

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

Brussels, 25 and 26 January 2024

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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Chapter 5: Systematic approach for investigations

Chapter 6

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6.2 Investigations conducted by the control bodies

6.3 Investigations conducted by the competent authorities

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OFFICIAL INVESTIGATION SCHEME

INPUTS

Substantiated information about the presence of non-authorized substance

Informed by an operator (art. 28.2)

CB detects non-authorized substances in organic products



Control Body



IMMEDIATELY

CARRY OUT OFFICIAL INVESTIGATION

PROVISIONALLY PROHIBIT:

- THE PLACING ON THE MARKET OF THE PRODUCTS CONCERNED AS ORGANIC PRODUCTS
- THEIR USE IN ORGANIC PRODUCTION

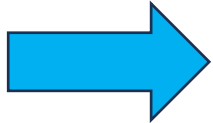
OFFICIAL INVESTIGATION SCHEME

AS SOON AS POSSIBLE - REASONABLE PERIOD

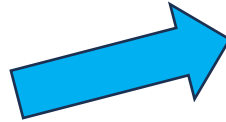
CASE COMPLEXITY

DURABILITY OF THE PRODUCT

CARRY OUT
OFFICIAL INVESTIGATION



DETERMINING
SOURCE AND
CAUSE OF
CONTAMINATION



INTEGRITY OF ORGANIC
PRODUCTS

COMPLIANCE OF THE OPERATOR

NOT USED NON
AUTHORIZED
SUBSTANCES

TAKEN PROPORTIONATE
AND APPROPRIATE
PRECAUTIONARY
MEASURES TO AVOID
CONTAMINATION

TAKEN MEASURES IN
RESPONSE TO
RELEVANT PREVIOUS
REQUESTS FROM
CA/CB

5.2.1 Actions in advance to be ready

Appropriate control measures and records

Operator files:

- description of proportionate and appropriate precautionary measures implemented;
- geo-location of the production units and premises

Inspections reports/records with:

- verification of precautionary measures implemented
- farming practices
- crop observation
-

Laboratory reports

Sampling reports:

- GPS tracker of sampling
- identification of sampling points/stage
- batch/lot

Storage of control samples:

- up to 1-1,5 years
- adequate place

Photo-reports:

- crops
- buffer zones
- storage/processing places
- sampling process
- consignments
- transport
- seed
- ...

Previous non-conformities/sanctions (last 3 years)

5.2.1 Actions in advance to be ready

Organizational measures

clear internal procedure
(e.g. Investigation procedure)

clear responsibility

trained personal for
official investigation

continuously increase
staff competence

available resources in place for:

- office activity
- inspection
- sampling activity



Short time

5.2.1 Actions in advance to be ready

Third Country CB

systematic documentary checks:

- the traceability of the products and ingredients (transparent flow chart for complex supply chains).
- the volume of the products of the consignment in line with the mass balance checks
- the relevant transport documents and commercial documents (including invoices)
- all relevant documents: the certificate of operators, records of the inspections, the production plan for the product concerned and records kept by the operators, transport documents, commercial and financial documents

art. 16 EU Reg. 2021/1698
art. 3 of EU Reg. 2021/2306

physical checks of:

- high risk products as defined in art 8 of EU Reg. 2021/1698
- high risk products according to the EU document for additional control measures in Third Countries (2024)
- consignments according to CB risk assessment

Travel Plan

any other document deemed relevant

**Before the consignment
leaves the third
country/origin**



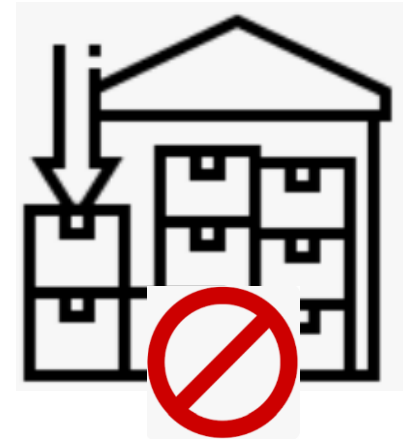
5.2.2 Information about presence of non-authorized products or substances

- Regulation 2018/848, Art. 29.1 where the control body
 - ✓ **receives substantiated information** about the presence of products or substances that are not authorized 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”
- ❖ CB checks if information is substantiated (reliable)
 - ✓ product or substance is relevant for compliance with organic production rules?
(→ not heavy metals, mycotoxines, microbiology etc)
 - ✓ sampling is reliable? → sample origin is tracked, who and when did sampling
 - ✓ testing is reliable? → laboratory is ISO/IEC 17025 accredited lab; residue >LOQ/LQ
 - ✓ can the laboratory result be traced back to the affected batch/consignment?



