„How do I proceed in case of a possible non-compliance with the Organic Regulation (Regulation (EU) 2018/848) according to Article 27 or Article 28 (2)?“

Quality Management Guide

Research Institute of Organic Agriculture (FiBL)| P.O Box 90 01 63 | 60441 Frankfurt am Main
Tel. +49 69 7137699-0 | Fax +49 69 7137699-9 | info.deutschland@fibl.org | www.fibl.org

Imprint

Publisher:	Forschungsinstitut für biologischen Landbau Deutschland e.V. [Research Institute of Organic Agriculture (FiBL)], Kasseler Str. 1a, 60486 Frankfurt am Main, www.fibl.org
Authors:	Dr. Alexander Beck (Office for Food Science & Quality), Marlene Ariana Milan (FiBL), Jana Furtwengler (FiBL)
Proofreading:	the English version was reviewed by Mirjam Schleiffer and Bernhard Speiser (FiBL)
Status:	November 2021

This guide was prepared within the framework of the project "Problem Analysis and Identification of Required Action in the Field of Pesticide Residues along the Organic Value Chain" (FKZ 2818OE078).

The project was funded by BMEL – the German Federal Ministry of Food and Agriculture – on the basis of a resolution by the German Bundestag. The project was sponsored by BLE – the Federal Office of Agriculture and Food – in the context of the federal programme Organic Farming and other Forms of Sustainable Agriculture (BÖLN).

Disclaimer

The guide sets out an informed understanding of the legal situation. It does not claim to be legally binding. It is intended to provide help with understanding and implementing the new requirements, in particular Articles 27 and 28 (2) of Regulation (EU) 2018/848, and to implement them in practice. The organic control bodies, the authorities and, ultimately, the courts decide whether the requirements are met. In practice, interpretations can change repeatedly. There is still no case law or administrative practice. The publisher and authors do not accept any liability for the information in this guide, in particular for its correctness, completeness and topicality.

Gefördert durch:

aufgrund eines Beschlusses
des Deutschen Bundestages

Content

1. Introduction

The new Organic Regulation (EU) 2018/848 specifies in detail the obligations and actions in the event of suspicion of non-compliance at company level. Article 27 regulates the handling of all kinds of possible infringements of the Organic Regulation. Article 28 (2), on the other hand, focuses on the presence of products and substances that are not authorised under the Organic Regulation. Both articles prescribe an almost identical systematic of the approach.

According to the new law, operators that suspect possible non-compliance with the Organic Regulation must carry out an investigation and decide whether the suspicion actually substantiates a violation. Where the suspicion has been substantiated or where it cannot be eliminated, the operator has to immediately inform the relevant competent authority, or, where appropriate, the relevant control authority and/or control body and fully cooperate with them in verifying and identifying the reasons for the suspected non-compliance.

Regulation (EU) 2021/279 sets out in detail what needs to be checked and how this report is to be made.

The present guide is divided into two parts. Part I addresses the legal stipulations and their interpretation and describes a possible sequence of checks and the procedure for reporting to the control body/authority and to the purchaser. Part II provides instructions on how to proceed if a suspicion on non-compliance is present (e.g., how to check whether the information can be substantiated and justifies a substantiated suspicion of non-compliance with the Organic Regulation).

Part I

2. Overview of the legal framework for assessing possible deviations from and non-compliance with the EU Organic Regulation (EU) 2018/848 in accordance with Articles 27 and 28 (2)

2.1 Legal classification

The requirements for handling deviations (possible non-compliance) under the Organic Regulation stipulate that operators are primarily responsible for assessing suspicious cases. The new EU Organic Regulation (EU) 2018/848 strengthens the responsibility of operators for such cases and clarifies the division of responsibility between control bodies/authorities and operators to the effect, that operators must carry out an investigation as a first step. Cases where the suspicion has been substantiated or where it cannot be eliminated must be reported to the control body or authority. This applies to all types of deviations (possible non-compliance) from the Organic Regulation.

The explanations below are based on the following essays and publications:

Beck A. (2018): *Die neue Bio Basisverordnung (EU) 2018/848 [The new organic basic regulation (EU) 2018/848*], LMuR 6/2018 S 221 – 228

Rombach M., Lach G., Friedle A., Eckert G., Schigulski S. (2020): *Manual Laboranalyse und Pestizidrückstände im Kontrollverfahren für Ökologischen Landbau [Manual - Laboratory analysis and pesticide residues in the control procedure for organic farming.],* Ed. Prüfgesellschaft ökologischer Landbau mbH Karlsruhe

Interpretations of the Reg. (EU) 2018/848 Art. 27-29

BÖLW (2019): *Interpretation der Artikel 27 bis 29, 41 und 42 in der neuen Bio-Basis-Verordnung (EU) Nr. 2018/848. Regeln zum Umgang mit Verstößen und Kontaminationen [Interpretation of Articles 27 til 29, 41 and 42 of the organic regulation (EU) No. 2018/848]*

