Good Implementation Practices
for Articles 28 and 29 of Regulation (EU) 2018/848

2024

A Vade Mecum on Official Investigation in Organic Products






IMPRINT

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INTRODUCTORY REMARKS

The objective of this Vade mecum is to provide a practical and operational document to support an official investigation which should be carried out where the control authority, control body or the competent authority receives substantiated information about the presence of products or substances that are not authorised for use in organic production pursuant to the first subparagraph of Article 9(3) of Regulation (EU) 2018/848.

These substances or products include:

- active substances in plant protection products
- fertilisers, soil conditioners, and nutrients
- food ingredients
- food additives
- feed material
- feed additives
- processing aids
- products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production
- products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding
- products for cleaning and disinfection in processing and storage facilities.

In order to propose an operational and structured approach, the different chapters of the Vade mecum concentrate on the presence of substances from plant protection products, which currently represent the vast majority of the cases notified in OFIS. However, the tools and methods proposed are also pertinent to the official investigations related to the other products or substances.

To keep the Vade mecum simple, most of the chapters focus on plant protection products in organic food. For organic feed and seeds, similar considerations apply.

PREFACE

Editorial Board[1]

The question of the presence of "non-authorised products and substances" (currently mostly pesticide detections) in organic products was one of the main sticking points in the discussions on the new EU organic regulation applicable from 1 January 2022. The compromise found[2] is based on three main points:

- An organic product could contain residues.
- When a control authority, control body or competent authority receives information about the presence of non-authorised products or substances suggesting a non-compliance 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 organic if the official investigation concludes that an operator has used non-authorised products or substances, has not taken the appropriate precautionary measures to avoid the risk of contamination, or has not taken measures in response to relevant previous requests from the competent authorities, control authorities or control bodies.

Operators in the organic food chain must take appropriate precautionary measures under their control to prevent contamination with non-authorised substances and products. A systematic approach on how to minimise such contaminations and how to act in the event of their presence is needed. This systematic approach must be assessed by the control authorities/control bodies and is therefore a new and crucial element in the protection of organic integrity. Beyond this, operators involved in organic production must comply with many other objectives to ensure compliance with the EU regulation.

Residue analyses (in particular pesticides analyses) have taken a central place in the control and certification of organic products during recent years. A laboratory result is considered to be of tangible and quantifiable nature; presence of pesticide residues is a sensitive topic.

After two years of implementation of the new regulation, the issue has generated numerous reactions and discussions. What are the concerns? There are pesticides everywhere; frequently we cannot determine their origin; a systematic investigation is burdensome, expensive and often long-lasting; residue findings lead to blocking of goods and thus create uncertainty in the entire trade chain; it could be problematic to block all affected products while waiting for the results, especially for perishable products.

What behaviours do we see emerge? On the side of trade, we observe a tendency to accept only residue-free organic products to avoid the burden and cost of an investigation and the risk of the product being blocked. On the side of control actors, the temptation may be to quickly conclude that contamination is caused by a natural presence or an accidental contamination, even if that conclusion is based on insufficient evidence or that convincing elements on such a source and cause is lacking.

This situation presents multiple risks. Some operators (importers, processors, traders) could turn away from organic (too complex, risk of blocking the product, etc.). On the other hand, if the focus on residues is overdone there is a risk that the core element of organic, the process-oriented quality approach is undermined. Finally, it should be remembered that determining the source and cause of

1 Lea Bauer, Alexander Beck, Sergiy Galashevskyy, Jochen Neuendorff, Tom Nizet, Roberto Pinton, Bernhard Speiser and Nicolas Verlet (see Annex I)

2 Reflected in Articles 28 and 29 of Regulation (EU) 2018/848

the contamination with a reasonable degree of certainty is also key to reinforce organic integrity – identifying prohibited use of non-authorised pesticides or commingling of organic products with non-organic products with a view to maintaining consumer confidence in products labelled as organic.

There will be no short-term modification of the legislative framework and of the compromise reached on the presence of pesticides, and in any case not before the presentation of a report by the Commission on the implementation of the measures related to the presence of non-authorised substances[3], scheduled for the end of the year 2025. Thus, until at least 2026 the current regulatory framework will apply. It is important to approach future discussion on the report and a possible legislative proposal after having fully taken stock of the implementation of the current regulation and explored the avenues for improvement based on its effective implementation.

Regarding these avenues for improving current practices, there are significant opportunities to explore investigation methods as the most obvious way to resolve a large part of the difficulties encountered while still respecting the legislative framework. It is a matter of finding the right balance to implement investigation methods that are compatible in terms of duration, practicability and cost to meet the constraints of operators and the market requirements while at the same time making it possible to effectively detect fraud / intentional use or inadequate precautionary measures and to arrive at fact-based conclusions on the sources of accidental contamination.

Relevant work and reflections have already been carried out on the subject. There are many publications available on investigation techniques (sampling, analysis, mass balance, case studies, etc.), but these are scattered and not structured in a comprehensive, operational document. The objective of this project on official investigation is to propose an organised and operational approach for official investigation related to the presence of non-authorised substances, making the best use of the expertise, experience, skills and scientific data acquired by all the actors involved.

This Vade mecum does not reflect the views of any particular organisation. The elaboration and publication of this work has been monitored by a steering committee with members from different backgrounds and countries. The drafting of the chapters has benefited from the long-standing professional experience of the authors. The members of the steering committee and the authors are fully involved in the organic sector in different capacities, both through their professional occupation (production, industry, control body, research sector, competent authority...) and through their participation in professional organisations in the sector. However, all contributed to the development of the Vade mecum individually and in their own name.

The Vade mecum does not intend to present any position. It has a purely technical nature and offers a toolbox and structured methodology to facilitate the implementation of the EU organic regulation, in particular the Articles 28 and 29 of Regulation (EU) 2018/848.

[3] Article 29(4) of Regulation (EU) 2028/848

CHAPTER 1: THE MOST COMMON CONTAMINANTS FOUND IN FOOD AND ORGANIC PRODUCTS

Rosi Fritz[4], Norbert Fuchsbauer [5], Christine Gonzalez[6], Julie Marchand [7], Rodolphe Vidal[8]

1.1 Introduction

The purpose of this chapter is to provide a comprehensive overview of the presence of pesticides in agricultural products, comparing conventional and organic products. The goal is to objectively compare the two production systems whenever possible. This is a challenging task due to the limited availability of data. The data primarily comes from the European Food Safety Authority (EFSA) which is extensively referenced in this chapter. In addition, other studies representing smaller geographical areas or specific products have been used to provide more detailed information on the substances and their contamination levels. The exercise faces methodological constraints in accurately reflecting the precise situation of the organic sector, which this chapter addresses:

- Contamination statistics for organic products include substances that may have different sources. Contamination can come from prohibited practices (use of pesticides by operators, commingling with conventional products). In other cases, the substances identified by laboratory analysis may originate from environmental contamination, could be naturally present in the plant, or be metabolised during processing.
- In the EFSA statistics, the results aggregate both unauthorised substances and plant protection products authorised by the organic regulation.
- Dried or processed products frequently could have a higher residue level than the original raw product. To address this issue, a processing factor may be applied (this aspect is developed in more detail in Chapter 4).

1.2 Overview of contamination in food

1.2.1 Contamination level of food in general at the EU level

We are living in a world where pollution is widespread and is estimated to cause 9 million deaths (16% of all deaths globally) (Fuller et al.[9]). A significant portion of this pollution comes from plant protection products used in agriculture. These chemicals can also be found in food which is ingested.

EFSA reports contamination frequencies among Member States annually through two programmes: the EU Multiannual Control Programme (EU-MACP) and the Multi-annual National Control

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This article exclusively reflects the personal opinions of the authors.

[9] Fuller, R., Landrigan, P.J., Balakrishnan, K., Bathan, G., Bose-O'Reilly, S., Brauer, M., Caravanos, J., Chiles, T., Cohen, A., Corra, L., Cropper, M., Ferraro, G., Hanna, J., Hanrahan, D., Hu, H., Hunter, D., Janata, G., Kupka, R., Lanphear, B., Lichtveld, M., Martin, K., Mustapha, A., Sanchez-Triana, E., Sandilya, K., Schaefli, L., Shaw, J., Seddon, J., Suk, W., Téllez-Rojo, M.M., Yan, C., 2022. Pollution and health: a progress update. The Lancet Planetary Health 6, e535–e547. https://doi.org/10.1016/S2542-5196(22)00090-0

Programmes (risk-based control plans). The 2021 EFSA pesticide monitoring programme report[10] illustrates that 13.845 samples were taken in the EU Member States, Iceland and Norway for the EU-MACP. The samples originated from domestic production (53,3% of samples), from other EU member states (22,8% of samples) and third countries (19,6%). 4.3% were of unknown origin.

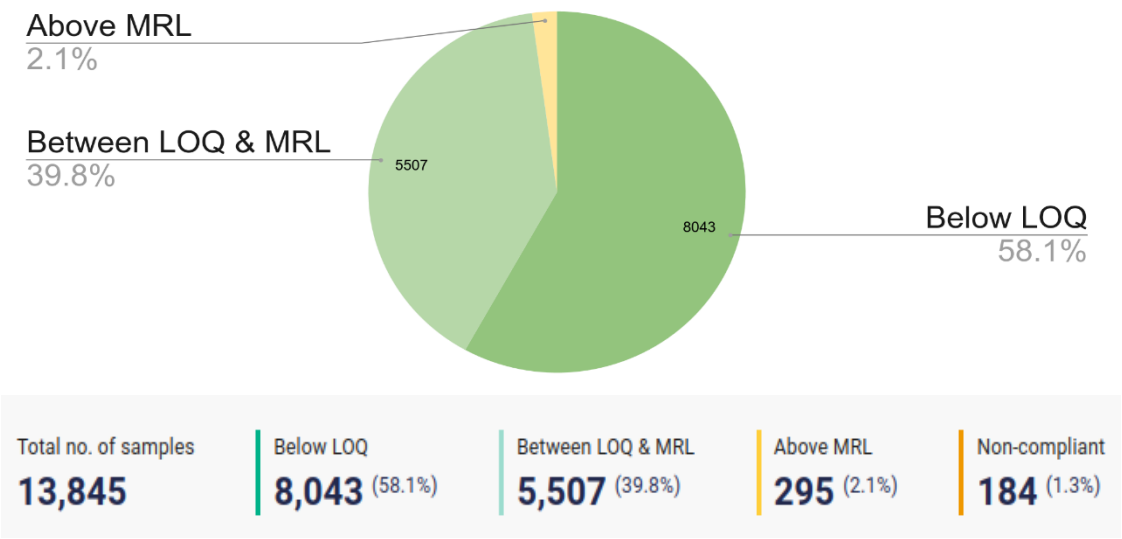

Figure 1.1: Residue findings in food (all food, conventional and organic)

41.9% of the analysed food samples contained quantifiable levels of residue, and 27% (3,734 samples) contained more than one active pesticide ingredient. Almost half of all food products contain residues, but these residues can come from different sources (agricultural, processing, or natural occurrences) and different environmental sources (soil, air, water). Any combination of these sources and compartments can happen, making it almost impossible to determine the source of contamination based solely on the analysis results.

According to risk analysis by country (n=87,863) from the multi-annual programme data (MANCP), 44.3% of the commodities analysed contained quantifiable residue(s). This percentage aligns with the findings from the MACP and has stayed steady over the last three years (refer to Figure 1.2).

[10] EFSA (European Food Safety Authority), Carrasco Cabrera L, Di Piazza G, Dujardin B and Medina Pastor P, 2023. The 2021 European Union report on pesticide residues in food. *EFSA Journal* 2023; 21(4):7939, 89 pp. https://doi.org/10.2903/j.efsa.2023.7939

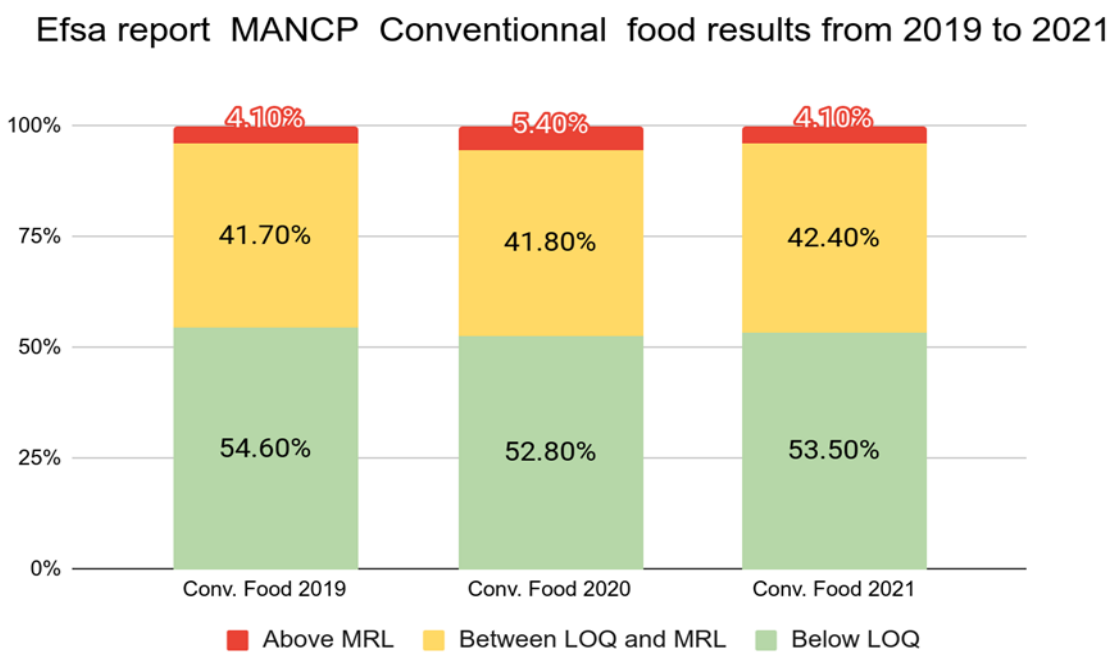

Figure 1.2: Level of contamination in conventional food

1.2.2 Commodities most impacted

In 2021, grapefruit, table grapes, and bananas had the highest rate of quantified results and the highest number of multiple residues found.

Figure 1.3: Residue findings in different commodities

1.2.3 Substances found in food

The active substances quantified in more than 100 samples and where the quantification rate is higher than 10% were:

- copper compounds (78.3%), with a 1.0% MRL exceedance rate[11],
- mercury (20.4%)[9],
- bromide ion (20.2%)[9],
- fosetyl[12] (17.2%),
- chlorate (12.0%), residue may come from disinfection of drinking water,
- chlordecone (11.2%),
- dithiocarbamates (10.8%), with a 1.2% MRL exceedance rate [9],
- ethylene oxide (10.2%) with a 6.6% MRL exceedance rate.

1.2.4 Contamination of organic food

EFSA has reported the frequency of contamination found in organic products in Europe. In 2021, 6,530 organic food samples (excluding baby food) were analysed. Overall, 5,408 organic samples did not contain quantifiable residues, which represents 82.8% of the analysed samples, compared to 80.1% in 2020 (see Figure 4).