5.2.2 Information about presence of non-authorized products or substances

❖ CB informs Operator and “*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*” (Regulation 2018/848, Art. 29.1(b)), if applicable;



❖ CB may request to the Operator needed information (e.g. traceability with supporting documents) and ask to start its own investigation and provide results as soon as possible.

5.2.3 Starting official investigation process

- ❖ CB... “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)” (EU Reg. 2018/848, Art. 29.1(a))
- 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**. (EU Reg. 2018/848, Recital 69, Art. 29.1(a))
- ...the provision on the conclusion of the investigation as soon as possible constitute merely an exhortation to carry out the investigation **as quickly as possible, without delay**.” (COM, Ares (2022)7959596, 17.11.2022)



Investigation shall be started **immediately, without any delay**, same or next working day after receiving information, with **high priority**, to be carried and completed out **as quick as possible**, up to **30 calendar days for OFIS**, taking into account product durability (shelf life) and complexity of the case, including external communication, e.g. with other CB's involved



5.2.3 Starting official investigation process

The official investigation (by CB) shall be pursued by using appropriate methods and techniques, including those referred to in Article 14 and Article 137(3) of EU Reg. 2017/625 (=OCR)

The official investigation shall **at least conclude** on (Reg 2021/279, Art. 2.3):

- (a) the **integrity** of organic and in-conversion products;
- (b) the **source and the cause** of the presence of non-authorized products or substances;
- (c) the elements provided in Article 29(2)(a), (b) and (c) of EU Reg. 2018/848. The operator
 - ✓ has used or not **products or substances not authorised** for use in organic production
 - ✓ has taken or not taken the **precautionary measures**
 - ✓ has taken or not **measures in response to relevant previous requests** from the competent authorities, control authorities or control bodies.

1st priority: is mass-balance/traceability available?

Decide, if:

- documentary review
(if CB has all needed data)
- on-the spot inspection (announced or unannounced), if there is a need
(e.g. sampling)

information exchange with other
CBs/authorities

5.2.4 Investigation workflow

For efficient investigation, collecting information and records keeping, CB may use an
Investigation workflow document:

information about sampling

- who did sampling?
sample representative?
what represents?
- sampling competent?
(with ref to Reg. 691/2013,
Commission Directive 2002/63)
- sample transportation
official/controlled?

information about testing

- laboratory accredited
(ISO/IEC 17025:2017)?
accreditation of method/matrix?
- LOQ for the residue detected?
- MRL for the residue detected?

information about sample

- type of sampled product, e.g. grain, final product, green mass etc. (indicate stage of plant development)
- at which stage of production, preparation, storing or distribution, where exactly the presence of non-authorized products been was detected; for plant production, if the sample was taken pre- harvest or post-harvest (EU Reg. 2021/279, Art. 2.1 (d))
- processing ratio, if applicable (drying or concentration factor), to be considered, but not directly implemented

5.2.4 Investigation workflow

Information about detected substance

- *the type, name, quantity and other relevant information of the present non-authorized products or substances (EU Reg. 2021/279, Art. 2.1 (c)), e.g.:*
 - scope and period for possible use
 - systemic or contact?
 - substance or metabolite?
 - volatility? water solubility?
 - banned or still authorized for use in conventional production in country concerned and in the EU?
 - DT50, DT90 (dissipation time)
(COM “*The half-life can help estimate whether or not a pesticide tends to build up in the environment*”)

5.2.4 Investigation workflow

Information about detected substance

Other relevant questions:

- Is the analysed active substance relevant for application in the crop/product concerned, does its use make sense from an agronomic or technical point of view?
- Are there different possible uses/purposes for the active substance?
- Substance can naturally occur or be authorized for use in organic?
- Can substance be present due to environmental contamination and/or spray drift (transported by air, water or being transferred by handling in the food)?
- Can substance be persistent in the soil for long period?
- Used in combination with other active substances (in the same PPP) or in a spraying program? Etc.