AöL (2019): *Interpretation der Artikel 27 bis 29, 41 und 42 in der neuen Bio-Basis-Verordnung (EU) Nr. 2018/848< (2. Version) [Interpretation of Articles 27 til 29, 41 and 42 of the organic regulation (EU) No. 2018/848]*

2.2 Requirements for all types of non-compliance (Article 27)

According to Article 27 of Regulation (EU) 2018/848, an operator is obliged to proceed as follows if it suspects that a product it has "produced, prepared, imported or has received from another operator", i.e. is in its possession, does not meet the requirements of the Regulation:

Regulation (EU) 2018/848

Article 27

Obligations and actions in the event of suspicion of non-compliance

Where an operator suspects that a product it has produced, prepared, imported or has received from another operator does not comply with this Regulation, that operator shall, subject to Article 28(2):

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 verifying and identifying the reasons for the suspected non-compliance..

Where possible non-compliance is suspected, the operator must isolate the products concerned (Art. 27 a) and check (Art. 27 b), whether this suspicion substantiates a non-compliance with the requirements of the EU Organic Regulation.

If the suspicion is substantiated or if it cannot be eliminated, this must be reported immediately to the control body or the competent authority (Art. 27 d).

2.3 Requirements in the event of presence of non-authorised products and substances (Article 28 (2))

In recent years, there have been considerable implementation difficulties, particularly with regard to the presence of non-authorised products and substances. Therefore, Article 28 of the legislation focuses on the "presence of a product or substance that is not authorised [...] for use in organic production". In principle, it follows the same systematic as Article 27.

First, Art. 28 Paragraphs 1 and 2 clarify that only the presence of products or substances not authorised for organic production within the scope of Article 9 Paragraph 3 Subparagraph 1 of Regulation (EU) 2018/848 are subject to this article.

Article 28 (2) targets products that are intended to be "used or marketed" by the operator as organic or in-conversion products, i.e., the products are in possession of the operator.

Regulation (EU) 2018/848

Article 28

Vorsorgemaßnahmen zur Vermeidung des Vorhandenseins nicht zugelassener Erzeugnisse und Stoffe

…(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 Paragraph 3 for use in organic production in a product that is intended to be used or marketed as an organic or in-conversion product, that the latter product does not comply with this Regulation, the operator shall:

a) identify and separate the product concerned;

b) check whether the suspicion can be substantiated;

c) er bringt das betreffende Erzeugnis nicht als ökologisches/biologisches Erzeugnis oder Umstellungserzeugnis in Verkehr und verwendet es nicht in der ökologischen/biologischen Produktion, bis der Verdacht ausgeräumt werden kann;

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 or substances.

The term *"presence"* requires, in view of a practical implementation of the requirement and the preservation of proportionality, as also required in Article 28 (1)[1], a focus on suspicious facts that call into question the integrity of the organic product (e.g. irregularities that indicate the use of a non-authorised product or that precautionary measures have not been taken[2]).

In other cases, it can usually be assumed that the origin of the contamination is beyond the control of the operator (e.g. ubiquitous pollution, drift, continuous processes in which preventive measures are technically limited). *"Proportionality"* must always be considered in the measures to be taken.[3].

If information on a possible deviation from the Organic Regulation is available, it must first be checked whether this information is correct/relevant, e.g. whether a laboratory finding is relevant.

If the information is relevant, this constitutes a cause for *"suspicion"*. The *"presence"* (e.g. confirmed positive laboratory result) of a non-authorised product or substance must then be checked to determine whether there are reasonable doubts about the integrity of the product (Art. 28 (2) b)).

2.4 Examination sequence

The investigation pursuant to Art. 28 (2) (b) aims to determine whether the information available indicates a violation of the integrity of the organic goods due to the use of non-authorised products or substances and/or inadequate precautionary measures.

The **first step** is to check whether the **available information is relevant.**

If the information is relevant, the suspicion is confirmed and, in a **second step**, the operator must identify and isolate the product[4] until the case has been clarified.

The **third step** is to **check whether the "suspicion" substantiates a non-compliance with the Organic Regulation or whether this cannot be eliminated**. The former is the case if the contamination indicates the use of a non-authorised substance or product or the inadequate implementation of precautionary measures (Art. 28 (1)) under the control of the operator, or if there are indications of non-compliance with official instructions.

The *"suspicion"* suggesting possible non-compliance can also be eliminated or substantiated by evaluation according to the systematic approach set out in Article 28 (1) of Regulation (EU) 2018/848 in compliance with the requirements of Article 1 (1) of Regulation (EU) 2021/279.

The systematic approach and documentation established in the company in accordance with Article 28 (1) is part of what is inspected and verified by the control body. Ideally, this methodological procedure should be integrated into the operator's existing Quality Assurance (QA) specifications.

Article 1 of Implementing Regulation (EU) 2021/279 clarifies the obligations of operators in relation to Article 28 (2) of Regulation (EU) 2018/848 – Dealing with indications of non-compliance due to the presence of non-authorised products and substances: Such as the type of information to be taken into account in an assessment.

