Article 28 + 29: Substantiate(d) suspicion by the operator and the CB

Proposal for a technical reading, 22th of March 2022

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This document is the result of discussions in the RESCUE network.

Representatives of AFI, AÖL, BioNederland, BioSuisse, EOCC, FiBL, OPTA-EU, R.O.O.S. and invited guests met on a monthly basis since February 2021 in the RESCUE network meetings.

The document illustrates the common reading of Articles 28(2) and 29 of Regulation (EU) 2018/848 (and the relevant parts of Regulations 2021/279 and 2021/1698). It contains the legal requirements and the outcome of technical discussions which is represented in three visual supports.

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2018/848 Whereas (24)

In order to support and facilitate compliance with this Regulation, operators should […] take, where appropriate, **proportionate precautionary measures which are under their control** to avoid contamination […] and to avoid commingling organic, in-conversion and non-organic products.

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Art 28 Precautionary measures to avoid the presence of non-authorised products and substances

1. In order to avoid contamination […], operators shall take the following precautionary measures […]:
   (a) […] identify the risks of contamination […];
   (b) put in place and maintain measures that are proportionate and appropriate to avoid risks of contamination […];

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848 Art 28 Precautionary measures to avoid the presence of non-authorised products and substances

2. Where an operator suspects, due to the presence of a product or substance that is **not authorised** * […] that the […] product does not comply with this Regulation, the operator shall:

(a) identify and separate the product concerned;

(b) check whether the suspicion can be substantiated;

(c) not place the product concerned on the market as an organic or in-conversion product and not use it in organic production unless the suspicion can be eliminated;

(d) where the suspicion has been substantiated or where it cannot be eliminated, immediately inform the relevant competent authority, or, where appropriate, the relevant control authority or control body, and provide it with available elements, where appropriate;

(e) fully cooperate with the relevant competent authority, or, where appropriate, with the relevant control authority or control body, in identifying and verifying the reasons for the presence of non-authorised products

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(e) fully cooperate with the relevant competent authority, or, where appropriate, with the relevant control authority or control body, in identifying and verifying the reasons for the presence of non-authorised products

2. Where an operator suspects, due to the presence of a product or substance that is **not authorised *pursuant to the first subparagraph of Article 9(3) for use in organic production*** […]

⇒ Products or substances meant are those referred to in Art 24 and 25 of Reg 2018/848 and that are authorised for use in conventional food/feed production. This excludes e.g. heavy metals, mycotoxins, … The latter product and substances are not authorised for use in conventional food/fed production are not to be taken into account in the context of the official controls for organic production and certification of organic products (EU and non-EU.

⇒ In case of presence of products or substances not authorised pursuant to other legal requirements, instructions given by the relevant competent authority for those legal requirements shall apply to the operator.

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(e) fully cooperate with the relevant competent authority, or, where appropriate, with the relevant control authority or control body, in identifying and verifying the reasons for the presence of non-authorised products or substances.

2021/279 Art 1 […] steps to be followed by the operator in case of a suspicion of non-compliance due to the presence of non-authorised products or substances

1. In order to check whether the suspicion can be substantiated […], the operator shall take into account the following elements:

(a) where the suspicion of non-compliance concerns an incoming […] product, the operator shall check whether:

(i) the information on the label […] and the accompanying documents match;

(ii) […] the certificate provided by the supplier relates to the product […];

(b) where there is a suspicion that the cause of the presence of the non-authorised products or substances lies under the control of the operator, the operator shall examine any possible cause […].

Art 29 Measures to be taken in the event of the presence of non-authorised products or substances

1. Where the competent authority, or, where appropriate, the control authority or control body, receives substantiated information about the presence of products or substances that are not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production, or has been informed by an operator in accordance with point (d) of Article 28(2), or detects such products or substances in an organic or an in-conversion product:

(a) it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 with a view to determining the source and the cause in order to verify compliance with the first subparagraph of Article 9(3) and with Article 28(1); such investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case;

(b) it shall provisionally prohibit both the placing on the market of the products concerned as organic or in-conversion products and their use in organic production pending the results of the investigation referred to in point (a).