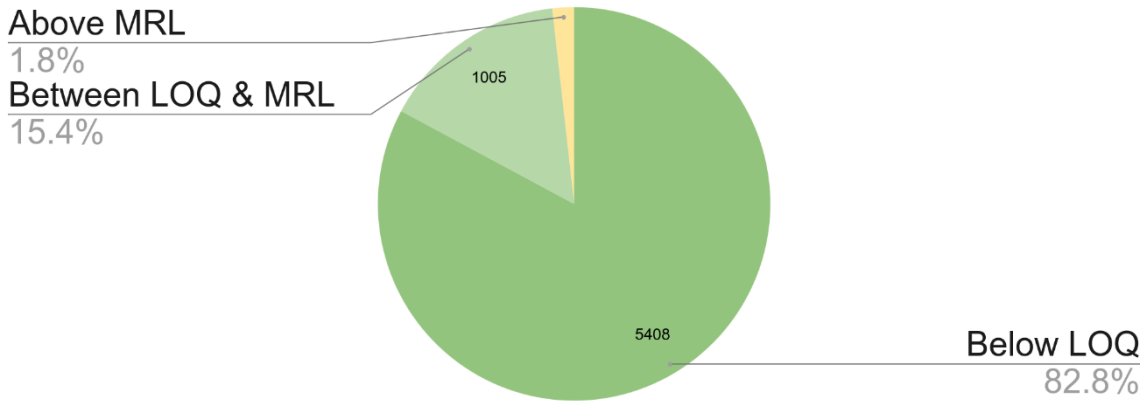

Figure 1.4: Residue findings in organic food

According to EFSA, 17.2% of organic food products contain quantifiable residues. It's important to note that the residues reported for organic food by EFSA include residues from substances that are authorised in organic production. These figures have remained stable for the past 3 years (see Figure 1.5).

[11] Substances naturally occurring or present in the environment from applications in the past (like persistent organic pollutants).

[12] Fosetyl is define here by Regulation EC 396/2005, i.e. it includes sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl

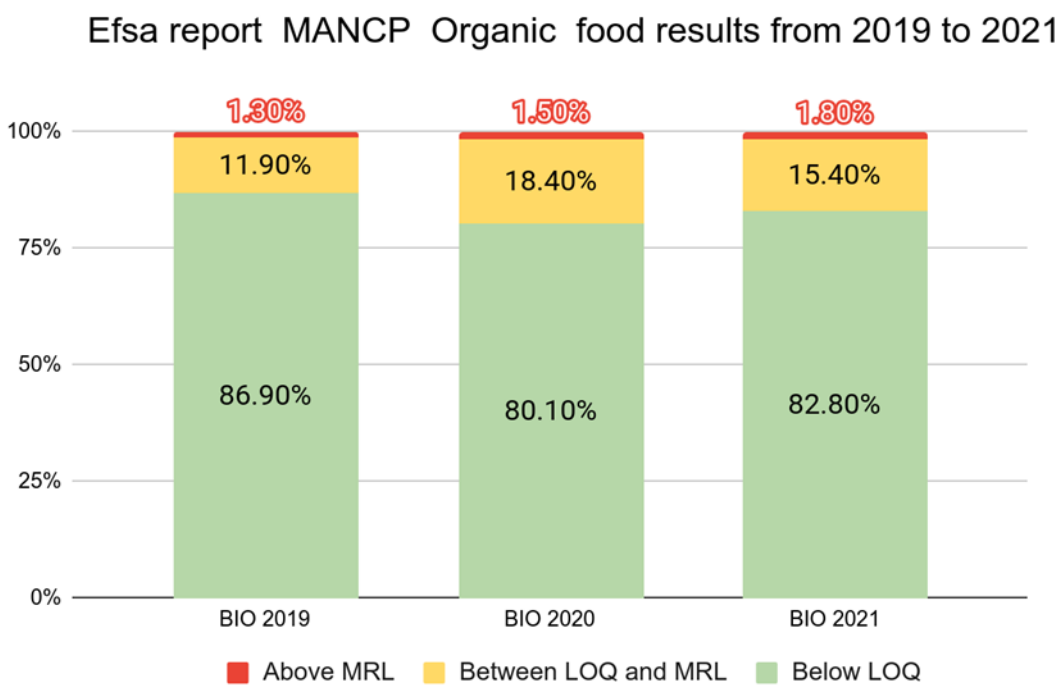

Figure 1.5: Level of contamination in organic food

1.2.5 Substances found in organic food

The active substances more frequently quantified below the MRL were:

- copper compounds (79%) (authorised in organic farming),
- bromide ion (15%) (might occur naturally),
- chlorate (7%) (might originate from allowed water chlorination/disinfection),
- fosetyl (6.5%) (might originate from a variety of sources as the laboratory reporting obligation converts phosphonic acid findings to Fosetyl, see Chapter 2),
- mercury (5.9%) (can occur naturally),
- and dithiocarbamates (5.6%) (CS_2 can occur naturally, see Chapter 2).

It is important to exclude analysis results that detect substances authorised for organic farming to provide a comprehensive overview of contamination in organic products. The following substances should be excluded: copper compounds, azadirachtin, spinosad, pyrethrum, and the synergist piperonyl butoxide. The BNN provides trends for the evolution of quantification in organic products over the last 15 years without the use of authorised pesticides. It shows that even quantification below the limit of quantification (LOQ) has seen a slight decrease, while the quantification rate above LOQ seems to be increasing. This suggests that analysis methods are becoming more accurate, and that environmental pollution may be on the rise.

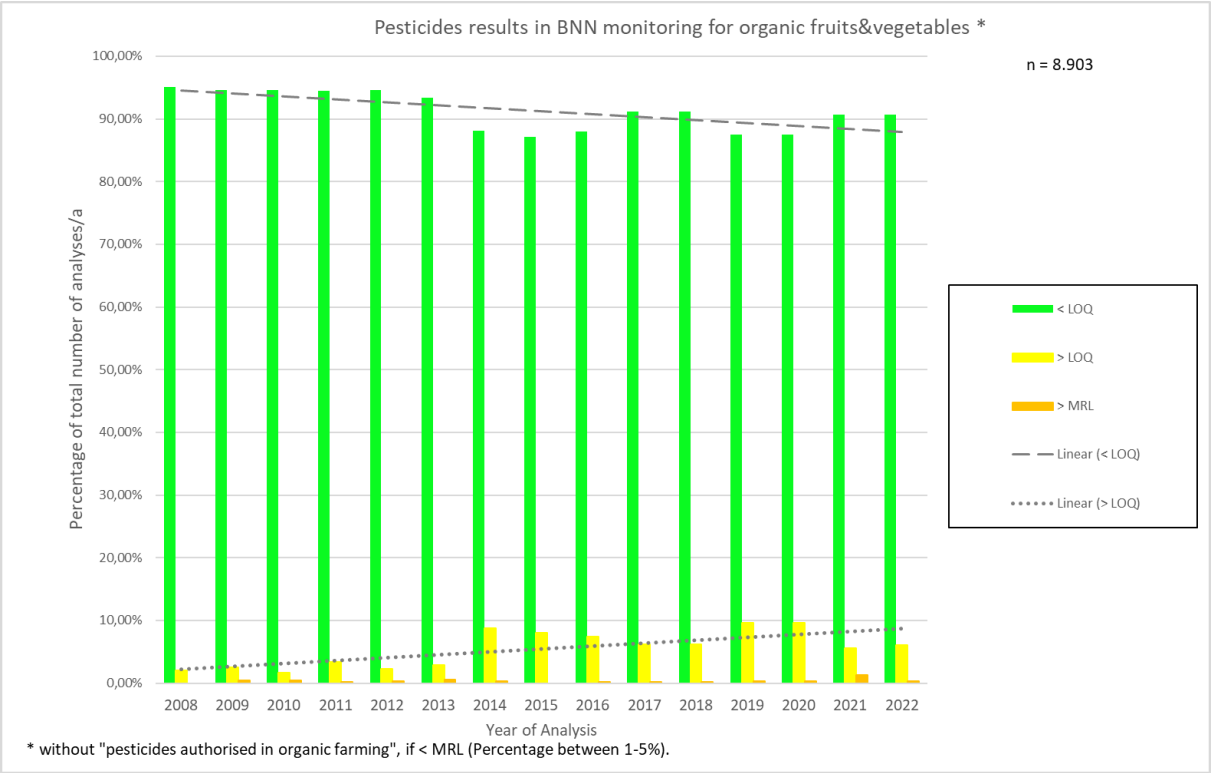

Figure 1.6: Residue findings in organic fruit and vegetables 2008 - 2022[13]

The BNN survey is based on analytical results from organic operators. Operators typically use a risk-based approach in pesticide analysis, which leads to varying results. While parameters such as copper, mercury, or bromide may not be frequently analysed, more attention is given to multi-methods or group-specific methods such as DFG S19, QuEChERs, or QuPPe. Findings by operators dealing with organic foodstuffs are likely to be influenced by substances like phosphonic acid, chlorate, QAC (quaternary ammonium compound), CS2 (disulfur bridges found in dithiocarbamates), or phthalimide, which are considered as multiple source substances (MSS) due to their sources other than pesticide use (see Table 1.1 and Chapter 2 and 3). Additionally, other pesticide residues are often found in traces below 0.01 mg/kg, examples of which include glyphosate, pendimethalin, and prosulfocarb.

[13] BNN, 2024: Residue findings in organic fruit and vegetables in BNN-monitoring (2008-2022), Bundesverband Naturkost Naturwaren e.V.

Table 1.1: Examples of multiple sources substances (MSS)[14]

Substance	Pesticide Use	Possible Other Sources
Phosphonic acid	Degradation product of fosetyl-Al or use of sodium or potassium phosphonate.	Previous use in particular in perennial plants. Unauthorised addition to plant protection products according to the EU organic regulation; contaminant in approved animal fertilisers (phosphonic acid findings e.g. from poultry manure are known, the cause is unclear).
Chlorate	Total herbicide (no longer authorised in the EU since 2008).	Contamination from the use of chlorine generating disinfecting agents in food processing. Use of chlorinated water. Chlorate background concentration in certain soil types.
CS_2	Indicator for dithiocarbamates, a group of fungicides.	Analytical artefact from natural ingredients of certain plant families like Alliaceae and Brassicaceae (e.g. onions, cabbage...) Vulcanisation accelerator in latex gloves.
Bromide	Indicator for methyl bromide (no longer authorised for decades in the EU).	Uptake from soil or seawater as a natural mineral/salt (crops grown near the sea usually have elevated levels). Uptake from fertilisers based on algae, mussels or other marine materials. Some foods (e.g. Brazil nuts) naturally contain increased amounts of bromide.
Phthalimide	Degradation product of folpet or phosmet.	Artefact in the GC injector during the analysis of food in the presence of ubiquitous phthalic acid or its anhydride. Formation during drying processes under the influence of heat, e.g. in tea, dried vegetables, spices.
Anthraquinone	Seed treatment for corn (no longer authorised in the EU).	Combustion processes (e.g. heating of greenhouses, direct drying of tea, smoking, exhaust gases from domestic and industrial furnaces and motor vehicles, possibly from forest and peat fires).
Biphenyl	Preservation of citrus peel (no longer authorised in the EU).	Combustion processes (e.g. heating of greenhouses, direct drying, smoking, exhaust gases from domestic and industrial furnaces and motor vehicles, possibly from forest and peat fires).
QAC (Quaternary Ammonium Compounds)	Fungicides (no longer authorised in agriculture)	Contamination from authorised and frequently used cleaning agents and disinfectants.
1,4-dimethylnaphthalene	Growth regulator, used as a sprouting inhibitor in potato storage.	Component of solvent naphtha, which is used for formulation purposes. Also occurs naturally in potatoes and acts as a phytohormone (auxin inhibiting).

[14] Adapted from AÖL Mitgliederinformation “Multiple Source Substanzen”; 01.02.2024

1.2.6 Levels of contamination found in organic products and in food in general

It can be challenging to find information about pesticide level, as most reports rely on MRL (maximum residue limits), which represent the legal thresholds. However, using MRL alone doesn't allow us to assess the actual exposure to these substances. We need to know the concentrations of the pesticides in order to evaluate the dose that is ingested. This is particularly important for fruits and vegetables, as they are often consumed raw or with minimal processing and they are frequently found to be the most contaminated commodities.

Figure 1.7: Comparison of contamination level between organic and conventional products (for sample below MRL)[15]

The report "Öko-Monitoring Baden-Württemberg 2022," carried out by the “Chemisches und Veterinäruntersuchungsamt Baden-Württemberg” provides insights. In 2022, 423 organic plant samples were analysed. The average level of pesticide residues in organic fruit samples was 0.005 mg/kg, while the average level in all organic vegetable samples was 0.003 mg/kg. The average content of pesticide residues in organic produce is 100 times lower than in conventionally produced goods.

[15]EFSA, 2021: Results for organic food products https://multimedia.efsa.europa.eu/pesticides-report-2021/chapter-two

Average Pesticide Amounts in Fresh Foods

The mere presence of plant protection substances can be seen by the average amounts of pesticide found in the samples, as the following tables show.

Average pesticide residues per sample (in mg/kg)

Fruit	2015	2016	2017	2018	2019	2020	2020	2022
Organically produced samples	0.002	0.001	0.002	0.004	0.003	0.004	0.002	0.005
Conventionally produced samples (excluding surface treatment substances or preservatives, phosphonic acid and bromide)	0.35	0.43	0.45	0.40	0.45	0.44	0.48	0.38

Vegetables	2015	2016	2017	2018	2019	2020	2021	2022
Organically produced samples	0.002	0.003	0.003	0.008	0.002	0.004	0.002	0.003
Conventionally produced samples (excluding phosphonic acid and bromide)	0.49	0.46	0.36	0.46	0.41	0.29	0.40	0.46

Figure 1.8: Average residues findings in conventional and organic fruit and vegetables[16]

Despite some concerns about the methods used, it is clear that organic products generally have much lower levels of pesticide residues compared to conventional products. This is evident in the lower frequency of positive samples, the types of substances present (especially fewer combinations of substances), and the overall level of contamination which very rarely approaches or exceeds the maximum residue limit (MRL).

The low level of contamination is a direct result of compliance with the EU organic regulations, which prohibit the use of synthetic pesticides. While fraud is always a possibility in any industry, the significant number of analyses conducted both in compliance with European regulations and by the operators themselves helps to minimise fraudulent cases. However, it is important to acknowledge that achieving a total absence of residues in organic products is unrealistic due to environmental factors. Nonetheless, identifying the source and cause of pesticide presence is crucial in minimising and maintaining contamination levels as low as possible.

[16] Ökomonitoring Baden-Württemberg 2022 https://www.cvuas.de/pesticides/beitrag_en.asp?ID=3889&subid=1&Thema_ID=5&lang=EN

CHAPTER 2: LABORATORY ANALYSIS: THE MAIN TOOL FOR DETECTING OF CONTAMINATION

Felix Lippert[17]*, Philipp Peter Könen*[18]

2.1 Introduction

The following chapter is focussed on pesticide analyses as an essential service for operators as well as for control authorities/control bodies. The service in this context is much more used as one of the inspection tools for supporting "integrity checks" of organic processes than for traded organic produce. The analytical result flows into the final assessment of a monitoring procedure and can therefore have consequences not only for the certification status of a batch, but possibly also for the operator.

The reliability of analytical results is of course always of the utmost importance for laboratories, which they demonstrate through their accreditation in accordance with DIN ISO 17025. However, laboratories that are used for monitoring organic processes in line with Reg (EU) 2018/848 are faced with special analytical challenges in some areas.