---

[1] Cf. Reg. (EU) 2018/848, Art. 28 (1) *operators put in place and maintain measures that are proportionate and appropriate to identify the risks of contamination of organic production and products with non-authorised products or substances, including systematic identification of critical procedural steps;*

[2] Cf. Reg. (EU) 2018/848, Art. 29 (2) a) and b)

[3] Cf. Reg. (EU) 2018/848, Recital 68

[4] Cf. Reg. (EU) 2018/848, Art. 28 (2) *"[...operators shall] not place the product concerned on the market as an organic or in-conversion product and not use it in organic production…"*

Regulation (EU) 2021/279

Article 1 (1)

(1) In order to check whether the suspicion can be substantiated in accordance with Article 28(2)(b) of Regulation (EU) 2018/848, the operator shall take into account the following elements:

a) where the suspicion of non-compliance concerns an incoming organic or in-conversion product, the operator shall check whether

i) the information on the label of the organic or in-conversion product and the information on the accompanying documents match;;

ii) the information on the certificate provided by the supplier relates to the product actually purchased;

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

According to this regulation, the operator must check the following information:

- the "*identity*" (e.g. designation, quantity, quality, etc.) of the product (a)i)),
- the organic certificate and its relation to the product ii) and
- the question of whether a cause for the finding that triggers the suspicion was under the operator's area of control or responsibility (e.g. relevant in the case of a finding during the final product inspection). This investigation can be carried out using the systematic approach for precautionary measures established in accordance with Article 28 (1).

This list limits the operator's legally specified obligations. These always concern products in the possession of the operator. This list specifically assumes that the successful organic certification of the supplier ensures compliance with all requirements of the Regulation, including the non-use of non-authorised products and substances, compliance with precautionary measures and official requirements.

Conversely, operators do not have to systematically check and document whether a supplier used non-authorised products or substances, has not taken precautionary measures or not complied with official requirements (Art. 29 (2), Regulation (EU) 2018/848), provided that the supplier can present a valid organic certificate and there is no suspicion of falsification of the certificate or of the identity of the product.

Many situations require that suppliers of products are informed of a suspicion by their customers and asked to comment. Involving the supplier's control body is advisable, depending on the case. Statements from suppliers and their control bodies can provide important information for deciding whether a suspicion is substantiated or can be eliminated. For example, the product may already have been checked and released again during an official inspection at the supplier level.

If the investigation reveals, that the suspicion is substantiated or cannot be eliminated, the operator has to notify the control body/authority (Art. 28 (2) d)) (Regulation (EU) 2018/848) (see next chapter). Cases of "*substantiated suspicion*".

If the investigation reveals that the "suspicion" of non-compliance with the Organic Regulation cannot be substantiated or can be eliminated, the product can be further processed by the operator and placed on the market. The case must be documented. The control body verifies the procedure and the documentation.

The procedure presented in Part II of this guide supports operators in assessing whether information of the presence of non-authorised products and substances substantiates possible non-compliance with the Organic Regulation, or whether this suspicion can be eliminated.

2.5 Reporting to the control body or authority and to the purchaser

If the operator's investigation substantiates the suspicion of non-compliance, this has to be reported to the control body/authority without unnecessary delay (Art. 28 (2) d)) (Regulation (EU) 848/2008). The operator is obliged to cooperate in clarifying the suspected case (Art. 28 (2) e) of Regulation (EU) 2018/848).

Article 1, Section 2 of Regulation (EU) 2021/279 clarifies how, in a **fourth step**, the operator has **to inform the control bodies or authorities about a substantiated suspicion or when a suspicion cannot be eliminated**.

Regulation (EU) 2021/279

Article 1

(2) When the operator informs the competent authority or, where appropriate, the control authority or control body in accordance with Article 28(2)(d) of Regulation (EU) 2018/848 about a substantiated suspicion or when the suspicion cannot be eliminated, the operator shall provide, if relevant and where available, the following elements:

a) information and documents about the supplier (delivery note, invoice, certificate of the supplier, Certificate of Inspection for organic products (COI));

b) the traceability of the product with the lot identification, stock quantity, and quantity of product sold;

c) laboratory results, from accredited laboratory when relevant and available;

d) any information about any previous suspicion with regard to the specific non-authorised product or substance;

e) alle Informationen über etwaige frühere Verdachtsfälle in Bezug auf das betreffende nicht zugelassene Erzeugnis oder den betreffenden nicht zugelassenen Stoff;

f) every other relevant document to clarify the case.

Obligations to inform actors in the organic supply chain, as defined under Article 1 (2) b) with regard to traceability, are based on the General Food Law Regulation (EU) 178/2002, and are limited to direct suppliers (see Art. 1 (2) EU (Regulation) 2021/279) and customers (see Art. 29 (1) d) iii) of Regulation (EU) 2018/848).

Article 39 (1) d) iii) of Regulation (EU) 2018/848 stipulates that in the event of a *"substantiated suspicion of non-compliance"* in accordance with Article 27 d) and Article 28 (2) d) that *"affects the integrity of those products"*, the buyer of the product must be informed without undue delay.