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Art 29 Measures to be taken in the event of the presence of non-authorised products or substances

2. The product concerned shall not be marketed as an organic or in-conversion product or used in organic production where the competent authority, or, where appropriate, the control authority or control body, has established that the operator concerned:

(a) has used products or substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production;

(b) has not taken the precautionary measures referred to in Article 28(1); or

(c) has not taken measures in response to relevant previous requests from the competent authorities, control authorities or control bodies.

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Art 29 Measures to be taken in the event of the presence of non-authorised products or substances

3. The operator concerned shall be given an opportunity to comment on the results of the investigation referred to in point (a) of paragraph 1.

The competent authority, or, where appropriate, the control authority or control body, shall keep records of the investigation it has carried out. Where required, the operator concerned shall take such corrective measures as necessary to avoid future contamination.

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Reg 2021/279 Art 2 Methodology of an official investigation

1. Without prejudice to Article 38(2) of Regulation (EU) 2018/848, when carrying out an official investigation referred to in Article 29(1)(a) of that Regulation, the competent authorities or, where appropriate, control bodies or control authorities shall determine at least the following:

   (a) the name, lot identification, ownership and physical location of the organic or in-conversion products concerned;

   (b) whether the products concerned are still placed on the market as organic or in-conversion products or used in organic production;

   (c) the type, name, quantity and other relevant information of the present non-authorised products or substances;

   (d) at which stage of production, preparation, storing or distribution and where exactly the presence of non-authorised products or substances has been detected, in particular for plant production, whether the sample was taken preharvest or post-harvest;

   (e) whether other operators in the supply chain are affected;

   (f) the results of previous official investigations on the organic or in-conversion products and operators concerned.

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Reg 2021/279 Art 2 Methodology of an official investigation

2. The official investigation shall be pursued by using appropriate methods and techniques, including those referred to in Article 14 and Article 137(3) of Regulation (EU) 2017/625 of the European Parliament and of the Council.

3. The official investigation shall at least conclude on:

(a) the integrity of organic and in-conversion products;

(b) the source and the cause of the presence of non-authorised products or substances;

(c) the elements provided in Article 29(2)(a), (b) and (c) of Regulation (EU) 2018/848.

4. The competent authorities or, where appropriate, control authorities or control bodies shall draw up a final report for each official investigation. That final report shall contain:

(a) the records of the specific elements required pursuant to this Article;

(b) the records of the information exchanged with the competent authority, other control authorities and control bodies and the Commission related to this official investigation.

Detailed overview of actions for operators

Legend Legal requirements | Technical reading

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Presence of non-authorised products or substances in organic products [2018/848 Art 28(2)]

Operator must confirm suspicion of non-compliance [2018/848 Art 28(2)]

- Q1: Is the substance relevant* for compliance with organic production rules?
- Q2: Is the analysis result reliable**?
- Q3: Is the sampling reliable?

If three times "Yes" ***

Suspicion of non-compliance for ORGANIC is confirmed [2018/848 Art 28(2)]

→ Identify and separate [2018/848 Art 28(2)a]

→ Provisionally block during substantiation [2018/848 Art 28(2)c]

Operator must substantiate suspicion of non-compliance by examining any possible cause for the presence [2018/848 Art 28(2)b; 2021/279 Art 1]

Focus and identify the most likely source and cause as follows:

1. Check the use of products or substances not authorised for use in organic production under own responsibility
2. Check risks, measures and records to avoid contamination and commingling under own responsibility (cross-contamination, mass balance, traceability)
3. If needed, check with the CB of the supplier and the supplier 1. & 2.

→ Suspicion has not been eliminated or has been substantiated [2018/848 Art 28(2)c]

→ Immediately inform CA/CB [2018/848 Art 28(2)d]

→ Do not place the product on the market as organic [2018/848 Art 28(2)c]

→ Suspicion has been eliminated [2018/848 Art 28(2)c]

→ Place the product on the market as organic

Detailed overview of actions for certifiers (EU)

Legend | Legal requirements | Technical reading

AntiFraud Initiative

CB/CA receives information about the presence of products or substances not authorised for use in organic products [2018/848 Art 29(1)]

CB substantiates this information [2018/848 Art 29(1)]

- Q1: Is the substance relevant* for compliance with organic production rules?
- Q2: Is the analysis result reliable**?
- Q3: Is the sampling reliable?