5.2.4 Investigation workflow

information about the product/lot:

- the name of product,
- lot identification,
- product ownership and physical location (at the stage of investigation)
- whether the products concerned are still placed on the market as organic or in-conversion products or used in organic production (EU Reg. 2021/279, Art. 2.1 (a) (b))
- quantity of products affected, other products affected?

5.2.4 Investigation workflow

information about the product/lot:

Other relevant questions:

- Is traceability of the batch ensured?
- The homogeneity of the product sampled is highly relevant with regard to the evaluation and error analysis in the process: Is it a product blend?
- Are there possibilities for contamination in the product due to the “post harvest” product route
- What is the risk of the products where the presence has been detected?
- Any other samples or analyses are available for the concerned product?
- Control samples available?
- Have other samples been taken and analysed? What are the results of the analyses (if any)?

5.2.4 Investigation workflow

information about the operator

- whether other operators in the supply chain are affected? (EU Reg. 2021/279, Art. 2.1 (e))
- the results of previous official investigations on the organic or in-conversion products and concerned (EU Reg. 2021/279, Art. 2.1 (f)), (e.g. OFIS cases)
- Have the operators identified been involved in other non-compliance/suspicion of non-compliance/other problem raised cases in the last 3 years?
- Have the operators concerned been submitted to a specific control? (EU Reg. 2021/1698, Ann III)
- Risk of Operator? (according CB risk assessment),
- Only organic activity?

5.2.4 Investigation workflow

information about the operator

Other relevant questions:

- Is traceability of the batch ensured?
- Critical points identified and related precautionary measures to avoid contamination and commingling at all relevant critical points and the accompanying records to confirm implementation of precautionary measures.
- Verification of possible use of the relevant product/substance by the operator
- Verification of possible drift, both long range and short range have to be taken into consideration
- Method of application and availability of equipment?
- Does the operator use subcontractors to apply inputs? How does he verify that they arrived with clean equipment?

! Operator may prepare results of his own investigation, that can be taking into consideration

5.2.5 Decision making process

❖ CB Evaluates all the available information and formulates a hypothesis.

Possible hypothesis:

? use of non-authorized products or substances

? mixing or substitution/replacement with conventional

? contamination
(e.g. commingling, overspraying)

? environmental contamination (=pollution):

- indirect drift (via soil, water, air)
- historical pollution (DDT)

? natural occurrence

? laboratory false detection

? use of authorized inputs

5.2.5 Decision making process

❖ CB specifies hypothesis (source and cause) with arguments “for” and “against” each of hypothesis

❖ CB prioritizes hypothesis, some hypothesis to be excluded, with paying special attention to the hypothesis of “use of non- authorized product/substances”, as the first hypothesis to be checked

❖ CB makes conclusions, based on the most likely and argued hypothesis, about the source and the cause of the presence

➤ Investigation process can be facilitated with certain investigation policies for the most common detected substances

❖ CB detects imazamox + imazapyr in sunflower cake during physical check of consignment at the level of processor

Hypothesis	Arguments in favor	Arguments against
Non-authorized use of PPP by agricultural producer (supplier of raw material)	Operator grew special hybrids of sunflower, that are resistant to Imazamox and imazapyr, and designed for conventional technology (ClearField); in the area where Operator located, there is a problem with e.g. Orobanche Cumana (parasitic weed), it is the main scope of Imazamox and Imazapyr use	
Spray drift of PPP from neighbor fields	Low amount of detected substance (found in cake, not in oil)	Operator claimed he harvested separately the product from the buffer strip to avoid drift
Commingling/mixing with non-organic		Only organic activity; only organic products; separation between lots is well organized
Contamination during processing or transportation		Responsibility for transport of processor/buyer; precautionary measures against contamination are well implemented
Laboratory false detection		Eliminated by additional analyses

Conclusions: cause → non-authorized use by Operator; source → PPP

❖ CB received substantiated information (through OFIS and from CB of buyer/importer) about presence of bromides in grain of winter wheat