Regulation (EU) 2018/848

Article 39

Additional rules on actions to be taken by the operators and groups of operators

(1) In addition to the obligations laid down in Article 15 of Regulation (EU) 2017/625, operators and groups of operators shall:

a) keep records to demonstrate their compliance with this Regulation;

……

d) provide, in form of a declaration to be signed and updated as necessary:

…

iii) an undertaking

- to inform in writing and without undue delay buyers of the products and to exchange relevant information with the competent authority, or, where appropriate, 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.

……

The operator is obliged to inform the control body or control authority immediately in the event of a substantiated suspicion of non-compliance, as described several times and also repeated in Article 39 of Regulation (EU) 2018/848. Since it is not always easy for an operator to assess whether the integrity of a product has been "*compromised*" and also how to maintain "*proportionality*" when reporting to actors in the supply chain, the required notification to customers should be coordinated with the control body or control authority.

Part II

3. Implementation guide for organic companies

This part of the guide supports you to act in accordance with the requirements of Regulation (EU) 848/2018, and in particular Articles 27 and 28 (2) of this Regulation.

Note: The exact internal procedure in the event of a suspicion of non-compliance in accordance with Articles 27 and 28 (2) of Regulation (EU) 848/2018 must be appropriately defined within each company and verified by the control body. In particular, the size of the company and the type of production must be taken into account in order to maintain the principle of proportionality.

The following chapters propose a procedure for verifying information on non-compliance in accordance with Article 27 as well as a procedure for possible infringement triggered by the presence of non-authorised substances in accordance with Article 28 (2).

This second section focuses on plant protection active substances. This is due to the fact that this group of substances has, currently and in the past, the greatest need for clarification. However, non-authorised products and substances from other groups of substances governed by the Regulation, such as fertilisers, feedstuffs, additives, enzymes, adjuvants, etc., have the same relevance with regard to possible non-compliance with the Organic Regulation as plant protection active substances.

For a better understanding of the procedure and question lists, the following sections refer to various example cases, which are presented in the Appendix. It is worth reading the examples, as they provide an insight into the procedures in practice.

3.1 Procedure for all types of possible violations of the EU Organic Regulation according to Article 27

Step 1

The information and source of information about possible deviations from the requirements of the EU Organic Regulation must first be checked to see whether these are relevant.

To do so, ask yourself the following questions:

- Is the information source trustworthy?
- Do competition issues in relation to the informant or the products come into play?
- Can the information be "confirmed" as such? (Example 1)
- Is more detailed information and data available on suppliers, products or processes, (e.g. information on origin, organic certification)?
- Is the traceability and thus the identity of the products ensured?

⇩

Step 2

If the information proves to be relevant, there is a cause for *"suspicion"* pursuant to Article 27 and the products or processes concerned are identified and isolated.

Subsequently, it must be clarified whether this *"suspicion"* substantiates non-compliance with the Regulation, or whether the "suspicion" can be eliminated.

To do so, ask yourself the following questions: (Example 2)

- Does the "suspicion" call into question the "organic integrity" of the goods or the process, i.e., would the violation possibly suggest the withdrawal of the organic status of the goods according to Art 42 (1) of Regulation (EU) 848/2018 (e.g., stocking density in the barn is too high)?
- Is there any further information available that supports or eliminate the suspicion or can further information be ascertained? (Example 3)

If the investigation shows that the "suspicion" is substantiated or cannot be eliminated and is relevant, the operator reports the suspicion to the competent authority or the control body and provides all available information. (Art. 27 d) and e) of Regulation (EU) 2018/848)	If the investigation process reveals that the information is not relevant, or that the "suspicion" is irrelevant to the organic integrity of the product, the product can be processed or placed on the market. The process must be documented. This documentation serves as verification of proper inspection and documents the arguments and facts with which the suspicion was eliminated. (Art 27 c of Regulation (EU) 2018/848)

3.2 Procedure and special recommendations in the event of presence of non-authorised products and substances in accordance with Article 28 (2)

Step 1

As a first step, it must be verified whether the information available is relevant. It may be advisable for operators to consult an association, consultant, laboratory or control body to clarify this.

This check is carried out in three steps:

a. First, clarify whether the product or substance found is subject to the authorisation requirement under Art. 9 (3) 1) of the Organic Regulation (e.g. as active substances to be used in plant protection products, fertilizers, food additives and processing aids) or affects its principles. If this is not the case, there is no need for action with regard to Art. 28 (2) Regulation (EU) 2018/848.

b. Check the relevance of the finding/information. Depending on the available information, this step can be carried out very quickly. (Example 4)

Questions related to laboratory results that help verify their validity;

- Can the laboratory result be traced back to the allegedly affected batch? (Example 6)
- Is any information about the sampling available?
- Does the sampling information technically meet the requirements (procedure and documentation, including a photo)?
- Is a counter sample available?
- Is the laboratory suitable for the relevant analysis?
- Is the reporting limit appropriate? Values below the reporting limit are not reliable.
- Is the accuracy of the results, including fluctuation range, correctly reported?