Therefore, the chapter intends to give insight into the analytical necessities and limitations with which laboratories are faced in the context of the involvement mentioned above.

2.2 The Role of Analytical Laboratories

Sampling and analysis are always considered to be tools which are able to prove the authenticity of production processes according to Regulation (EU) 2018/848. Other tools like on-site inspections, document checks and cross & traceability checks are mentioned in Chapters 4 and 5.

As the methods used in laboratories used to check for authenticity of organic production are always science-based, stakeholders put a high value upon their outcome.

For this key role there is an immense demand on reliability and finally trust in the offered services. Although the lab service has an extremely high standardisation level in contrast to other control methods, the role of an involved laboratory must adapt its service profile according to the needs of its customers.

On the one hand, there are two types of qualified institutions providing their service to the supply chain: governmental and private laboratories, although the latter may occasionally also be charged by governmental designation (Regulation (EU) 2017/625).

On the other, samples for residue analysis come from three groups: operators, control authorities (CA) and control bodies (CB). As the last two are playing a similar role, they may have identical interests and demands of laboratories. The role of labs may differ therefore according to what is required by its customer.

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This article exclusively reflects the personal opinions of both authors.

2.2.1 Operators

At every stage of production, the operator must be able to prove that no prohibited substances have been used, organic and conventional products have not been commingled, and contamination with unauthorised substances has been avoided in its own sphere of influence. Analysis may help to identify risks as the first step of precautionary measures, where other methods are ineffective. Once a risk is identified, the operator is obliged to take precautionary measures in accordance with Article 28(1) of Regulation (EU) 2018/848. An analysis can be useful to determine the effectiveness of the measures taken or even represent a precautionary measure itself.

Even if such a risk cannot be eliminated with suitable measures (e.g. regional drift with pendimethalin), analyses are useful simply to document a risk and dispel any doubts which may arise.

2.2.2 Control Authorities (CA), Control Bodies (CB) and competent authorities

Demands of CA/CB are like those of competent authorities as both are designed to take over governmental tasks in line with Regulation (EU) 2017/625. The requirements for the approval of private inspection bodies for the monitoring of organic farming, production and trade are set out in the EU organic regulation. One important condition for designation by national authorities is the proof of having a standardised control procedure, which involves sampling and analytical measures.

Authorities are obliged to take samples where there is concern about food safety in accordance with Regulation (EU) 2023/731[19] which is summed up within the EU for the years 2024 till 2026 by at least 683 samples for 10 commodities to be taken per year; in Germany 106 samples for 10 commodities per year. Organic samples should be included with the corresponding market share. This results in a total amount of organic samples arising in the food safety monitoring system of less than 60 samples per year for all member states. The EU organic regulation obliges the EU Member States in Article 7 c) of Regulation (EU) 2021/279 that a minimum 5% of operators excluding exempted ones shall be subject to sampling. For the organic control in Germany, 2,980 samples can be calculated for 2024.

2.3 Analytical Methods

In the above-mentioned context laboratories are mainly used as a monitoring tool delivering information about pesticide residues in organic products and operating resources.

To make monitoring results legally compliant within the meaning of Regulation (EU) 2017/625, it is crucial that the analytical methods are reliable and suitable for organic samples. To ensure this precondition many statutory regulations as well as international and private standards exist, which laboratories must comply with as soon as they offer their service to the market.

The most important basis for this is the SANTE document entitled “Analytical quality control and method validation procedures for pesticide residues analysis in food and feed” in its latest version[20]. To follow this guideline is essential for laboratories active in the pesticide residue sector.

Procedures and methods undergo specific adaptation in each laboratory. The following chapter looks at how laboratories implement the guideline in order to meet the specific challenges of measurements in the context of Article 28 of the Regulation (EU) 2018/848. Methodological problems are highlighted in order to make clear to users the limitations of the analysis of organic samples.

[19] Annex II of Commission Implementing Regulation (EU) 2023/731 of 3 April 2023 concerning a coordinated multiannual control programme of the Union for 2024, 2025 and 2026 to ensure compliance with maximum residue levels of pesticides and to assess consumer exposure to pesticide residues in and on food of plant and animal origin and repealing Implementing Regulation (EU) 2022/741

[20] European Commission, 2023: Analytical Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed. https://food.ec.europa.eu/system/files/2023-11/pesticides_mrl_guidelines_wrkdoc_2021-11312.pdf .

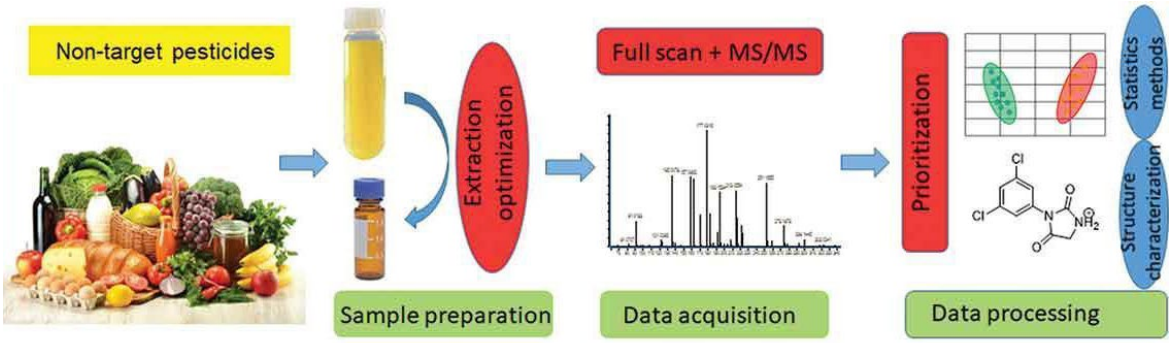

Figure 2.1: Process sequence in pesticide residue analysis.[21]

2.3.1 Sample description

The description of the sample is conducted by both the sampler and the laboratory and builds the interface between customer and laboratory, most often with the definition of the need for specific analytic methods (see Chapter 3). Information from both parties will be combined in the final report to characterise the sample by its invisible and visible attributes to ensure traceability.

The laboratory is obliged to describe the sample in a way that may contribute to the later interpretation of the result. Attributes like sample size, condition (i.e. spoiled), temperature, packaging etc. should be observed and registered. For example, sample transport in an unsuitable environment may result in severe decay of sensitive samples, which in turn accelerates degradation of pesticide residues. (See chapter sampling). The final report should indicate which information was provided by the sampler and which was supplemented by the laboratory.

2.3.2 Sample Preparation

To prepare the sample for the analytical process includes measures to transfer field information into the final lab report and the first physical steps taken to make the sample available for the analytical methods. The process therefore includes standard procedures such as sample characterisation and homogenization as well as strategic procedures such as mixing or dividing samples.

2.3.3 Decision on pooling

Pooling of individual samples is a budget saving strategy for commodities with low frequency of pesticides residue. This method, however, assumes that the combination of samples without residues should also show no residue in the overall result. As soon as even one sample has a residue, this will be visible in the overall result. However, it must be considered that the limit of detection (LOD) for the individual active substance is increased by the number of individual samples combined (see Chapter 2.3.6).

Pooling of samples is therefore only advisable if the sensitivity of the subsequent instrumental analysis is very high. Otherwise, there is a risk of overlooking active substances which are present with a low concentration but nonetheless with some relevance. This risk of overlooking a substance is all the higher the more difficult the matrix (i.e. tea > cucumber; see Chapter 2.3.1).

[21] Zeqin et al. 2020: Non-target screening of pesticides for food analysis using LC high-resolution mass spectrometry -a review. Food additives & Contaminants: Part A.

2.3.4 Cutting homogenising and weighing

Sample preparation is a crucial step in analytical chemistry where the sample must be transferred in a state that allows for accurate and efficient analysis. The basic requirement for valid analysis results is sufficient homogenization of the sample material. Sample preparation may involve in general various comminution processes such as cutting, crushing, grinding. These are all designed to maximise the subsequent extraction process, which aims to achieve the most complete possible transfer of the analytes into the extracting solvent and ensures that sub-sampling variability is acceptable.

A) Representative approach

If the samples submitted are food and feed of plant and animal origin in the legal sense and no other information is provided, sample preparation must follow Annex I of the Regulation (EC) 396/2005, which aims at the comparability of results and the representativeness of parts (i.e. onions "*after removal of the outer skins*"). This means that the samples must be prepared to be representative of the material to be analysed and that the results are comparable between different samples or different laboratories (CVUA Stuttgart). If a sample is to be examined for compliance with the maximum residue levels (MRLs) laid down in Regulation (EC) No 396/2005, it is essential that only those parts of the product to which MRLs apply are analysed. However, this is not the case for samples embedded in monitoring systems along Regulation (EU) 2018/848.

B) Non-representative approach

Analysis within monitoring systems noted in Regulation (EU) 2018/848 aims to qualify organic processes and not to observe toxicity issues in food or feed. Therefore, sometimes the use of parts of the laboratory sample is preferable to a representative use of the whole sample. This should be done, however, in close consultation with the client as it does not correspond to a representative procedure. Rather, the aim is to precisely analyse those sample areas where the highest concentrations of residues are to be expected.

The advantage of the non-representative method lies in the higher concentration of residues that can be assumed, provided that the inhomogeneous distribution within the sample is well known (see info box). This allows the analytical and matrix related LOD to be overcome (see Figure 2.2).

High concentration samples

As a consequence of the targeted application of many plant protection products, their distribution on the target plant is often (systematically) inhomogeneous. The surface/weight ratio in the sample plays a very important role here. This is why the concentration on leaves is much higher than on fruits of the same plant. In order to analytically verify such an application (even after a certain period of time), it can be advantageous to take this into account when taking samples.

2.3.5 Sample Processing

It is important to note that the specific methods and techniques of sample processing depend on the type of sample, the purpose of the analysis, and the specific requirements of the relevant regulations. It is crucial to choose the right methods for sample preparation and to apply these methods correctly to ensure accurate and reliable analytical results.

Multi-residue methods (MRM)

Multi-residue methods (MRM) are analytical procedures designed to identify and quantify multiple residues or contaminants in a single analysis[22]. In the SANTE guideline there is one method defined called QuEChERS multimethod, which stands for "Quick, Easy, Cheap, Effective, Rugged, and Safe". Developed by reference laboratory Stuttgart (CVUA)[23.] it is the EU wide authorised method for the extraction and cleanup of samples commonly used in food analysis and particularly useful for the analysis of pesticide residues in food and feed and frequently used by public and private labs (SANTE/11312/2021 v 2.)[20].

QuEChERS MRM:

An important aspect of the QuEChERS multimethod is the non-targeted screening which refers to analytical procedures designed to identify a wide range of potential contaminants without predefining specific substances in advance. The type of extraction depends on the type of sample and contaminants to be analysed. Typically, the water-soluble organic solvent acetonitrile is used to extract contaminants from the sample.

The QuEChERS multimethod should detect at least 190 different analytes, as they are specified in Regulation (EU) 2023/731. In fact, there are large differences between laboratories in the number of substances detected by this method (more than 500)[23].

MRM would not be possible without ending up in high resolution chromatographic analysis coupled to tandem mass spectrometry (MS/MS). Along the chemical diversity of the residues, it needs both gas chromatography (GC-MSMS) and liquid chromatography (LC-MSMS) in combination to determine them all in a single run each[24]. The high selectivity of those systems enables the acquisition of a "theoretically unlimited number of pesticides and metabolites in a single run, by means of accurate mass measurements (< 5 ppm mass error) combined with high resolving power limiting the risk of false identifications in such complex matrices, where endogenous matrix components of similar mass may be co-eluted"[25].

The method can detect a variety of substances, including pesticides, veterinary drugs, mycotoxins, and other contaminants. In practice, however, the sensitivity of an analysis is primarily dependent on the presence of interfering substances. The wide range of different samples results in an equally wide range of extracts charged with different co-eluting compounds, which overlies targeted substances, making the systems less sensitive.

Thus, a multimethod coupled with GC-MSMS and LC-MSMS also means that it consists of various methods adapted to different loads of interfering substances as is the case for QuEChERS. Indeed, there are 11 matrix groups for food and 8 matrix groups for feed, as defined in the SANTE guideline[20]. Figure 2.2. shows the influence of 10 matrix groups on the sensitivity of methods in the analysis of pesticide residues, illustrated by the achievable LOQs [24]. It becomes very clear that information about the chemical properties of a sample/matrix is very important to choose the analytical setup accordingly. Otherwise, the lab risks overseeing compounds which are relevant. See Chapter 4, where a laboratory's specialisation in certain sample types is therefore highlighted as a quality feature.

[22] Narenderan S.T. et al. (2020): Review of pesticide residue analysis in fruits and vegetables. Pre-treatment, extraction and detection techniques. Food research International (133)

[23] Chemisches und Veterinäruntersuchungsamt Stuttgart CVUA (2016): QuEChERS und QuPPe – die Multimethoden der Pestizidanalytik

[24] Sanchez et al. 2023: Evaluation of automated clean-up for large scope pesticide multiresidue analysis by liquid chromatography coupled to mass spectrometry. Journal of chromatography A: 1694

[25] Gomez et al.2020: pesticide residues evaluation of organic crops. Food Chem. 100079

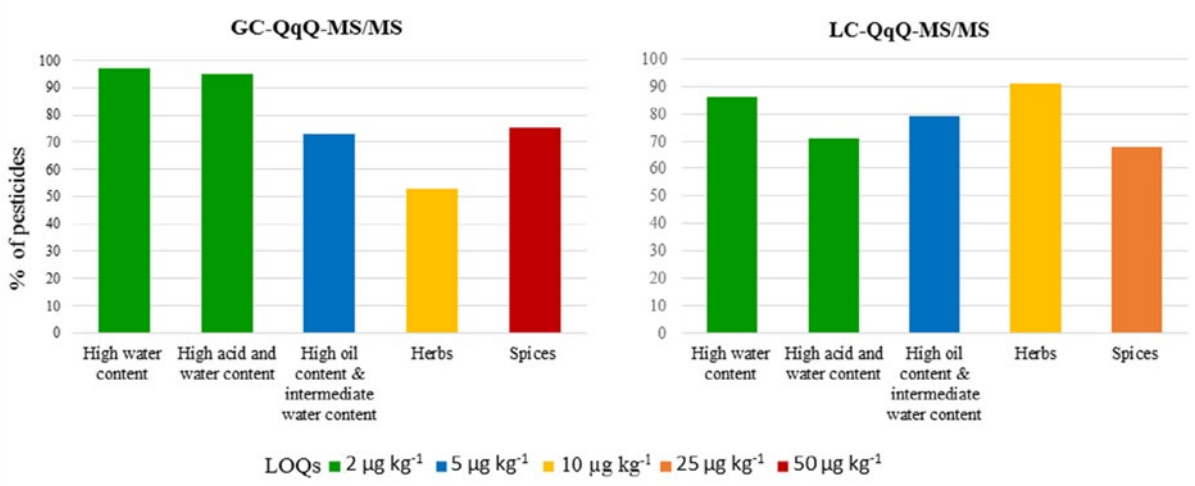

Figure 2.2: Analytical impact of different matrix groups on level of quantification (LOQ) for GC-MSMS- and LC-MSMS-analysis, expressed as percentage of the total pesticides analysed [25]

Some substances undergo conjugation within plant organisms, a detoxification process. In this process foreign substances, including pesticides, are chemically altered to facilitate their excretion from the organism. Conjugation can alter the chemical structure of a pesticide in a way that renders it unavailable for certain analytical methods, such as the Multi-Residue Method (MRM)[26].