Hypothesis	Arguments in favor	Arguments against
Non-authorized use of PPP (soil treatment)		it used only for small scale farms, mostly with vegetables; Operator has no equipment for it; very rare practice in region.
Non-authorized use of PPP during cultivation (herbicides, desiccants)	there are 2 products with bromide allowed in the region	bromide was found in green mass of several crops of this Operator, samples were taken before possible desiccation; would cause higher residues; other active substance would be found (e.g. diquat)
Spray drift of non-authorized substances from neighbor fields		bromide was found in green mass of several crops of this Operator, samples were taken far from possible drift
Non-authorized use by during storage (fumigation)		bromide was found in green mass of several crops of this Operator; would cause higher residues; very rare practice for this substance; not allowed to be used in region
Natural occurrence	was found many times in different Operators from this location/region; was found in green mass of several crops of this Operator; there are scientific research confirm higher content of bromides in local soils	

Conclusions: cause → natural occurrence; source → soil

5.2.6 Conclusions and recommendations


Conclusions should include the following:

- ✓ status of “the **integrity** of organic and in-conversion products” = status of the related lot/consignment (possibly yield, unit, activity or Operator)
- ✓ information about “the **source and the cause** of the presence of non-authorized products or substances”
- ✓ Operator has **used or not products or substances not authorized** for use in organic production
- ✓ Operator has **taken or not the precautionary measures**
- ✓ Operator has **taken or not measures in response to relevant previous requests** from the competent authorities, control authorities or control bodies. (EU Reg. 2021/279, Art. 2.3)

*“A **non-conclusive investigation on the source and the cause** of the presence of non-authorized products or substances **can exceptionally be closed** if it is demonstrated explicitly by ... control bodies... - and assessed as satisfactory by the assessing competent authority - that, independently from considerations regarding time, all possible means of investigation have been exhausted.”*

(Ares(2022)7959596-17/11/2022)


5.2.6 Conclusions and recommendations



❖ CB defines corrective measures /recommendations for Operator, if applicable
(e.g. about preventive/precautionary measures, implementing organic risk management plan)

❖ CB communicates conclusions with Operator

➤ *The operator concerned shall be given an opportunity to comment on the results of the investigation (EU Reg. 2018/848, art. 29.3)*



❖ CB evaluates respond from the Operator:

- if not agree with conclusions: Operator should provide additional information and/or appeal
- if agree: information about measures to be taking/implemented (Action Plan) by Operator if any irregularities

❖ CB communicates with others involved parties for external cases
(e.g. CB of supplier/buyer, OFIS, CA)

5.2.6 Conclusions and recommendations

The control body shall keep records of the investigation it has carried out (EU Reg. 2018/848, art.29.3)

The control bodies shall draw up a final report for each official investigation (EU Reg. 2021/279 art 2.4)

That final report shall contain:

(a) the records of the specific elements;

(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.

❖ CB keeps chronology and records of investigation (for further investigations or external control)

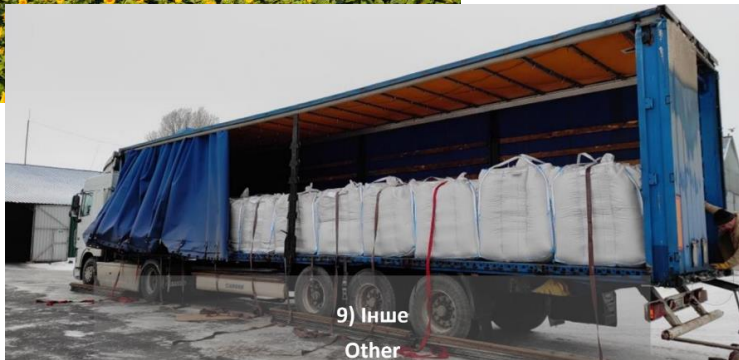
5.2.7 Follow up with the Operator

❖ CB reassess the **risk of the operator** (and risk of product, if applicable), based on the outcome of the investigation: might be that the risk is increased therefore also the control plan would need to be readjusted



- ❖ CB checks during next physical control and/or documentary control:
- what actions were taken on the operators and/or the products concerned?
 - to check if Operator removed reference to organic/in conversion, if applicable, in case of decertification/downgrading
 - verify if operator concerned took corrective measures as necessary to avoid future contamination (EU Reg. 2018/848, art.29.3)

AntiFraud Initiative



Thank you for attention!

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