How do you assess the suitability of a laboratory?

- Is the laboratory accredited for the combination of sample (matrix) and method according to the current version of DIN EN ISO IEC 17025?
- Was a suitable method used?
- Does the laboratory have experience with this matrix – substance combination? (Initial findings or previously unknown matrices occasionally lead to incorrect findings; these should be specially validated)?
- In the case of findings with complex residue definitions: was the result correctly stated (sum marked as such, all individual components listed, correct calculation of the sum)?
- In the case of findings of substances that have different sources of entry (e.g. phthalimide, anthraquinone, phosphonic acid, dithiocarbamates) is this fact taken into account in the assessment?
- If applicable: is the laboratory a member of a quality circle or listed for certain associations or similar (e.g. BNN-Monitoring, QS, DeLOG, relana ®)?

c. Exclusion of false positive results

To exclude false positive results, proceed as follows:

- Analyse counter sample in second laboratory.
- Commission a second expert opinion in accordance with Article 35 of Regulation 2017/625.
- Or, take a new sample with representative sampling – possibly with a tiered check.

⇩ ⇩

If steps 1 a), b) and c) confirm the relevance of the information, there is cause for "suspicion" according to Article 28 (2). Go to step 2.	If the finding/information turns out to be invalid or false positive, this situation is documented and the products are processed/traded.

Step 2

If the result is confirmed, there is a **suspicion of non-compliance under Article 28 (2)**. In this case, the product has to be **identified and isolated** – if this has not already been done in Step 1.

Step 3

The third step is to verify whether the products and substances found indicate the use of a non-authorised substance or product, inadequate precautionary measures and/or non-compliance with other process criteria of the Regulation.

First of all, the requirements of Article 1 (1) of Regulation 2021/279 must be worked through.

According to Art 1 (1) of Regulation (EU) 2021/279, **at least** the following must be checked:

- The operator is at least obliged to check whether the information on the label of the organic product and the information on the accompanying documents match, and whether the certificate provided by the supplier relates to the product actually purchased. (Art. 1 (1) a))
- The operator also checks whether the cause of the presence of non-authorised products or substances lies under the control of the operator. If this is the case, the operator shall examine all possible causes. (Art. 1 (1) b))
- In addition to the requirements of Regulation (EU) 2021/279, it makes sense to follow up with the supplier and/or its control body and to ask them about the problem.

In many cases, the assessment of whether a suspicion is substantiated or can be eliminated will, depending on the situation, be clarified quickly. In other cases, a closer look is required in order to examine a suspicion as to whether it substantiates non-compliance with the Regulation, or whether it can be eliminated. For many operators, it is advisable to consult an association, consultant, laboratory or the control body[5].

Very often, information indicating a possible suspicion is revealed during the inspection of incoming goods. After checking for relevance, a suspicion can be raised pursuant to Art. 28 (2). This must then be verified in accordance with the requirements of Article 1 (1) of EU (Regulation) 279/2021. However, it should be noted that a product only triggers a procedure according to 28 (2) if the procuring company is in possession of the product. If, during the sampling of goods (procurement of goods taken into consideration - no possession of the goods), information appears that indicates a possible suspicion, the supplier of the product and, if applicable, its control body must be informed. This supplier then has information that may trigger a suspicion in accordance with Article 28 (2).

For a more differentiated assessment (Art. 28 (2) b)) of the contamination in a (raw) commodity with the aim of evaluating whether the suspicion is substantiated or can be eliminated, the following questions can serve: (Examples in Appendix I)

On using the substance or product:

- Does using the analysed active substance make sense for application in the culture or food concerned, i.e., does its use make sense from an agronomic or technical point of view?
- Are there different possible uses/purposes for the active substance?
- What other sources of the active substance are possible?
- Are several/additional substances detectable that make an application or a conventional origin probable?

On traceability and batch

- Is traceability/transparency of the batch ensured? Does the operator have any relevant data?
- 6. The homogeneity of the raw material is highly relevant with regard to the evaluation and error analysis in the process: Is it a product blend? If yes:

  a) is it a product blend of only one supplier?

  b) is it a product blend of many suppliers?

  c) is it a product blend from one region or many different origins?

  d) if many suppliers are involved and/or c applies, is it possible to identify the various origins? Can possible impurities be assigned to one or more of the origins?

- Are there possibilities for impurities in the product due to the product route e.g. by:

  a) contact materials from transport and storage sites or contact with conventional goods?

  b) different possible uses of the active substance in the supply chain (plant protection, storage protection, disinfection...)?

[5] The control bodies can also be contacted and involved in this process. In accordance with the requirements of Article 29 of the Organic Regulation, control bodies can support operators in deciding (Art. 27 c) Art. 28 (2) c)) whether or not the relevant information substantiates the suspicion of non-compliance (or the suspicion cannot be eliminated). This is not a report to the control body.