These pesticides require an additional hydrolysis step to fully cover the residue definition. This particularly concerns pesticides with carboxyl groups and their esters and conjugates after alkaline hydrolysis. Unfortunately, they are commonly used pesticides like 2,4-D (2,4-dichlorophenoxyacetic acid), MCPA (2-methyl-4-chlorophenoxyacetic acid), haloxyfop, and fluazifop, which may also be present in organic samples [27].

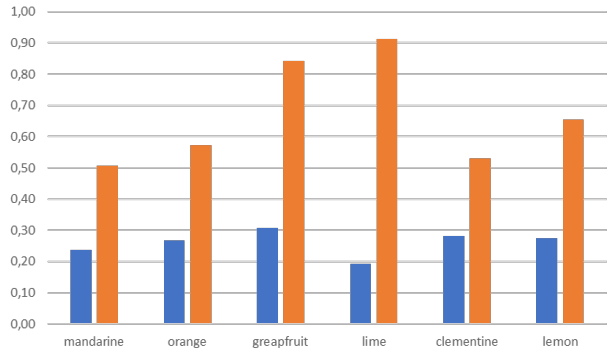

Figure 2.3: Measured concentration of 2,4-dichlorophenoxyacetic acid [in mg/kg] in citrus extracts without (blue) and with (orange) hydrolysis [27]

Hydrolysis is an additional step within the QuChERS preparation processes, which should be explicitly requested from the laboratories as it is not always included in general offers.

QuPPe MRM:

QuPPe multimethod, which stands for "Quick Polar Pesticides", is a method for the analysis of polar pesticides that cannot be effectively extracted using conventional methods such as QuEChERS [23]. This

[26] https://www.eurl-pesticides.eu//docs/public/tmplt_article.asp?LabID=200&CntID=670&Lang=EN

[27] Statistic evaluation Labor Dr. Lippert 2023

adapted method has to be used for polar analytes of particular interest. Such compounds are shown in Table 2.1, where an overview of findings of QuPPe-compounds in produce of plant origin is given. It should be taken into account, that some analytes on this list (i.e. Fosetyl) are also amenable by QuChERs MRM. In 2021, a total of 2445 samples, mainly fruit and vegetables, but also cereals, pulses, processed goods, tea and others were analysed for QuPPe-amenable compounds at the CVUA Stuttgart. 1863 samples (76 %) contained quantifiable residues of one or more of the tested QuPPe compounds. Table 2.1 lists the substances with concentrations above LOQ and their frequency of occurrence.

Table 2.1: Residue findings of QuPPe-compounds in a QuPPe screening of 1863 samples [28]

Frequency of findings > respective RL	Compounds (pesticides and legally relevant metabolites shown in bold)
> 10 % of samples.	*Cyanuric acid,* ***Phosphonic acid****, Perchlorate,* ***Chlorate*** *and 2-Chloroethanol**
1 - 10 % of samples.	*Melamine,* ***Thiocyanate****,* ***Propamocarb****, Propamocarb-N-oxide,* ***Bromide****,* ***Trimethylsulfonium cation****,* ***Nicotine****, Ethephon metabolite HEPA, Propamocarb-N-desmethyl,* ***Chlormequat-chloride****, sum,* ***Ethephon*** *and Ammelide*
0.1 -1% of samples	***Chloridazon-desphenyl****,* ***Diquat****,* ***Maleic hydrazide****, Dimethoate-O-desmethyl,* ***Glufosinate met. MPPA****,* ***Mepiquat-chloride****,* ***Cyromazine****,* ***Fosetyl****, ETU,* ***Glyphosate****, Nereistoxin, Morpholine,* ***Mepiquat-*** *4-hydroxy,* ***Amitrole*** *and* ***Daminozide***
Not detected above LOQ	*Ammeline,* ***Difenzoquat****, Diquat-dipyridone, Diquat met. TOPPS, Diquat-monopyridone, Ethylene oxide*,* ***Glufosinate****, Glyphosate met. N-Acetylglyphosate,* ***Matrine****, N-****Acetyl-glufosinate****,* ***Oxymatrine****,* ***Paraquat*** *(very few analyses) and PTU* (two times below LOQ)
* technically not QuPPe compounds but still shown here (see towards the end of this document)	

The QuPPe method is periodically updated by the EU Reference Laboratories for Single Residue Methods (EURL-SRM) as more pesticides or separation possibilities are being introduced. Since 2009 this method became part of a second non-target screening, which covers 24 analytes in products of plant origin (incl. honey) for which satisfactory chromatography and detection sensitivity is achievable. (EURL 21.12.2023 part I Version 7.1). For analytes in food of animal origin currently 25 reliable methods are available, although based on higher LOQs of up to 0,2 mg/kg. (EURL 14.05.2019 part II Version 3.2).

Referring to Table 2.1, samples that originate from organic processes must be subjected to an analysis that promises the highest possible information gain. From this point of view, the (increasingly extensive) Quppe method should be commissioned in particular for a monitoring approach that is not based on suspicion.

Single residue methods (SRM)

In food and feed analytics, single residue methods (SRM) play a crucial role. They enable the examination of individual residues in samples, which is particularly useful when the substances to be analysed are not suitable for multi-residue methods or are difficult to analyse. SRM are also used by laboratories internally to clarify doubtful results out of MRM in focussing on a single substance (see Chapter 4).

The monitoring of organic production processes must be orientated towards the most frequently occurring risks. If necessary, an analytical assessment of individual residues outside the MRM should also be considered. Here are some important examples:

Dithiocarbamates are organic sulfur compounds used in agriculture as fungicides, herbicides, and insecticides. The analysis of dithiocarbamates is often done through their common degradation product, carbon disulfide (CS_2) which can be measured easily by gas chromatography coupled with different detectors. However, this method also brings challenges. One of them is the difficulty in attributing the results to possible application scenarios. Since carbon disulphide is a common degradation product of various dithiocarbamates, it can be challenging to identify the specific

[28] EURL-SRM 2022: Residue Findings of QuPPe-Compounds in Samples of Plant Origin from the German Market in 2021

dithiocarbamate originally present in the sample. Additionally, carbon disulphide can also originate from other sources further complicating the interpretation of results, which makes this method uncertain in the context of process controls of organic sources.

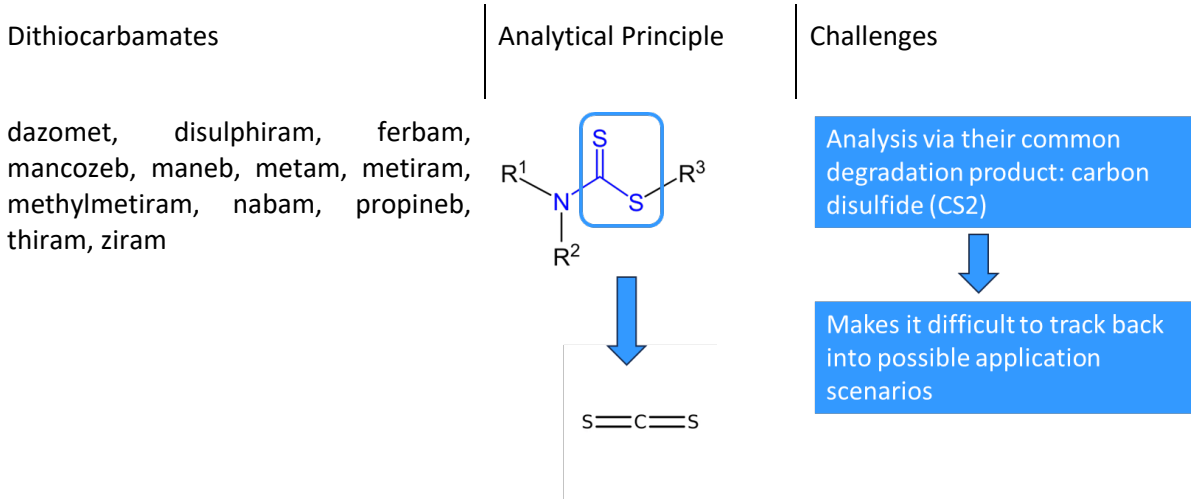

Figure 2.4: Principle and challenge of dithiocarbamate analysis

For this reason, many samples analysed using the CS_2-method result in confusing interpretations. Samples containing sulfur compounds (e.g. glucosinolates in cabbage) convert them during extraction into CS_2 and simulate an application with dithiocarbamates (Figure 2.4). CS_2 is well-known but not the only so-called multiple source substance. Meanwhile LC-MSMS-methods are in development to analyse the single sulfur compounds themselves.

Phosphonic acid, chlorate, bromide, phthalimide, anthraquinone, biphenyl and 1,4-dimethylnaphthalene can also be mentioned as examples.

DDAC (didecyldimethylammonium chloride) and BAC (benzalkonium chloride) are quaternary ammonium compounds used in disinfectants. They have also been used as pesticides against microbial infestation. Their residues in food and feed can be analysed via SRM. With high spectroscopic sensitivity, these compounds are detectable within the QuEChERS screening. However, due to background contamination, a single method is necessary for accurate detection.

This demonstrates the need for continuous improvement and adaptation of analytical methods to keep pace with changing requirements and challenges. If the MRM method is very sensitive, qualitative detection of DDAC and/or BAC can be achieved within standard MRM. This indication can then subsequently motivate to conduct the specific SRM for qualitative and quantitative analysis and does not have to be commissioned initially. This makes it even more important for a laboratory to keep its methods very sensitive.

2.3.6 Measurement of the extract

As described above, the measurement of residues in MRM extracts is accomplished by coupling chromatography (separation) and tandem mass spectrometry (identification and quantification). As this instrumental analysis is in principle very selective and therefore very sensitive, it is crucial for measurements in a concentration range of about 0,01 mg/kg, thus, for organic samples.

The performance of the system depends strongly on the loading of the extract with co-eluting substances (see above). These substances cause a "background noise" behind which the target

substances can "disappear" - this is a loss of detection sensitivity. For this reason, the detection sensitivity for a substance in a matrix must be defined separately in each case. According to SANTE, the signal-to-noise ratio must be at least 3:1 in order to call it a reliable detection, the so-called limit of detection (LOD). To quantify the substance in a certain matrix the ratio has to be minimum 10:1, the so-called limit of quantification (LOQ). The indication of “traces” on the report depends on the laboratory’s own policy[29].

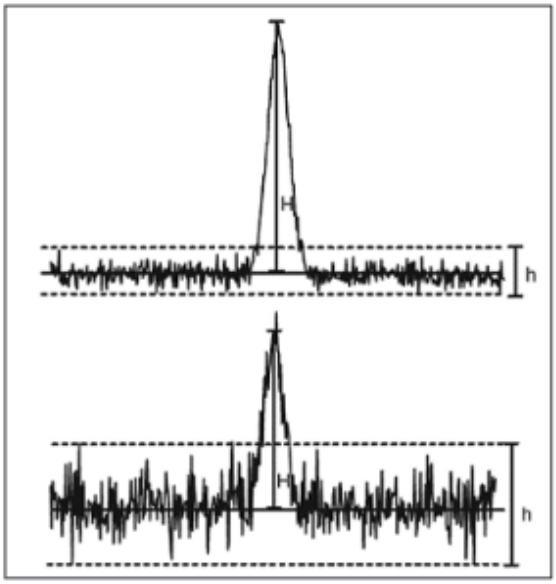

Figure 2.5: Signal-to-noise ratio of 10:1 (top) indicating LOD and 3:1 (bottom) indicating LOQ.[29]

The level of reporting (LOR) is defined through the laboratory's own quality management system and is usually set at 50% of LOD. However, this level can be agreed with the client, while LOQ must be reported as of mandatory.

Figure 2.5 shows that the identification of substances in very low concentrations requires the highest demands on the specific adaptation of the extraction systems (like cleaning up QuEChERS-extracts, dilution etc.) especially for organic samples, which often show pesticide “traces” which also could relevant to the judgement of whether the observed process is suspicious (see Chapter 4).

In addition, the sensitivity of mass spectroscopy varies greatly for individual substances. For example, the sensitivity (response) for chlorpyrifos is 1000 times higher than for azadirachtin in the same matrix preparation.[30]

If a positive finding is made, the substance will be evaluated as to whether the amount lies near or even above the legal limit. These legal limits are defined in Regulation (EC) 396/2005 and are used to characterise food safety. Thus, in the case of organic samples these limits apply only for substances listed in the Regulation (EU) 2021/1165 assuming that the sample represents a “food” in the context of Regulation (EC) 396/2005.

[29] Shrivastava A. and & V.B. Gupta, 2011: Methods for the determination of limit of detection and limit of quantitation of the analytical methods. Chron. Young Sci 2011;2:21-5

[30] Data Labor Dr. Lippert Gmbh

2.3.7 Quality measures to verify obtained results

Rigorous quality control ensures reliable results and contributes to accurately assessing pesticide residues in organic samples. For detailed guidelines, one can refer to guidance document SANTE/11312/2021 v2.

Quality control is crucial when verifying the results of pesticide residue analysis in organic samples measured by mass spectrometry as the expected measurement results are often at the lower performance limit of the analysis, this may lead in a concentration range, e.g. where linearity is no longer achievable.

Here are some key considerations and measures, conducted in the routine, when doubtful results have to be verified[31]:

- Repeated analysis starting from original sample
- Use of isotopic labelled internal standards
- Comparison of results from different analytical systems (when available)
- Single residue measurement (more data points per time in the mass spectrometry)
- Hydrolysis and derivatisation (as mentioned above)
- Standard addition to subtract the matrix effect

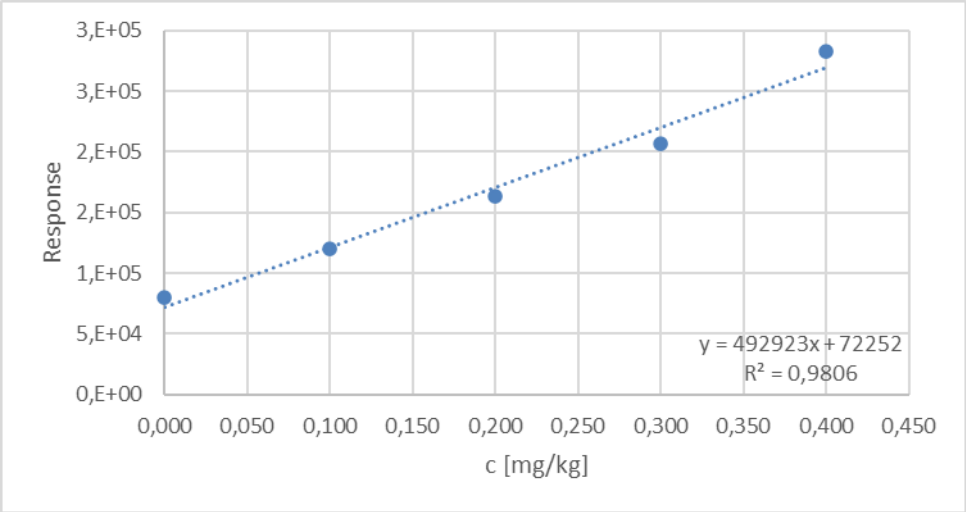

Figure 2.6: Example of a 5-point standard addition in blackberry with 0,154 mg/kg clopyralid

Standard addition as well as external calibration assesses linearity, precision, and accuracy across the concentration range of relevance. Although these measures deliver high reliability, this is a very time-consuming process (i.e. 5 measurements as shown in figure 2.6) and will cause a collision with costs and time frame). Thus, it has to be conducted after informing the client.

