第 1 页）。

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