On concentration and its classification:

- Are comparative data available on the specific product or process with regard to the active substance findings and the product or process concerned?

  a) in the supply chain?

  b) or within the company from the same or different origins?
- Does the level of the active substance found indicate a possible application or non-compliance with due diligence obligations in production, transport and processing, or is this an indication of, for example, carry-over or drift?
- Which processing factors have to be taken into account? (EFSA https://zenodo.org/record/1488653#.YNBWg0xCRPY // BFR https://www.bfr.bund.de/cm/343/bfr-datensammlung-zu-verarbeitungsfaktoren.pdf)
- Are there specifications in the operator's internal Quality Assurance QA and external comparative values, e.g. from monitoring programmes, available?
- What is the Maximum Residue Level (MRL) for the residue?

  a) is the concentration below the general precautionary value of 0.01 mg/kg (Reg. (EC) 396/2005)

  b) is the concentration below the reporting limit?[6]
- Are there any further data and analysis results available from the supplier?
- Are any expert opinions available from relevant organisations or authorities that help classify the findings? www.qm-votum.bio , residues.fibl.org , www.authent.bio

⇩	⇩
If the investigation shows that the "suspicion" is substantiated or cannot be eliminated and is relevant, the operator reports the suspicion to the competent authority or the control body and provides all available information. (Art. 27 d) and e) of Regulation (EU) 2018/848)	If the investigation process reveals that the information is not relevant, or that the "suspicion" is irrelevant to the organic integrity of the product, the product can be processed or placed on the market. The process must be documented. This documentation serves as verification of proper inspection and documents the arguments and facts with which the suspicion was eliminated. (Art 28 (2) c) of Regulation (EU) 2018/848)

[6] In Guidance Document SANTE/12682/2019, the EU Commission defines the term Reporting Limit (RL) as the lowest value at which residues are reported as an absolute number. The reporting limit is equal to or higher than the limit of quantification (LOQ) and should be reliably guaranteed by laboratories over a period of 12 months.

4. Appendix - Examples

The following examples illustrate process flows and practical questions for different types of businesses. These relate to operators that produce, manufacture or distribute organic food. The appropriateness of the procedures described cannot be conclusively assessed due to the diverse corporate contexts.

Example 1

A butcher is informed by a worried customer that he has the impression that the poultry at their organic supplier XZ looks very bad, does not have enough outdoor access and that the outlet flaps are never open. The butcher knows the supplier personally. He immediately visits the supplier unannounced to get an impression of the situation on-site. He interrogates the supplier and consults with the control body as to whether the poultry farmer has any difficulties.

It turns out that everything is in order on the farm and that the customer giving the information is a neighbour of the farmer who is in a dispute with the farmer about odour nuisance.

Based on these clarifications, the information is not considered to be relevant and will be filed.

Example 2

The egg producer XYZ keeps 400 chickens in mobile stalls and buys organic supplementary feed for her animals, which is regularly delivered in bags from the ABC feed mill. For every delivery, she checks that the delivery documents, including the tags of the bags, match the invoice. Sheregularly checks that the feed mill's organic certificate is up to date via www.bioc.info. She also randomly inspects the goods and checks their appearance and smell.

In one delivery, the delivered batch shows clear deviations in smell (different) and appearance (significantly darker) compared to the previously delivered goods. A comparison with remaining stocks from the previous delivery clearly confirms the discrepancies.

Situation 1

Farmer XYZ checks the delivery papers and the organic certificate again and determines that all the information is correct and that the goods can be clearly assigned.

However, in order to make absolutely sure and to comply with her duty of care, farmer XYZ calls the feed mill ABC and confronts the responsible employees with her observations. They answer without hesitation and explain that the sensory deviations are due to a new batch of an organic ingredient in the feed with significantly different sensory properties, but with the same feed value. They send a photo of the raw materials via a messenger service, as well as information on the organic certification of the raw material, and invite the farmer to take a look at the raw materials herself on the farm.

The farmer is reassured, documents the information and makes a small memo about the process. The next day, she feeds her chickens the new feed.

Situation 2

Farmer XYZ checks the delivery papers and the certificate again and determines that all the details are correct and that the goods can be clearly assigned.

However, in order to be absolutely sure and to comply with her duty of care, farmer XYZ calls the feed mill ABC and confronts the responsible employees with her observations. They react irritated. More detailed inquiries are not answered and the feed mill categorically rejects that there is anything wrong with the feed. The farmer does not receive a plausible explanation or evidence that could explain the difference.

Farmer XYZ remains very uncertain. She therefore reports the incident to her control body. She does not use the feed for the time being. She still has some in reserve from the previous delivery, and tries to get a replacement delivery immediately.

Example 3

A tea producer produces aromatic flavoured tea. Organic orange oil is added to an organic black tea. The finished product is organoleptically tested, and the output and input quantities are compared. The sensory test reveals a strange odour that is strongly reminiscent of mint. The goods are consequently not approved and blocked. The production logs do not indicate the manufacturing of a mint flavour-based item. The cleaning of the production plant(s) was also confirmed and the calculated input-output quantities are identical. Investigations in the production facility showed that, for reasons of space, the warehouse manager has stored a pallet of conventional peppermint leaves in the production rooms. A violation of the Organic Regulation is therefore not suspected.