2.4 Result Interpretation

Result interpretation must consider not only the chemical properties of the analysed substances but also the specific conditions of the analytical process. Furthermore, it must be viewed in the context of

[31] EURL (08.10.2020): Guidance Document on the Quality control during routine analysis (ongoing method performance verification)

applicable regulatory requirements to ensure that results are correctly interpreted and appropriately handled.

Article 28 of the Regulation (EU) 2018/ 848 lays down the obligation for operators to develop and maintain precautionary measures to avoid contamination by products or substances in organic production. This has direct implications for interpreting the result as contamination can distort analysis results and lead to incorrect conclusions. This is the reason why it should be clarified, how deeply the laboratory should be involved in the subsequent case studies. There are two ways of interaction between lab and client in the context of:

i) delivering reliable results in reporting substance findings and their concentration
ii) additionally interpreting such information

There are several reasons for including the commissioned laboratory in the interpretation of the measurement result - at least on a case-by-case basis.

In interpreting results, the following aspects related to the analytical background must be considered.

Table 2.2: Parameters for validation of analytical results

Applicability	suitability of the method used for analysing the particular sample.
LOD	sensitivity of the method used.
LOQ	ability to reliably quantify the amount of a substance within the range
Precision	the similarity of repeated measurements under unchanged conditions.
Repeatability	consistency of results within a short period under the same conditions.
Reproducibility	consistency of results under changed conditions, such as different laboratories
Recovery rate	ratio of the measured concentration to the known concentration
Selectivity	ability to measure a specific compound in the presence of other compounds
Linearity	ability to provide results that are directly proportional to the concentration
Uncertainty	indicating the spread of values associated with the measurement result.
Sample size	indicates the representativeness of the sample
Sample type	matrix refers to the distribution of the samples drawn within a crop
Logistical history	conditions of storage conditions, transportation, and handling
Processing	Level of processing with dilution, concentration, degradation effects
Phenotype	physiological age, senescence, metabolic activity

2.4.1 Experience from the conventional sector

Laboratories have gained a high level of knowledge about the contamination of samples from their experience with conventional production (agronomic plausibility check). This covers acute

contamination situations such as pendimethalin drift risk after massive application within a region because of favourable weather conditions. But one can also expect knowledge about long-term contamination: e.g. chloridazon-desphenyl in soils in which sugar beet has been cultivated before starting with the conversion process to organic farming.

The laboratory's knowledge of common pesticides as they occur in commercial formulations (brands) may be used by operators / as well as CA/CB to form a picture of major or critical nonconformities, for example in findings of commercially available substances in certain combinations (see Table 2.3).

Table 2.3: Some combinations of substances in commercial pesticides (examples from German market)

Commercial product	active substance 1	active substance 2
Luna sensation	Fluopyram	Trifloxystrobin
Luna care	Fluopyram	Fosetyl
Signum	Boscalid	Pyraclostrobin
Switch	Cyprodinil	Fludioxonil
Signum	Boscalid	Pyraclostrobin
Folpan	Folpet	Metalaxyl-M
Curamat	Tebuconazol	Trifloxystrobin

As laboratories are often involved in interpreting the design of spray schedules according to the demands of their conventional clients, such information helps in interpreting similar findings of organic samples.

2.4.2 Metabolism of residues

In Chapter 2.3.1 the problem of the metabolization of pesticides was already addressed by pointing out that metabolites are often not detectable in the multi-analysis (MRM). Metabolites, which are detectable in the MRM on the other side, have the advantage that they occur together with the parent substance in a known pattern. The ratio of the metabolites to the parent substance can provide information about the time of contamination. This in turn is important information to help distinguish contamination from application (see Figure 2.7).

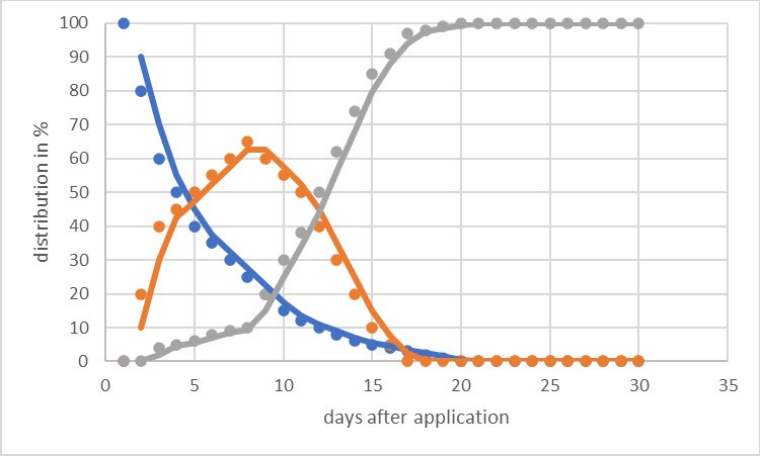

Figure 2.7: Degradation of Flonicamid (blue) into its metabolites TFNA (orange) and TFNG (grey); sample: broccoli

2.4.3 Evidence of low concentrations

Even findings of substances close to the LOD may support the interpretation of whether the contamination could be unintentional or intentional, such as the combination of detected substance traces (see Table 2.3). Maximum limits as defined for food safety in Regulation (EU) 2005/396 for each individual product/active substance combination do not apply to the unauthorised use of active substances in organic production systems.

Regulation (EU) 2018/848 does not provide maximum residue limits for the definition of a case of non-compliance. Nevertheless, there are few examples where a suspicion may be derived from exceeding an active substance concentration above the LOQ (e.g. BNN[32]).

Applying any uniform maximum residue level (i.e. LOQ) for the definition of a non-compliance according to Regulation (EU) 2018/ 848 is not recommended for two reasons. On the one hand the non-presence of residues is not proof of organic integrity, on the other hand differences between lab results are unavoidable at least to an extent of ± 50%[20]. Furthermore, the risk of contamination is ubiquitous.

However, one can expect even higher differences between lab results when identical samples do not exist. This means that sampling (which most often is not under the control of the lab) contributes the most to differing results[33] which makes the interaction between laboratory and sampler crucial for interpretation of the result.

2.5 Selection criteria for Lab Services

The selection of a laboratory that has the competence to perform analytical verifications according to Article 28 of Regulation (EU) 2018/848 is of course based on some minimum requirements which are:

- Accreditation according to ISO 17025
- Reporting
- Designation along Regulation (EU) 2017/625
- Participation in ring tests
- List of pesticides with LOQ in QuEChERS
- List of pesticides with LOQ in QuPPe

2.5.1 Accreditation

Accreditation is defined by Regulation (EU) 765/2008 as “an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements […] to carry out a specific conformity assessment activity.”

For Labs working in the area of testing for pesticide residues the main “harmonised standard” is the SANTE guidelines mentioned above. It is very important to check not only whether the lab is accredited in general but also for each relevant method and even each relevant substance. This has to be indicated on the list of analytes, for which the lab offers a testing schedule. On this list one will find the indication as well of the LOQ for the single substance.

[32] Bundesverband Naturkost Naturwaren e.V. 2021: Orientation Value for pesticides - A guideline to evaluate pesticide residues in organic products. https://n-bnn.de/fileadmin/user_upload/Leistungen_Services/Richtlinien_und_Empfehlungen/BNN-Orientierungswert/OW-Allg._Dokumente/230712_BNN-Orientation-Value_EN.pdf

[33] relana® Position Paper No. 19-03 “Differing results of competent laboratories” version 2019/06/25

In this context, it is important to note that laboratories can also achieve flexible accreditation for individual methods. This has the advantage that single substances that were previously not included in the scope of testing can be included at any time (after their successful validation). This gives the laboratory greater agility to be able to include new substances in the accredited test programme promptly.

However, many analyses of samples from process controls take place in the non-accredited area because their definition is not standardised (e.g. leaves, dust, filters, etc.). In such cases, it is important for the lab to adapt verified methods, which means as a consequence that the results are to be understood as purely qualitative. Such analyses are particularly useful, as they may characterise the surveyed process much more than well-defined samples from the very end of the value chain.

2.5.2 Reporting

Test reports should be clear and legally compliant. Operators do expect the laboratory to classify the results as stated in the Regulation (EU) 2018/848 and/or evaluate them according to specific industry standards (e.g. BNN [32]). However, the final classification of a case can only be done by embedding the laboratory's result into the overall context of the evaluated process. Therefore, analysis of organic samples may result in reporting the pure findings (qualitative and quantitative), without any interpretation referencing Regulation (EU) 2018/848.

As reports are often a central document in fraud cases and discussed internationally, they should be written in English. Following a standardised template avoids missing important information.

The report with analytic results of organic samples should contain at least the following information[34]:

- information on sample and sampling (see Chapters 2.2 and 2.4) Details given by the sampler and obtained by the laboratories have to be assigned as such
- photos of the original sample with traceability items
- sample receipt date and investigation period
- all tested active substances and metabolites as well as the corresponding limits of quantification (substance spectrum incl. version number; i.e. with reference on website)
- Test method/s (see Chapter 3)
- Subcontracting (if necessary)

In case of positive results:

- Summary of the active substances and metabolites detected (above LOQ see 2.3.6)
- Definition of residues via active substances, metabolites and conversion factors in accordance with currently valid regulations; the regulations must be named, e.g. Regulation (EC) No. 396/2005, Regulation (EU) 2023/915,
- Reference to the maximum levels, if the sample can be defined as indicated in Regulation (EC) No. 396/2005
- Classification of the substance according to Regulation (EU) 2018/848
- Measurement uncertainty
- Commenting the result along customer requests and based on above information

[34] QS -GmbH (2024): Guideline Residue Monitoring Fruit, Vegetables, Potatoes (Version 01.01.24)

2.5.3 Designation

Designation along Regulation (EU) 2017/625 is a compulsory precondition for labs to be charged by CBs and authorities. This is not a selection criterion for operators as designation does not indicate a higher quality level. Consequently, the effort for analyses (and thus costs) and the type of reporting is the same for all stakeholders.

2.5.4 Participation in ring tests

Ring tests are an effective means of comparing laboratories. Samples with unknown active ingredients and active ingredient contents are offered by a ring test organiser. Customers can ask for results of those ring tests to be able to assess the situation of the laboratory in comparison with others. However, the proficiency tests are usually announced and therefore reflect less of the routine. Some ring test organisers try to overcome this by sending unannounced samples as well as to set up ring tests with concentrations near LOQ, which most frequently represents the cases for organic samples [35].

In addition to these above-mentioned indicators of a laboratory's competence, some "soft" factors are no less important. These include

- accessibility
- personal competence
- flexibility

2.5.5 “Soft” factors

The laboratory should be easily accessible so that cases requiring rapid clarification can be discussed quickly. An exchange of analytical findings must be done in the shortest possible time to be able to quickly assess a case of fraud.

Within the laboratory, there should be at least one person (designated organic representative) who has both analytical knowledge and the necessary experience of active substance/matrix combinations (organic and conventional). Both above mentioned factors result in a highly flexible lab. Communication with the client should take place on an open-ended and trusting level, as further measures in the case of processing may often result in the need for further analytical measures.

[35] https://www.proof-acs.de/competenceschemes/118/

CHAPTER 3: POTENTIAL SOURCES, CONTAMINATION PATHWAYS AND CAUSES OF CONTAMINATION

Bernhard Speiser[36], Laurence Vido[37]

3.1 Understanding and investigating residue cases

3.1.1 Importance of understanding residue cases

A good understanding of potential sources, contamination pathways and causes of contamination is of high practical relevance. In routine organic production, it helps to define appropriate precautionary measures for reducing contamination risks. When a non-authorised substance is detected in organic food, it guides the official investigation in the right direction.

Contamination in organic products is usually the result of a combination of physical, technical, environmental and organisational conditions that interact with human motivations. For a thorough understanding of a residue case, it is important to understand *all aspects* of the situation.

3.1.2 Legal obligations for investigating residue cases

Article 29 of Regulation (EU) 2018/848 specifies the measures to be taken. This Vade mecum focuses mainly on pesticide residues, but the measures apply also in other cases (see also section 3.3.10). According to Article 29.1 (a), an official investigation shall be carried out with a view to determining the source and cause. However, no definitions are provided for 'source' and 'cause'. To fill this gap, this chapter proposes a practical approach to this issue (details see below).

Three situations are explicitly mentioned in Article 29 and require a decision by the certification authority / certification body (CA/CB) (for details on investigation, see Chapter 5):

- use (Article 29.2 (a)) (='main category 1' in this guideline)
- precautionary measures not taken (Article 29.2 (b)) ('neglect of precautionary measures', see section 'Causes')
- instructions from CA/CB not followed (Article 29.2(c)) (also 'neglect of precautionary measures')

3.2 Systematic approach for grouping residue cases

The diversity of residue cases (substances, crops, regions, agronomic and technical conditions, organisational aspects, motivations etc.) is overwhelming, and at this moment, different actors investigate residue cases differently. This Vade mecum proposes a standardised approach for investigation in Chapter 5. As a prerequisite, a standardised and exhaustive list of potential sources (based on our current knowledge) is needed, which is presented in this chapter (see Table 3.1). The categories are intended to facilitate an easy understanding. However, we acknowledge that other classification schemes are also possible and might lead to comparable results. Despite the systematic approach presented here, we emphasise that each residue case is a unique combination of situations and conditions which have to be considered separately.

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This article exclusively reflects the personal opinions of both authors.

The systematic approach presented here is aligned with the terminology of ‘source’ and ‘cause’ given in Art. 29. This terminology deviates slightly from everyday language. In everyday language, a ‘source’ would describe a substance or a location from where a residue originated.

Residue cases are always an interaction of a source with one or several causes. Each source can interact with different causes, but there are combinations of sources that are typical and frequent while others are rare. A residue case can only be fully understood if *both* the source and the causes have been clarified.

3.2.1 Sources

Every residue has a ‘source’. The term source describes the technical and physical aspects of a residue case, such as the detected substance, residue level, crop, underlying physical processes (e.g. persistence in soil, wind speed) etc. The source is the major characteristic of a residue case and is therefore used for systematic grouping. This chapter distinguishes five sources:

- use
- commingling
- cross-contamination
- environmental contamination
- natural presence

The investigation of technical aspects addresses the question “how did it happen?”. It often requires literature studies (for understanding the general background) and chemical analyses (for clarifying individual cases). The five sources are characterised by different contamination pathways, i.e. direct application, contamination via conventional crops, installations and equipment, the environment or natural presence. Figure 3.1. illustrates how the five contamination sources may occur in organic food production, and how they relate to different origins (from pesticides or other origin) and contamination pathways. Within each source, several subcategories can be distinguished (see Table 3.1). For more explanations, see Chapter 3.3.