If three times "Yes" ***

Instruct the operator to provisionally prohibit placing on the market and/or use of the products as organic [2018/848 Art 29(1)b]

Carry out an official investigation**** with a view to determine source and cause in order to verify compliance [2018/848 Art 29(1)a]

Focus and identify the most likely source and cause as follows:

1. Check and confirm mass balance/traceability of the lot
2. Check the use of products or substances not authorised for use in organic production on the holding of the operator
3. Check risks, measures and records to avoid contamination under own responsibility of the operator (cross-contamination)
4. If needed, check with the CB of the supplier and the supplier 1., 2. & 3.

- Detection of non-compliance / irregularity / infringement
  - Unauthorised use [2018/848 Art 29(2)a]
  - Precautionary measures not taken [2018/848 Art 29(2)b]
  - Previous non-compliance not properly followed up by the operator [2018/848 Art 29(2)c]

  → Do not place the product on the market as organic [2018/848 Art 29(2)]
- Absence of non-compliance

  → Presence of indicators of and technical justification for unavoidable exposure of organic production to non authorised products / substances despite proportionate and appropriate identification of risks and precautionary measures put in place.

  → Place the product on the market as organic

Give the operator the possibility to comment on the outcome of the investigation, conclude and draw up the final report [2018/848 Art 29(3)]

Detailed overview of actions for certifiers (non-EU)

Legend | Legal requirements | Technical reading

AntiFraud Initiative

CB/CA in a third country receives information about the presence of products or substances not authorised for use in organic products [2018/848 Art 29(1)]

CB substantiates this information [2018/848 Art 29(1]

- Q1: Is the substance relevant* for compliance with organic production rules?
- Q2: Is the analysis result reliable**?
- Q3: Is the sampling reliable?

If three times "Yes" ***

Instruct the operator to provisionally prohibit placing on the market and/or use of the products as organic [2018/848 Art 29(1)b]

Carry out an official investigation**** with a view to determine source and cause in order to verify compliance [2018/848 Art 29(1)a]

Focus and identify the most likely source and cause as follows:

1. Check and confirm mass balance/traceability of the lot
2. Check the use of products or substances not authorised for use in organic production on the holding of the operator
3. Check risks, measures and records to avoid contamination under own responsibility of the operator (cross-contamination)
4. If needed, check with the CB of the supplier and the supplier If needed, check with the CB of the supplier and the supplier 1., 2. & 3.

Detection of non-compliance / irregularity / infringement

- Unauthorised use [2018/848 Art 29(2)a]
- Precautionary measures not taken [2018/848 Art 29(2)b]
- Previous non-compliance not properly followed up by the operator [2018/848 Art 29(2)c]

→ Do not place the product on the market as organic [2018/848 Art 29(2)]

- Absence of non-compliance affecting integrity of organic (or in-conversion products) [2021/1698 Art 22(2)]

→ Place the product on the market as organic [2021/1698 Art 22(2)]

Give the operator the possibility to comment on the outcome of the investigation, conclude and draw up the final report [2018/848 Art 29(3)]

Footnotes

***Relevance**

The scope of Art 28(1) is limited to the non-intentional contamination with prohibited products or to substances of the groups mentioned in Art 9(3) §1 and the non-intentional commingling of organic products with conventional products or in-conversion products. A substance characterized by proven specific behavior and other relevant information that permits to eliminate suspicion may be considered to conduct the investigation without an on-the-spot inspection by the CA/CB (cfr whereas recital 69 of Reg (EU) 2018/848). The operator informs the CA/CB hereof.

** **Reliability**,

An analytical result is considered as reliable, when the following conditions are met:

- The concentration of the non authorised product/substance is exceeding the LOQ-value of the analytical method applied
- Traceability sample and representativity
- Accredited analytical method

*** **Confirmation of suspicion**

These flowcharts show only the proceedings in case that all three questions can be answered with yes. In case that one or more answers are answered with no, the further procedure has to be determined case by case.

**** **Official investigation**

The official investigation shall be carried out as described in 2021/279.2.1+2, referring to methods and techniques mentioned in Reg (EU) 2017/625 with a view to determine source and cause in order to verify compliance.

The investigations could include any method and technique **[…]**, including the use of any relevant information that would permit the elimination or confirmation of any suspicion of non-compliance without an on-the spot inspection (cfr Recital 69 of EU Reg 2018/848).