Example 4

A tea producer produces a flavoured tea. Organic orange oil is added to an organic black tea. The finished product is organoleptically tested, and the output quantities are compared with the input. The sensory test reveals a strange odour that is strongly reminiscent of mint, and green flakes are also noticeable in the product sample. The goods are consequently not approved and blocked. The production logs document the production of a conventional Moroccan mint tea on the same plant in the morning of the same day. The output quantities are also 5% higher than the calculated input quantities. The initial suspicion arises that the flavoured tea was contaminated through mixing. As a result, samples of each container of flavoured tea are tested and non-authorised substances are found in the first two of twelve containers.

The suspicion that cleaning after the production of the mint tea was inadequate is confirmed, and non-compliance with the Organic Regulation cannot be excluded. The process is reported to the responsible control body, which revokes the organic status of the two affected containers and confirms the status of the other ten for reasons of proportionality.

Example 5

A trading company sells flavoured sweets from a variety of manufacturers. Comparable products show significant price differences.

Through written contact with a test magazine, the company becomes aware that the price difference could be due to the flavours used and that these may not be legally compliant in individual products.

The test magazine provides extensive evidence and indicates that the flavours used are flavours that are to be classified in accordance with Article 16 (5) and (6) of Regulation EU 1334/2008, and that they are therefore not authorised for organic foods. A more detailed examination of the documents submitted and the information provided by the supplier on the composition of the products, as well as consultation with the in-house experts, confirms the assumption.

The company immediately takes the goods off the market and informs its control body.

Example 6

The QA department of company XZY is confronted by a customer with an analysis report showing increased levels of the storage protection agent pirimiphos-methyl. Neither the sampling report nor any other information indicates which product and which batch the analysis relates to. References to the goods of the company were only made in the email sent by the customer.

The responsible person in the QA department of the company XZY explicitly asks the customer for the associated sampling protocol and proof that this analysis result actually relates to the goods delivered by company XZY. Since no clear reference to the origin of the goods delivered can be made in the transmitted sampling protocol either, the QA department of company XZY suspends the investigation. This is communicated to the customer and at the same time he is informed about the complaint-free investigations commissioned by the company XZY on the delivered lots.

Example 7

A tea producer receives an analysis report from a control body on a batch of black tea from India that is in his warehouse. The laboratory commissioned in India has detected a non-authorised substance.

The tea producer has examined the tea himself upon arrival and did not detect the substance. Also in previous batches the substance had never been detected. He lets the control body take a counter sample and analyse it in his laboratory. The substance is also not detectable in the counter sample.

The result makes the tea producer suspicious and he begins to investigate the incident more closely. To do this, he asks the control body to check the type of sampling and the accreditation of the testing laboratory. The control body determines that the Indian laboratory is not accredited for examining tea products. The Indian laboratory specialises in fruit and vegetables and does not have the experience and equipment to meet the specific requirements for testing tea products. In addition, the analytical methods used are not suitable for testing tea. They do not correspond to the EU's testing regulations. A sample was sent to the Indian laboratory for analysis, but it was not a representative sample, but a taste sample. The assignment of the taste sample is unclear: it cannot be assigned to the batch, nor is the origin of the sample traceable in any way.

The control body withdraws the analysis results from the Indian laboratory and all decisions made based on them, and recognises the result of the counter sample. The organic status of the goods is thus confirmed.

Example 8

A herbal tea producer carries out a pesticide analysis upon arrival of. The laboratory analysis reveals 0.03 mg/kg of the active ingredient carbendazim in the delivery of organic chamomile tea from Egypt. The herbal tea producer blocks the goods. The herbal tea producer purchased the goods directly from the producer and therefore asks the agricultural expert, whether the substance carbendazim is used in chamomile crops and in which use-cases carbendazim is used.

The organic chamomile tea producer knows his business and provides the following information:

Carbendazim is a fungicide used against fungal attack in fruit and vegetables. In chamomile crops, however, treatment with carbendazim is neither necessary nor useful.

The organic camomile field is located in a region with many conventionally farmed orange plantations. Fungal infestation is a problem in orange plantations, which is why the fungicide carbendazim is used.

The chamomile tea producer knows that carbendazim is used in the orange plantations with a maximum permissible amount of 0.2 mg/kg. He therefore regularly carries out carbendazim analyses on representative samples of fresh chamomile.

He has the analyses carried out by an accredited laboratory. The laboratory regularly finds slight traces of carbendazim, especially in the detection limit range of 0.007 mg/kg. Carbendazim is transported through the air via wind drift and is also deposited on the organic chamomile plants.

Drying the chamomile has the effect of concentrating the traces of carbendazim. A concentration factor of 4 is realistic according to the stage analyses carried out.

If levels of 0.007 mg/kg are found in the fresh raw material, the drying process leads to a concentration in the chamomile and levels of 0.03 mg/kg carbendazim are detected.