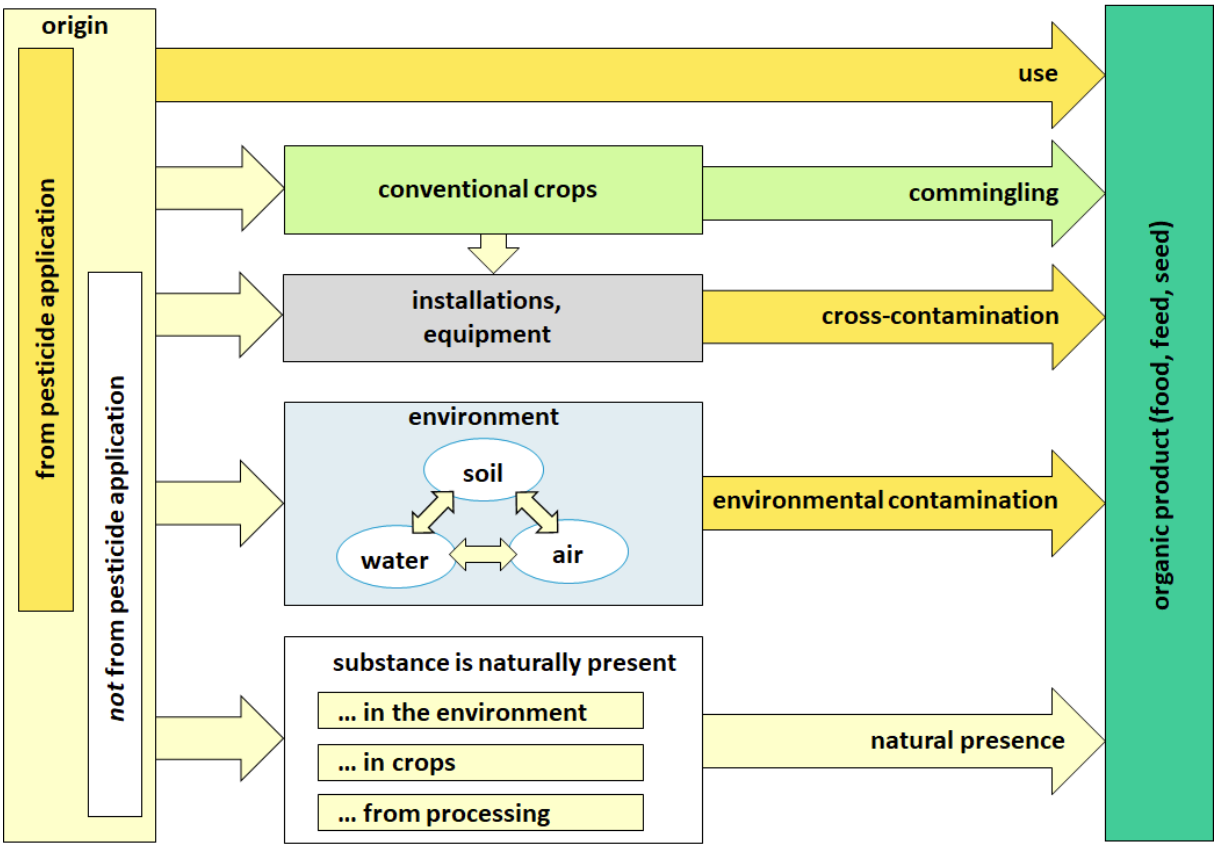

Figure 3.1: Relationship between the five contamination sources (use, commingling, cross-contamination, environmental contamination and natural presence) shown as yellow/light green arrows), pesticidal and non-pesticidal origin of substances and different contamination pathways in organic food production.

3.2.2 Causes

Every residue has at least one 'cause'. The term cause describes the organisational and motivational aspects of a residue case, such as the processes established by the operator and the behaviour of individual members of staff. Because human behaviour is a continuous spectrum, it is not possible to present a closed list of all possible causes. In addition, many residue cases are due to a coincidence of several causes which may have contributed to the contamination to variable degrees. Although it is impossible to list all possible causes, the following causes are frequently encountered and illustrate the range of possible causes:

- intentional
- insufficient precautionary measures (including absence of precautionary measures)
- neglect of precautionary measures (including non-awareness about them)
- lack of knowledge
- external factors (not under the operator's control)

The investigation of causes addresses the question "why did it happen?", and indirectly also the question of how such residue cases can be avoided in the future. Last but not least, the underlying causes greatly influence our moral attitude towards a residue case. Causes are mainly clarified by studying the operator's quality assurance (QA) documents or by on-site inspections. In practice, it is often difficult to clarify the operator's true intentions and thus to classify the causes adequately. Taking into account that several causes may have interacted in one residue case, the challenge is to identify

the key aspects that need to be amended in order to avoid future contaminations. Of course, there may be more than one possible organisational solution for many problems.

Table 3.1: Sources for residues of non-authorized pesticides in organic products

The grouping is based on sources. For explanations, comments and examples, see section 3.3.

1	**Source no 1: Use of non-authorized substance**
1.1	Non-authorised substance (pesticide, fertiliser, ...) applied in the field
1.2	Use of treated seeds or seedlings
1.3	Non-authorised substance applied during handling, storage, transport or processing (fumigant)
2	**Source no 2: Commingling with non-organic products**
2.1	Conventional product labelled / sold as organic ("100% commingling")
2.2	Organic product mixed with conventional product ("partial commingling")
3	**Source no 3: Cross-contamination**
3.1	Contamination from the operator's equipment (during harvesting or processing)
3.2	Contamination from external equipment (not under control of the operator)
3.3	Contamination from workers (insect repellents ...)
3.4	Contamination from packaging/storage (e.g. re-use of old packaging)
3.5	Contamination from the use of disinfectants (e.g. chlorate, QAC)
4	**Source no 4: Environmental contamination**
4.1	Contamination by heritage chemicals in soil
4.2	Contamination by heritage chemicals in woody plant parts
4.3	Contamination by drift from spraying in the neighbourhood
4.4	External aerial contamination (other forms of airborne contamination, such as long-range drift and contamination from aeroplane-based pesticide application)
5	**Source no 5: Natural presence**
5.1	Natural presence of the substance in crops or environment
5.2	Substance formed during authorised processes

3.3 How causes interact with sources: some typical situations

In this section, we briefly comment on each main category of sources and briefly describe how different causes interact with each source.

3.3.1 Use (main category 1)

The category 'use' describes situations where a substance is directly applied to an organic crop. Use is explicitly mentioned in Article 29.2 (a) of Regulation (EU) 2018/848 and therefore requires special attention in every investigation. Use is perceived very differently, depending on the underlying causes.

Some typical situations for use in the field are discussed below, but very similar causes may also underlie use of treated seeds and post-harvest use.

Intentional use: Any instance of intentional use will severely impact the reputation of organic farming. In general, the operator will try to hide this fact from the CA/CB, which complicates the investigation. Intentional use is always done for a specific purpose. For example, a herbicide is used under conditions of severe weed pressure, or an insecticide is used when there is a serious threat by insect pests. Thus, there can be indirect evidence for intentional application such as fields that are unusually clean of weeds, or to crops that suffer unusually little insect attack, which provides a lever for investigation ('why is this field completely free of weeds?'). High levels of residues (comparable to residues on conventional crops) are also good indicators of application.

Use prescribed by authorities: Use prescribed by authorities may involve the same crops and substances as in intentional application, but the causes are completely different. Such situations are linked to the appearance of quarantine pests or diseases. Neither the occurrence of this organism nor the prescription of the control measures is under the operator's control, so this can be attributed to the cause of 'external factors'. It can be expected that such treatments are well documented, and very little investigation is needed.

Use by mistake: On a farm with parallel organic and conventional production, a member of staff may use a non-authorised pesticide by mistake. This can be due to various causes ranging from intention to neglect.

Unconscious use: Unconscious use occurs when an operator applies an input that seems to be authorised according to the declaration on the label, but in reality, contains undeclared, non-authorised components. Some residue cases of phosphonic acid could be attributed to this cause, so it is worth mentioning specifically here. In these cases, organic farmers used inputs labelled as 'plant strengtheners' or 'seaweed extracts' (which would be authorised), without knowing that they also contained phosphonic acid (which is not authorised). This cause is best classified as 'lack of knowledge' or as 'external factors'. Unusual efficacy claims are sometimes indicators that an input might contain undeclared components (for example: 'a highly efficient phosphorus fertiliser for grapes which suffer from Powdery Mildew'). However, the presence of an unexpected claim is not a proof for non-authorised components, and the absence of such claims is not a proof for the absence of non-authorised components. The only reliable way for verification is analysis of the input.

3.3.2 Commingling (main category 2)

The category 'commingling' describes situations where non-organic food that contains a non-authorised substance is labelled as organic or commingled with organic food. Commingling does not occur while a crop is growing in the field, but it can occur at any stage after that, i.e. during harvest, transport, storage or processing. Commingling occurs only in installations which handle organic and conventional (or in-conversion) produce in parallel (for example storage of organic grains in a silo which was insufficiently emptied, and therefore contains some conventional grains of the previous lot, or an insufficiently cleaned metal bin with remains of conventional butter that is commingled with organic butter). For every operator in the trade chain, there is a possibility that the product has been commingled before it reached his premises and for every operator with parallel production, there is also a risk that commingling occurs on his premises. Commingling is perceived very differently, depending on the underlying causes.

Intentional commingling of organic and conventional products: Intentional commingling of organic and conventional products is another instance which has a severe impact on the reputation of organic food. This is a form of fraud, which is done to gain unjustified profit from the difference in prices for organic and conventional products. It is revealed only if the quantities of organic products sold are greater

than the quantities bought and can thus be investigated by checking trade chains. In simple fraud cases, the mislabelled products will show a similar pattern of pesticide residues as that of non-organic products. However, there have been cases where fraudulent operators deliberately purchased residue-free non-organic products, in order to minimise the risks of detection. Sophisticated fraud of this type can be characterised by (i) complex international trade chains, (ii) faked organic certificates, and (iii) large quantities of produce.

Unintentional confusion of organic and conventional food lots: Unintentional confusion of organic and conventional food lots is usually the result of insufficient precautionary measures or neglect of precautionary measures. Unintentional confusion may be an occasional event, but it is done neither systematically nor intentionally, because it does not lead to unjustified profit.

Unintentional commingling of organic products with a minor quantity of conventional products: Unintentional commingling occurs when conventional products are handled on an installation, and not completely removed before organic products are handled on the same installation. It should not be mixed up with cross-contamination (see next paragraph). It can be prevented by cleaning the installations between handling conventional and organic lots. Another possibility to minimise commingling is the use of 'separating batches' (flushing or purging). Thus, unintentional commingling is usually the result of insufficient precautionary measures or neglect of precautionary measures.

3.3.3 Cross-contamination (main category 3)

The category 'cross-contamination' describes situations where organic products are contaminated with non-authorised substances by contact with installations or equipment (after harvest, during transport, storage or processing). The difference between commingling and cross-contamination is that with commingling, the organic product is contaminated by a conventional product that contains pesticide residues, while in cross-contamination, only the pesticides are transferred from the conventional to the organic product. Cross-contamination occurs only in installations which handle organic and conventional produce in parallel (for example a processing facility which handles organic and conventional carrots and has a common cycle for the washing water, so that the organic carrots are contaminated via the washing water, or an insufficiently cleaned filter in a wine cellar that contaminates the organic must). Operators handling organic products are obliged to put in place and maintain precautionary measures to avoid cross-contamination. Thus, cross-contamination is usually the result of inadequate precautionary measures, or neglect of precautionary measures. Such circumstances are explicitly mentioned in Article 29.2(b) and (c) of Regulation (EU) 2018/848 and therefore require special attention in every investigation.

In practice, there is often not a single cause but rather a complex interaction from inadequate precautionary measures, neglect of precautionary measures and lack of knowledge. For example, worker A is sick and replaced by worker B who causes cross-contamination. Investigation shows that worker B neglected an instruction ('neglect of precautionary measures'). However, the investigation also shows that this instruction was placed inconspicuously in a corner ('insufficient precautionary measure'). Finally, since worker B normally does not perform this task, he was not aware of the contamination risk and did not look out for potential instructions ('lack of knowledge').

Contamination from the operator's own equipment: A wide-spread example for contamination from the operator's own equipment is the fumigation of conventional cereals, oilseeds or pulses with phosphide tablets on the operator's premises. In this treatment, phosphide-rich dust particles are formed which adhere to the grains. During transport, storage and processing, the dust settles in the installations and equipment, from where it can contaminate other food lots including organic food. Precautionary measures include changes in pest control (e.g. application of phosphide in bags instead of tablets), cleaning of installations and separating batches.

Contamination from workers: A common example for this type of contamination is the use of insect repellents. These may adhere to the hands of field workers and contaminate the harvest. Such contamination is especially found in wild-collected foods such as berries, herbs or mushrooms and in foods that are manually handled after harvest, e.g. cocoa beans. Such contamination often stems from a lack of knowledge, inadequate precautionary measures and neglect of precautionary measures. However, there may also be important public health reasons to use insect repellents, in which case the contamination is, at least in part, due to external factors.

Contamination from disinfectants: A wide-spread example for this type is the use of chlorine-based disinfectants in food processing, which may lead to the presence of chlorate. Precautionary measures include sufficient rinsing after disinfection. Such residues are usually caused by inadequate precautionary measures or neglect of precautionary measures. Note: this occurrence is placed in the category of 'cross-contamination', because disinfection is under the operator's control. By contrast, if an operator uses tap water that has been treated with chlorine by the communal water supply, we would consider this as 'environmental contamination'. A second example is the use of QAC (quaternary ammonium compounds) as disinfectants.

Anthraquinone: Anthraquinone can be used as a bird-repellent seed treatment (not authorised any more in the EU). However, it is also formed during combustion and is thus a natural constituent of smoke. It may contaminate organic products which are dried over a wood fire or with hot air generated by fossil fuels[38].

Biphenyl: biphenyl can be used as a fungicide (not authorised any more in the EU). However, it is also *formed* during combustion and is thus a natural constituent of smoke. It may contaminate organic products which are dried over a wood fire or with hot air generated by fossil fuels. It has frequently been found in parsley grown in heated glass houses, probably due to the exhaust fumes from the heating[39].

Phthalimide: phthalimide can be used as a fungicide. However, it can also be a product formed from phthalic acid during analysis. Phthalic acid is ubiquitously present in dust (Bio Suisse 2021[40]).

3.3.4 Environmental contamination (main category 4)

The category 'environmental contamination' describes situations where organic products are contaminated with non-authorised substances in the environment. Pesticides are used for a wide variety of purposes in modern society. They are applied in conventional agriculture, stock-protection, private gardening, forestry, road and railroad maintenance, conservation of industrial goods, human and veterinary medicine. Once pesticides have entered the environment, they may remain there for variable time periods, and may also be dispersed to other environmental compartments (e.g. from seed to soil, from soil to water, from water to air, from air to soil, etc. For a review, see Schleiffer and Speiser, 2022[41]). Thus, a multitude of potential contamination sources and pathways exist. Two contamination sources occur frequently: heritage and drift. For these two sources, we have assigned separate sub-categories.

