

Good implementation practices for Articles 28 and 29 of Regulation (EU) 2018/848

**Handles, keys and levers for investigation of residue cases
in EU organic production**

Open discussion on the concept and the content

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Introduction

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Chapter 2: Laboratory analysis: the main tool for detecting of contamination

Chapter 3: Potential sources and causes of contamination

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1. The compromise that has been achieved in the new EU Organic Regulation

Article 29 reflects the compromise reached in negotiating the new organic regulation (EU) 2018/848 concerning the presence of non-authorized substances.

- An organic product may not necessarily be free of residues.
- When a control body or competent authority receives substantiated information about the presence of non-authorized products or substances indicating a noncompliance with the EU Organic Regulation, it shall conduct an official investigation to determine the source and the cause.
- The product concerned shall not be marketed as an organic product if the operator has used non-authorized substances, or if he has not taken the necessary precautionary measures, or if he has not taken measures in response to relevant previous requests from the competent authorities, control authorities or control bodies.

2. The legal framework

The systematic launch of an official investigation to determine the source and cause is a key issue of the new organic regulation.

- *“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, it shall immediately carry out an official investigation in a view to determining the source and the cause.”*(Article 29(1) of Regulation 2018/848).
- According to Article 2(3) of Regulation 2021/279, *“The official investigation shall conclude on the source and cause of the presence of non-authorized products or substances”*.

3. The principle of proportionality

- The temporary blocking of organic batches for the duration of official investigations has significant economic consequences, sometimes leading to the destruction of the products concerned.
- Official investigations lead to additional administrative burdens for operators, control bodies, and authorities.
- The EU Organic Regulation sets out the principles of official investigations.
- An official investigation is not applied research. It is carried out based on the current state of science and research.

These arguments are considered in the EU Organic Regulation: “*Such investigations should be **proportionate** to the suspected non-compliance, and therefore should be completed as soon as possible within a reasonable period, taking into account the durability of the product and the complexity of the case*” (Whereas 69 of Regulation 2018/848).

4. Maintain the effectiveness of the control system

The effectiveness of the organic control system is key to preserving the confidence of consumers in the EU organic logo.

- Keep the focus on fraud as well as on major and critical non-compliances.
- Determining the source and cause are key to setting up effective and efficient precautionary measures, thus limiting the risk of presence.
- The investigations should be carried out in line with the legal requirements. No change of the legal framework is expected before the presentation of the report referred to in Article 29(4) by the EU Commission (end 2025).

5. Balance control effectiveness and proportionality

- Right balance to be found between identifying source and cause and the associated costs.
- The regulation establishes the obligation to carry out an official investigation and to conclude on the source and cause of the presence, as well as on the integrity of the organic product, but gives great freedom in investigation techniques to comply with this obligation (cf. Article 14 of Regulation 2017/625 and Article 2 of Regulation 2021/279).
- The corner stone of this balance: a systematic approach for investigation.

6. Basic principles of the systematic approach for investigations

- Assessment of source and cause of the contamination by the operator.
- Control body/control authority: Setting up a hypothesis on the possible sources and causes (from the inventory of chapter 3).
- Ranking the hypothesis according to their probability.
- Define the most relevant and promising investigation methods and techniques (from the tool box of chapter 4) to confirm or eliminate these hypotheses.
- Carry out the investigation on a risk-based approach.
- Documentation of the investigation results.

7. Overall considerations (1)

Should the investigation determine source and cause precisely, and with what degree of certainty?

- Scientifically (and in life), nothing is 100% sure.
- In any case, evidence should be provided that the investigation carried out included methods and techniques which are considered appropriate to effectively confirm (or eliminate) a suspicion of non-compliance.
- There is a legal obligation for the investigation to conclude on the source and cause.
- The investigation shall also conclude on the integrity of the organic product.
- A conclusion allowing to release a lot under suspicion to be sold as organic needs to be based on solid evidence that use, replacement/commingling and inappropriate precautionary measures can be excluded.

8. Overall considerations (2)

Confirming or eliminating a specific hypothesis does not necessarily require the same investigation method and approach, according to different cases:

- The most probable hypothesis on the source and cause can be confirmed with a sufficient certainty by the investigation to be able to conclude on the integrity of the product.
- The hypothesis used as a starting point of the investigation is confirmed as the most probable, but some other possible sources (mainly use or commingling) should be eliminated to be able to conclude on the integrity of the product.
- The most probable hypothesis cannot be confirmed by the investigation. Then other less probable hypothesis should be investigated, either to determine the source with a sufficient degree of certainty, or to conclude on the most probable source, even with a lower degree of certainty, on the basis of the elimination of the other main possible sources.

9. Main steps of a systematic approach (1)

First steps, review of documents:

- Type of chemical compound detected
- Reliability of sampling and analysis
- Relevance of the chemical compound found
- Risk analysis related to the specific product and the country of origin
- Result of previous controls (non-compliances).
- Operator risk classification
- Circumstances (lack of product, extreme sanitary conditions, etc.)

10. Main steps of a systematic approach (2)

Based on the analysis of documents, listing of the possible sources ranked by order of probability, among 5 main categories (as defined in chapter 3)

- I. Use
- II. Commingling (in a large sense, covering the sale of conventional product as organic)
- III. “Internal” contamination (within the scope of action of the operator: contamination by equipment, premises, storage....)
- IV. Environmental contamination
- V. Natural presence

11. Main steps of a systematic approach (3)

Implementation of the most relevant investigation techniques to successively confirm/eliminate the different hypotheses.

An approach based on risk analysis, in particular, to choose the most relevant investigation methods:

- Documentary checks (e.g. traders)
- Additional inspection on site (unannounced / announced)
- Additional sampling and analysis
- Additional information requested to the operator.

CB 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 products or substance relevant for compliance with organic production rules?

Q2: Is the analysis result reliable?

Q3: Is the sampling traceable, without risk of contamination and sealed?

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/subcontractor and the supplier/subcontractor 1., 2. & 3.

Detection of non-compliance / irregularity / infringement

Absence of non-compliance

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)]

Place the product on the market as organic

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.

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)]

Example 1: Glyphosate in green coffee found after import in the EU

- **Sampling result: Above LOQ, 0.025 mg/kg**
- **Sampling report available**
- **Traceability and mass balance on trading level compliant**
- **Hypothesis: Comingling with conventional coffee**
- **Case closed. Commingling risk confirmed by the third country certification body.**

Example 2: Anthraquinone in tea found after import in the EU

- **Sampling result: Above LOQ, 0.049 mg/kg**
- **Sampling report available**
- **Traceability and mass balance on trading level compliant**
- **Hypothesis: Direct drying of tea. Anthraquinone use in tea is extremely unlikely.**
- **Case closed. The drying method for organic tea is not regulated in the EU Organic Regulation.**

12. Documentation of investigation results

The documentation of investigation results needs to follow the requirements as laid down in Art. 29 of Reg. (EU) 2018/848.