The producer has had samples of his chamomile fields examined in the region for a number of years (including dried goods). The test results are in the order of magnitude listed above. He makes this information on unavoidable contamination levels available to the herbal tea producer.

Based on the information provided by the chamomile producer, the herbal tea producer does not see any reason for suspicion of non-compliance with the Organic Regulation in relation to the delivered organic chamomile tea. The information is comprehensible and the organic integrity of the goods is guaranteed. The herbal tea producer releases the goods based on the information available.

Example 9

Before a batch of black tea from India is purchased, the supplier's organic certificates and the supplier are checked as part of the internal risk assessment procedure. The supplier has been in business for many years, and the risk is classified as "low". After receiving the pre-shipment sample from India, the batch is checked for pesticides in the laboratory.

The analysis shows the following:

Anthraquinone 0.023 mg/kg

Cypermethrin 0.014 mg/kg

Folpet/phthalimide total: 0.39 mg/kg

The identified cypermethrin residue means that it is not possible to simply release the batch for shipping. According to internal instructions, all residues found above 0.01 mg/kg must be investigated. Due to this irregularity and a given initial suspicion, the importer makes the results available to the supplier and asks for a detailed statement on the cypermethrin residues. In a written statement, the supplier states that this substance is used frequently and intensively in conventional cultivation, and therefore wind drift could potentially contaminate non-target areas to a lesser extent.

The importer's residue assessment system does not require any further investigation on anthraquinone and folpet, because it has already been scientifically verified that these findings cannot be clearly attributed to active use during cultivation or a lack of precautionary measures.

The supplier's statements are conclusive and plausible and the investigation is clearly recorded, wherefore the batch can now be approved for shipping and the initial suspicion is eliminated.

Example 10

Before a batch of green tea from China is purchased, the supplier's organic certificates are checked and the supplier is classified according to the internal risk assessment procedure. As no goods have been purchased from this supplier so far, he is assigned to the "increased risk" category. After receiving the pre-shipment sample from China, the batch is checked for pesticides in the laboratory.

The analysis shows the following:

Anthraquinone 0.023 mg/kg

Cypermethrin 0.014 mg/kg

Glyphosate 0.018 mg/kg

Lambda-cyhalothrin 0.004 mg/kg

Folpet/phthalimide total: 0.39 mg/kg

The importer's residue assessment system does not require any further consultation on anthraquinone and folpet, because it has already been scientifically verified that these findings cannot be clearly attributed to active use during cultivation.

The identified residues of the other substances mean that the batch can't be simply released for shipping. According to the company's internal work instructions for other active ingredients, any residues above 0.01 mg/kg must be investigated. Due to this irregularity and an initial suspicion, the importer makes the results available to the supplier and asks for a detailed statement on the three other pesticide findings (glyphosate, lambda-cyhalothrin, cypermethrin). In a written statement based on the supplier's investigations, the supplier describes that these substances are used frequently and intensively in conventional cultivation, and therefore wind drift could potentially contaminate non-target areas to a lesser extent. The supplier's statements seem very general, a possible source of contamination was not investigated any further and the records are inconsistent, which reinforces the suspicion of conventional raw material entry (admixture). The batch is rejected and not shipped, the contract is cancelled. Reporting the incident to the responsible control body is optional in this case, since the goods were not yet owned by the importer.

Example 11

A control authority in country XY makes a complaint about a sample of tea bags from a local tea brand based on the following pesticide findings:

Anthraquinone 0.018 mg/kg

Cypermethrin 0.014 mg/kg

Glyphosate 0.008 mg/kg

The producer is instructed to immediately suspend sales and is asked to comment, as there is an initial suspicion of non-compliance with the Organic Regulation. The manufacturer of the tea bags procures the goods from an importer and presents the importer's valid organic certificate. He can also rule out contamination within his company by means of cleaning protocols of his filling systems and batch traceability protocols. The incoming goods inspection also found the supplier documents to be correct. It is therefore concluded that the problem lies with the raw material and the importer is contacted.

In his statement, the importer describes his extensive residue assessment system and his organic certificate proves that it has been audited. The importer's internal residue analyses are compared with the analysis of the control authority and only minor deviations can be found within the analytical variance. This does not substantiate the suspicion of non-compliance for the importer, and he refrains from blocking his remaining stocked goods.

(Scenario A) The control authority accepts the statement, can eliminate the suspicion and approve the goods again.

(Scenario B) The control authority does not accept the statement: a legal dispute ensues.

Example 12

A herbal tea producer carries out a pesticide analysis when upon arrival of goods. In the analysis of the delivery of organic rooibos tea from South Africa, the laboratory found the substance iprodione at a level of 0.285 mg/kg. The legal maximum amount (EC 396/2005) for iprodione in dried herbal teas is 0.1 mg/kg. The herbal tea producer blocks the goods.

With a finding of this magnitude, the herbal tea producer suspects that the non-authorised substance iprodione was used. He therefore reports the findings to the control body.

The control body investigated the incident and determined that iprodione had indeed been used in a non-authorised manner. The producer didn't know the substance was banned. The goods were decertified.