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[38] Tong B, Speiser (2017) Rückstände von Anthrachinon in Lebensmitteln. Forschungsinstitut für biologischen Landbau (FiBL), CH-Frick. https://orgprints.org/id/eprint/34122/

[39] Speiser B, Bickel R (2017) Rückstände von Biphenyl bei Kräutern – Literaturstudie zu Vorkommen, Ursachen und Vermeidung. Forschungsinstitut für biologischen Landbau (FiBL), CH-Frick. https://orgprints.org/id/eprint/34121/

[40] Bio Suisse (2021). Informationen und Stellungnahme zu Rückständen von Phthalimid und «Folpet (Summe)». https://knospe.bio-suisse.ch/dam/jcr:e4a38edd-1b74-4d18-b0fb-19884e32ce7e/d_grundlagenphthalimid.pdf

[41] Schleiffer M, Speiser B (2022). Presence of pesticides in the environment, transition into organic food, and implications for quality assurance along the European organic food chain – A review. Environmental Pollution 313 (2022) 120116. https://orgprints.org/id/eprint/44485/

Environmental contamination differs from cross-contamination by the fact that cross-contamination sources are under the operator's control, while environmental contamination sources are not. Some kinds of environmental contamination can be avoided or reduced by precautionary measures while other kinds can hardly be prevented, or only with great effort (see Chapter 7 'decision-making'). In the latter case, the cause is classified as an external factor not under the operator's control.

3.3.5 Contamination by heritage chemicals in soil (sub-category 4.1)

In the soil, some pesticides degrade very quickly, while others remain for prolonged periods. If a pesticide degrades more slowly than the conversion period, it may have been used formerly during the time of conventional production and persist into the present time of organic production. In this case, it is called a 'heritage pesticide'. The best-known examples are the so-called 'organochlorine pesticides', which degrade extremely slowly, and may be present in soils for decades after their use. Organochlorine pesticides include substances such as DDT, aldrin, dieldrin, endosulfan, lindane, hexachlorobenzene and chlordecone. These substances were widely used from the 1950s onward. In Europe, they have been removed from the market several decades ago, but in a few third countries they are still available. Due to their wide usage and persistence, organochlorine pesticides are present in many soils. Crops from the family Cucurbitaceae (cucumbers, zucchini, pumpkins etc.) take up organochlorine pesticides from the soil with residue levels highest in seeds (relevant for pumpkin seeds; Speiser and Stampfli 2012[42]). Organochlorine pesticides have also occasionally been found in carrots, but this has not been extensively researched. Many other crops do not take up organochlorine pesticides. Residues due to this source are only found with certain combinations of pesticides and crops. The only way to avoid such residues is to avoid growing Cucurbitaceae on contaminated soils. However, organic farmers do not necessarily know the contamination levels in each field. Correspondingly, the causes for such contamination vary from 'lack of knowledge' to 'neglect of precautionary measures' or 'external factors'.

Flooding: During floods, pesticides originating from conventional fields may be deposited on organic fields. Because this contamination pathway is similar to heritage chemicals in the soil, the two contamination pathways are placed in the same sub-category here.

3.3.6 Contamination by heritage chemicals in woody plant parts (sub-category 4.2)

When applied to perennial crops, some pesticides are transported into woody plant parts, where they may remain for prolonged periods. When these substances are re-mobilised and transported into leaves or fruit, this may cause residues in the harvest. A well-known example for such a source and contamination pathway is phosphonic acid. Residues of phosphonic acid are frequently found in perennial fruit such as apples and grapes. It has been shown that residues can be caused by applications dating back several years (e.g. Bögli and Speiser 2019[43]). For bare-root strawberry plants it has been shown that phosphonic acid can be stored in the roots and later re-located into the fruit (Speiser and Schärer 2018[44]).

[42] Speiser B, Stampfli N (2012). Rückstände in Kürbisgewächsen. So werden Rückstände aus Altlasten von Organochlorpestiziden vermieden. FiBL-Merkblatt Nr 1478, 4 pp. https://orgprints.org/id/eprint/25426/

[43] Bögli S, Speiser B (2019). Mögliche Rückstände von Phosphonaten auch nach der Umstellung auf Bioweinbau. *Agrarforschung Schweiz*, 2019, 10: 344-345. https://orgprints.org/id/eprint/36455/

[44] Speiser B, Schärer HJ (2018). Translocation of phosphonate from frigoplants to fruits in strawberries. In: Proceedings of the Ecofruit Conference 2018, February 19–21, 2018, University of Hohenheim, Germany, pp. 218–220. https://www.ecofruit.net/wp-content/uploads/2020/04/58_Speiser_218-220.pdf

3.3.7 Contamination by drift from spraying in the neighbourhood (sub-category 4.3)

When pesticides are sprayed onto crops, a certain proportion of the spray solution will end up on the target crop, while the remainder is carried away and will end up elsewhere (drift). In this way, non-authorised pesticides can be carried from conventional crops to organic crops in neighbouring fields. When drift occurs, residue levels are usually much higher in the immediate vicinity of the neighbouring plot than in the field centre, which offers an indicator for investigating this type of contamination (see Chapter 5 'investigation'). Drift is particularly important in crops that are grown in small plots, such as grapevines. A pilot study showed that drift is extremely frequent in grapes grown in small plots (Speiser and Schleiffer 2023[45]).

Organic farmers have limited possibilities for reducing drift (e.g. planting hedgerows). By contrast, conventional farmers can greatly influence the extent of drift going out from their fields (adjustments of type of sprayer, nozzles and spraying pressure, as well as respecting wind speed and direction). Thus, the most important precautionary measure for organic farmers is to talk to their conventional neighbours. Practical hints on how to avoid drift are given by Speiser and Kretzschmar (2021[46]). Depending on the individual situation, an organic farmer may or may not have control over incoming drift and the causes have to be classified accordingly.

3.3.8 Other airborne contaminations (sub-category 4.4)

Besides the classical drift described above, pesticides may also be transported in the environment together with soil particles to which they adhere, or with clouds or rainwater. A poorly known contamination pathway is 'long-range drift', which can carry pesticides over distances up to 1000 km[47]. With such distances, a contamination can never be traced back to the original source and there are no precautionary measures against such contamination. Of course, there can also be drift at intermediate distances, where, for example, residues of prosulphocarb can be traced back to potato production in the region, but they cannot be traced back to an individual farm or field.

Contamination from aeroplane-based pesticide applications can also be placed in this category. In regions where pesticides are routinely applied by aeroplanes, there is a substantial risk of such contamination, while in other regions such contamination is unlikely. CBs/CAs who are familiar with local farming practices know whether there is a risk of such contamination.

In crops that are air-dried or stored outdoors, airborne contamination may also occur after harvest.

3.3.9 Natural presence (main category 5)

The category 'natural presence' describes situations where no pesticides are involved but a naturally present substance triggers an investigation because it falls under the 'residue definition' of pesticides. Regulation (EC) 396/2005 defines maximum residue levels (MRLs) for substances that are either pesticides or metabolites of pesticides. When such substances are detected, this is considered to be a 'residue case' and triggers the procedures described in this Vade mecum. However, there are a few substances which can also be present for reasons unrelated to pesticide use (besides being a potential pesticide or pesticide metabolite). In such cases it is important to determine whether the residue is due to a pesticide application or whether it has another source. For an overview of such substances,

[45] Speiser B, Schleiffer M (2023). Rückstandsrisiko durch Abdrift bei kleinen Schweizer Biorebbergen. Agrarforschung Schweiz, 2023, 14, S. 191-196. https://orgprints.org/id/eprint/51521/

[46] Speiser B, Kretzschmar U (2021). Abdrift auf Bioparzellen vermeiden. FiBL-Merkblatt Nr 1138, 10 pp. https://www.fibl.org/de/shop/1138-abdrift-vermeiden

[47] FOCUS (2008). Pesticides in Air: Considerations for Exposure Assessment. Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev 2 June 2008. 327 pp.

see AÖL 2024[48]. This grouping system distinguishes between substances that are naturally present in crops or the environment and substances that are formed during authorised processes. The most important substances with natural presence in crops or environment are:

Carbon disulphide: carbon disulphide is taken as an indicator for the presence of dithiocarbamates. However, plants from the cabbage family (*Brassicaceae*) and from the leek genus (*Allium*) naturally contain sulfur compounds that form carbon disulphide during analysis (Bio Suisse 2021[49]).

Inorganic bromide: inorganic bromide can be a metabolite of methyl bromide (which is no longer authorised in the EU). However, it is also a natural constituent of sea water and occurs in traces in all soils, water, plants and animals. There are crops that naturally accumulate larger quantities of bromide (e.g. Brazil nut). Due to the presence in sea water, bromide levels are generally elevated in crops grown close to the sea and also in fertilisers derived from the sea-borne materials such as algae and mussel shells.

1,4 dimethylnaphthalin: 1,4 dimethylnaphthalin can be used as a sprouting inhibitor in potatoes. However, it is also naturally present in potato tubers where it is involved in the natural regulation of dormancy (Bio Suisse 2023[50]).

Phosphonic acid: residues of phosphonic acid can originate from unconscious use and from heritage in woody plant parts, for which reason it is already mentioned in category 3.3.1 and 3.3.6. However, there are indications that phosphonic acid can probably also originate from other sources, for example as a metabolite of microbial phosphorus metabolism[51]. At the time when this handbook was written, conclusive evidence for natural occurrence is still lacking.

Please note that *anthraquinone*, *biphenyl* and *phthalimide* are not categorised here, but under 'cross-contamination'. These substances also have non-pesticidal origin (see AÖL 2024[52]). However, contamination with these substances is connected to processing or storage and can be avoided with appropriate precautionary measures. For this reason, we decided to categorise them under 'cross-contamination'.

3.3.10 Note on special cases

The present categorisation was written mainly with pesticide residues on plant-based organic food in mind. However, we anticipate that it might also be applied to other commodities and to other types of contamination. For these cases, the following considerations apply:

Feed: For plant-based feed the same considerations apply as for plant-based food.

Seeds: The categories presented above apply also to seed, but not all of them will be relevant in practice. For processed seeds (pelletised, coated etc.), aspects of cross-contamination are particularly important.

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[48] AÖL (2024). Multiple Source-Substanzen - AöL-Information zu Multiple Source-Substanzen in Bio-Produkten. AöL-Mitgliederinformation, Fassung vom 01.02.2024. Download from https://www.aoel.org/themen/unerwuenschtestoffe/

[49] Bio Suisse (2021). Informationen und Stellungnahme zu Rückständen von Dithiocarbamaten. https://knospe.bio-suisse.ch/dam/jcr:0c70251d-1d6b-4b05-abfe-bd62412f3516/d_grundlagendithiocarbamate.pdf

[50] Bio Suisse (2021). Informationen und Stellungnahme zu Rückständen von Dimethylnaphthalin. https://knospe.bio-suisse.ch/dam/jcr:72252301-9d14-4786-b440-d21426be6588/d_grundlagendmn.pdf

[51] Nader W, Zahm A, Jaschik J (2023). Phosphonic acid in plant-based food and feed products – Where does it come from? Food Control 150 (2023) 109701

[52] AÖL (2024). Multiple Source-Substanzen - AöL-Information zu Multiple Source-Substanzen in Bio-Produkten. AöL-Mitgliederinformation, Fassung vom 01.02.2024. Download from https://www.aoel.org/themen/unerwuenschtestoffe/

Animal-based food and feed: The use of pesticides is less important in animal husbandry, but there is some use for parasite control.

Honey and beeswax: The main contamination risks are (i) collection of pollen or nectar from conventional crops (environmental contamination), (ii) control of wax moth or varroa mite with non-authorised substances (use), (iii) use of contaminated wax (cross- contamination).

Processed food and feed: Residue findings on processed food and feed are more complex to interpret than findings on raw food/feed. So-called 'processing factors' may be applicable, and if several components are involved, it is necessary to determine from which component the residue originates. For details, see Chapter 4 (investigation).

Non-authorised inputs other than pesticides: the use of non-authorised inputs of any kind is a non-compliance and should have the same consequences. In practical terms, however, the tools for analysing pesticides allow the detection of small traces, while many other input categories can hardly be analysed.

GMO: analysis for GMOs is very sensitive but detection is limited to products which contain DNA. As GMOs are hotly debated, this topic is not further discussed here.

3.3.11 Note on non-confirmed residues

In everyday work, operators and certifiers are sometimes confronted with 'residues' that are not confirmed by further investigation. Possible reasons include contamination during sampling, transport, storage and processing of the sample. There may also be technical problems with the analytical equipment and organisational problems such as confounding of samples, data or analytical reports. To eliminate this possibility, a 'counter sample' of the same product can be analysed. In general, it is recommended to send counter samples to a different lab, because this also eliminates methodical shortcomings of an individual lab.

Although 'non-confirmed residues' have some relevance in everyday work, we have deliberately not included them in Table 3.1, to avoid confusion.

CHAPTER 4: THE TOOLBOX FOR INVESTIGATION METHODS AND TECHNIQUES

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4.1 Introduction

The content of this chapter is specific to official investigations in organic production. General aspects of inspection techniques are not covered. It is primarily written for experienced inspectors although it may also inspire operators. This chapter focuses on residues of non-authorised pesticides and labelling deficiencies as these are the most relevant for suspect cases at present. However, the toolbox explained in this chapter can also be used for other suspicious cases.

Each official investigation is an individual, specific case that requires the effective and efficient use and combination of different inspection techniques. In this chapter, we therefore present single tools that allow investigators to carry out a forensic profiling of each case.

Official investigations can be conducted off-site or on-site, and a variety of inspection techniques can be used in both situations.

4.2 Documentary checks (off-site and on-site)

For each residue case, the first thing to do is a documentary check.

Evaluation of the analytical report received by a control authority/control body (CA/CB)

Accredited laboratories may report a wide range of substances and products that are not authorised in organic production (see Chapter 5). Most cases leading to official investigations today concern residues of non-authorised pesticides. There are several aspects to be considered when reviewing an analytical report. In all cases, much useful information can be deduced from the evaluation of the analytical report.

4.2.1 The product analysed

Perishable products (spinach, lettuce, strawberries and other fresh small fruits that are typically unfit to be kept in storage for more than a week) may contain residues due to application before harvest (likely). The shorter their "natural" post-harvest lifespan, the less likely the post-harvest use of prohibited substances. In case of pre-harvest samples, commingling can be excluded. Fresh products (apples, potatoes, carrots, etc.) that may be kept in storage for several weeks even months) may still contain residues from applications before harvest. Certain fresh products are also kept in storage units where post-harvest pest control and/or non-authorised preservation techniques may also have been applied. Taking into account when the sample was taken (before or after harvest) allows for elimination of post-harvest application and commingling. In addition, certain fresh products are characterised by specific chemical properties:

- Plants or unprocessed plant products of the *Alliaceae* family are known to contain natural organosulfur compounds (Zippert, 2021[55]). This may result in false positive detection of

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This article exclusively reflects the personal opinions of both authors.

[55] Zipper, Hubert, 2001: Facing Analytical Challenges of Dithiocarbamate Analysis - Step-by-Step https://www.eurl-pesticides.eu/userfiles/file/EurlFV/Joint2021/Zipper2.pdf

dithiocarbamates in samples of such plants (see also Chapter 2). For such products, natural presence is a realistic source.

- Plants or unprocessed plant products of the *Cucurbitaceae* family are capable of taking up and accumulating significant amounts of persistent organic pollutants (POPs). They are a group of toxic and sometimes pesticidal compounds with global distribution and long persistence in the environment including the soil. POPs are hydrophobic with the potential to bioaccumulate in the fatty bodies of tissues. For such products, environmental contamination is a realistic source.

Dried products (raisins, dried mangoes, etc.) are typically characterised by a reduction of moisture content which may result in a "higher" concentration (expressed in mg/kg) but may also result in a lower concentration due to degradation of the active substance because of the drying process (e.g. heat drying by heating) with time and light. For more information, please check the EU database for processing factors (https://zenodo.org/records/10984823). Processing factors can be helpful to understand and explain different analytical results from processed and unprocessed products but should only be applied if mass balance and traceability checks do not unveil non-compliance.

- A special category of dried products are **herbs and spices** and also hops which are not only dried but also contain many aromatic molecules. The detection of products and substances containing aromatic cycles (benzene, biphenyl etc.) may be linked to the natural presence of such molecules generated by the plant itself.
- Another category is **Brazil nuts** (dried) which are known to contain naturally higher amounts of bromide. Detection of bromide in these nuts is linked to its natural presence but may also indicate the application of the insecticide methyl-bromide, although use of this substance has been banned in the EU since March 2010.

Processed products like oils and essential oils are known to originate from plants which absorb and integrate molecules into their metabolism, whereby substances accumulate in parts of the plant (e.g. volatile pesticides in oils and essential oils, see Rombach et al. 2020[56]) which could result in accepting "environmental contamination" as the source.

Another way to classify products is by considering their composition.

Mono-ingredient products (cereals, apple juice, …) may be unprocessed or processed products but may still consist of multiple lots, originating from different suppliers or different fields of the same supplier. According to CAC/GL 33 from FAO (https://www.fao.org/input/download/standards) a lot is defined as follows: A quantity of a food material delivered at one time and known, or presumed, by the sampling officer to have uniform characteristics such as origin, producer, variety, packer, type of packing, markings, consignor, etc. A suspect lot is one which, for any reason, is suspected to contain a non-authorised residue. The presence of prohibited substances in mono-ingredient products can also be due to commingling. In their summary of point 1.4.3, Rombach et al[56] specify that liquids in tanks have a higher degree of homogeneity than solid products.

Multi-ingredient products (e.g. dried fruit mix) contain different types of ingredients (processed and/or unprocessed), and each ingredient may be composed of one or more (sub)lots of that product. The presence of non-authorised substances may be linked to one or more of the ingredients. Where possible and relevant, sampling of multi-ingredient products shall also cover sampling of the riskiest ingredients individually. In addition, instead of testing the mix, it is equally relevant to test only the

[56] Rombach, M., Lach, G., Friedle, A., Eckert, G., Schigulski S. 2020: MANUAL "Laboratory analysis and pesticide residues in the control procedure for organic farming", https://pruefgesellschaft.bio/wp-content/uploads/2020/06/Manual_English_web_2020-06-04_s.pdf based on the manual "Risikomanagement von Pflanzenschutzmittel-Rückständen in Lebensmitteln aus Ökologischem Landbau", https://www.gfrs.de/fileadmin/files/manual_rueckstaende_03OE461_Stand_1-2015.pdf

riskiest ingredients e.g. after physically separating that ingredient from the other ingredients in the mix.

Other classifications

Samples taken from **frozen products** need to be kept in a frozen condition until the preparation of the sample for analysis. If there are indications that this could not be the case, then the analytical result may not be reliable due to microbiological activity enhanced by the broken cell structure after unfreezing.

Certain **combinations of products and non-EU countries of origin** have been/will be listed by the EU Commission as high-risk products and require particular attention in terms of identification of the scope of analysis. The full overview of high-risk products for 2024 can be found on the European Commission's dedicated webpage on trade in organics.[57] For such products, the possibilities of "use" are wider because relevant EU regulation does not apply in third countries.

The particularity of interpreting analytical results of **leaves** is related to the sampling technique. Sampling (further discussed in point 4.5) of leaves is a time sensitive activity which is useful at times when there are no fruits (including roots and tubers) yet and when leaves are vulnerable to damage due to fungi or insects. Sampling of leaves allows the exclusion of commingling. This paragraph does not concern sampling of leaves from leafy vegetables (spinach, lettuce, chard etc.)

Drip irrigation systems may contain soluble fertilisers and/or e.g. nematicides in the case of cultivation of tuber crops (potato, carrots etc.) During on-site inspections (see further), check for remaining traces of prohibited products to prove "use". Aerial irrigation systems are less likely to be used for application of pesticides or soluble fertilisers.

Analytical results after analytical testing of remaining liquid in tanks from **spraying devices** used in organic production, has been proved to be a very effective method to detect the use of prohibited pesticides, thus identifying the source.

Fertilisers are not supposed to contain active substances used in plant protection. However, sometimes they do. In the EU, labelling rules for fertilisers are laid down in Annex III of Regulation (EU) 2019/1009[58], it is stated[59] that the list of ingredients shall contain all ingredients whose mass % exceeds 5%. This ingredient list allows farmers and inspectors to verify the components of the fertiliser and the composition[60]. But this Regulation also states[61] that "phosphonates shall not be added intentionally to any EU fertilising product. Any unintentional presence of phosphonates shall not exceed 0,5% by mass. That means that an application of 200 kg of fertiliser could result in also an application of 1 kg phosphonates while remaining "invisible" for farmer and inspector.

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[57] DG AGRI working document on additional official controls on products originating from certain third countries Ref. Ares(2023)8135188 – 29/11/2023 https://agriculture.ec.europa.eu/document/download/a654b3be-ba65-4bfd-b3bb-cf392f577773_en?filename=swd-additional-controls-products-from-certain-third-countries_en.pdf

[58] Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilizing products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003

[59] Annex III, Part I point (1)(h) of Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilizing products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003

[60] The total amount of phosphorous (P) is expressed as P_2O_5, (P^{+V}) thus ignoring the amounts of phosphonic acid and the salts of phosphonic acid (P^{+III}).

[61] Annex I Part II point (6) of Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilizing products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003

4.2.2 The plant protection product

The main question to answer is: Could use of the prohibited active substance make sense for the plant or plant product concerned? The answer to that question is also relevant to evaluate the likelihood of commingling with conventional products.

Another important question is: could the active substance found be explained by contact without use due to failing precautionary measures?

Active substances used in plant protection products are characterised by a set of chemical properties. The University of Hertfordshire has set up a publicly accessible database where such information has been centralised and may be consulted free of charge (Lewis, K.A. et al., 2016[62]).

> The term "active substance" is used in relation to plant protection products (Regulation (EU) 1107/2009), but also in relation to biocidal products as defined in the Biocidal Products Regulation (EU) 528/2012. The approved active substances for conventional plant protection products are listed in Regulations (EU) 540/2011 and 541/2011. The approved active substances for biocidal products are listed in Regulation (EU) 1062/2014.
>
> Compared to the conditions for the use of active substances in plant protection products, Regulation (EU) 2018/848 does not refer to specific conditions for the use of products and substances as biocides. Therefore, Regulation (EU) 528/2012 and its implementing regulation on biocidal products and their use also apply to organic production and active substances covered by these regulations may be used as biocides in organic production.

Systemic active substances are absorbed by the plant, mostly through the leaves but also by the roots. They enter the plant tissue and maintain their function inside the plants. **Contact** substances are not absorbed by the plant. Their action takes place shortly after application. They are washed off by rain. Detection of active substances with contact activity indicates recent contact between the crop and the active substance.

Active substances which may be used in the EU as plant protection products are authorised at EU level. Each EU Member State has the authority to approve plant protection products that are authorised to be available on the domestic market for use in conventional production. At member state level, the authorised use of plant protection products in conventional farming is also subject to conditions (limitation in crops, limitations in time, number of applications per season, dosage per application etc.) An overview of the websites where these authorisations can be consulted can be found in Table 2.5. This of course does not exclude the possible use of prohibited plant protection products. In countries outside the EU (third countries), other active substances may be approved which are not authorised for use in the EU. Additionally, the national registration process for plant protection products may be deficient, resulting in non-approved plant protection products being used more frequently.

The **persistence** of an active substance(s) is an important factor. After use, some active substances degrade quickly resulting in the formation of residues or metabolites, while other active substances degrade slowly or not at all. The rate of persistence in soil is expressed as the “degradation rate” (DT). Persistence in soil can be expressed as DT_{50} or DT_{90}, where the 50 and 90 stand for 50% and 90% reduction. In the plant matrix, degradation is expressed as “Dissipation Rate” (DL, again as DL_{50} or DL_{90}). According to the EU Commission “The half-life can help estimate whether or not a pesticide tends to

[62] Lewis, K.A., Tzilivakis, J., Warner, D. and Green, A. (2016) An international database for pesticide risk assessments and management. *Human and Ecological Risk Assessment: An International Journal*, **22**(4), 1050-1064. DOI: 10.1080/10807039.2015.1133242 The database is directly accessible here: https://sitem.herts.ac.uk/aeru/ppdb/en/atoz.htm

build up in the environment. Pesticide half-lives can be divided into three groups in order to estimate persistence:

- low (less than 16 days half-life),
- moderate (16 to 59 days),
- and high (over 60 days)"

(source: PPT COM's expectations in terms of PES RES approach, 20.04.21).

Active substances in plant protection products may be **volatile**. Pesticide volatilisation can be defined as the movement of pesticide vapours through the air. People such as farm workers and bystanders can be exposed to pesticides by breathing these vapours after an application has occurred. Volatilization is considered differently than pesticide movement by spray drift, erosion, or windblown dust/soil particles.[63]

Volatile substances change aggregation conditions easily as a result of changing temperature or air pressure. The higher the volatilisation rate (max % of the applied dose found on plant surface) the higher the possibility of uncontrolled transport of the active substance by air.

For certain substances (like e.g. metazachlor, haluxifen, fosetyl-aluminium and flocanamid), laboratories have the legal obligation to report the presence of the active substance as a sum of the concentration of the active substance and the concentration of its **metabolite(s), isomers, conjugates or otherwise related molecules**. If the active substance itself is detected, then "use" is very likely. In cases where the active substance itself is not detected, the likelihood for recent use in a plant protection product may be less – depending on the substance and its chemical properties.

Table 4.1: An example of the detection of phosphonic acid in a concentration of 0,087 mg/kg without the detection of fosetyl, has to be reported by the lab as a detection of fosetyl-Al in a concentration of 0,117 mg/kg even if there is no detection of fosetyl

Parameter	Unit	Result	Testing technique	Method
Fosetyl	mg/kg	< 0,01	LC-MS/MS	EURL-QePPe-PO
Phosphonic acid	mg/kg	0,087	LC-MS/MS	EURL-QePPe-PO
Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts expressed as fosetyl)	mg/kg	0,117	LC-MS/MS	EURL-QePPe-PO

This is a typical example of a product containing phosphonic acid only and reported as detection of fosetyl-Al because of the residue definition of the latter. In such cases the measured concentration of phosphonic acid is multiplied with a factor which represents the ratio of the molecular masses of fosetyl and phosphonic acid (resp. 104 g/mol and 77 g/mol).

Safeners, synergists, adjuvants and co-formulants authorised for use in conventional farming may be used in organic production as well. In the EU, the presence of these substances in a plant protection

[63] https://www.epa.gov/reducing-pesticide-drift/pesticide-volatilization

https://www.corteva.us/products-and-solutions/land-management/articles/minimize-effects-of-volatility-and-spray-drift-when-applying-herbicides.html

product is not subject to labelling[64]. Differences in application of EU rules may have an impact on intra-EU trade e.g. piperonyl-butoxide (PBO) which was not authorised for use in organic production according to the French competent authorities.[65] This situation is no longer the case since the application of Regulation (EU) 2018/848 which states that all safeners, synergists, adjuvants and co-formulants (including PBO) authorised in Europe for agriculture uses can be used in organic farming.

The FAQ from the EU Commission provides the answer to the question whether pyrethrins containing PBO may be used in organic production: Pyrethrins extracted from plants are allowed in organic farming including the use of synergists if generally approved for this purpose by the authorities of the corresponding EU member state.

The detection of sulfur dioxide in coconut sugar is an indication of unauthorised bleaching resulting from the use of a non-authorised processing aid and possibly other non-authorised practices (e.g. blending of coconut sugar with other products). Such a detection is expected to be investigated by Authorities, competent in food safety.

The **concentration(s)** of the active substances identified as such, is not a basis for organic certification decision making in the EU, but nevertheless, it has to be evaluated. The legal requirements for reporting of analytical tests by labs are described in Chapter 2.

In the lower range, unquantifiable presence of residues on its own (e.g. without indication of suspicion of use during sampling taking) and sometimes reported by the lab as "traces", does not qualify as "substantiated information about the presence". By consequence, the detection of "traces" of one single active substance, shall not initiate an official investigation. However, as exceptions to the previous statement, the presence of traces of active substances needs to be evaluated carefully:

- where such presence is also associated with quantifiable presence of other active substances
- the active substance has a low DT_{50} value (persistence)
- when use of non-authorised substances or mixing are suspected during an inspection and sample is taken
- when non-compliances were previously found

On the other side of the spectrum, concentrations of active substances exceeding the applicable **"Maximum Residue Level"** (MRL), shall be reported to the authority competent for food or feed safety. MRLs for unprocessed products exist at EU level and can be found at a dedicated website of the European Commission [66]. For certain active substances, the MRL is a default MRL value, indicated by an asterisk (*). Default MRLs are also to be considered as the lower limit of analytical determination. Default MRLs apply to active substances that have been banned for use on the EU market like chlorpyrifos and is 0,01 mg/kg regardless of the product.

For processed products, the application of a processing factor is useful to support the determination of a source and cause but only if the contamination occurred before processing. The processing factors to be applied in such cases are those laid down in the EU database for processing factors in relation to the MRL regulation. For more information see https://zenodo.org/records/10984823

[64] For more details see Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products.

[65] https://www.phytocontrol.com/veille-reglementaire/le-piperonyl-butoxide-pbo/ in French

[66] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls

4.2.3 Evaluation of the operator file

A review of the **non-compliance history** from previous inspection reports and reviews delivers valuable information about the situation on site and the risk probability of a major or critical non-compliance occurring. Operators that have been previously certified by another CA/CB and those involved in mixed production are of particular relevance for verification of compliance with Art 28(1) of Reg 2018/848. In addition, operators and farmers starting organic production deserve particular attention as regards use of unauthorised products and substances and cross-contamination.

The **description of the organic activity** can deliver useful information: maps providing information about the physical location of fields, buildings belonging to production and/or preparation activities, recipes of processors etc. The description allows a review of the feasibility of the organic activities and capacities (yields, storage, transport, etc.).

Precautionary measures shall include the identification of risks for contamination and commingling as well as the actions put in place by the operator to avoid such problems. Once certified, the operator may be reassured that the design of the precautionary measures presented to the CA/CB is appropriate and proportionate. Even where the operator is able to demonstrate that he has applied those measures, the presence of non-authorised products and substances may be due to (i) inappropriate identification of risks, or (ii) inappropriate implementation of the precautionary measures.

4.2.4 Records

In many countries, the **official registration documents for legal entities** can be checked online. This allows for a reality check of the different operators involved in an organic supply chain and might also include the latest annual financial statements to enable plausibility checks during an official investigation.

Record keeping requirements for all types of operators involved in organic production are regulated by the EU organic regulation. Depending on the nature of the investigation, specific records may be selected to be inspected. Typically, all records concerning parallel production activities including records on the separation of in-conversion and organic products at farming level or on cleaning prior to organic production runs in preparation/processing facilities have particular relevance.

The EU organic regulation furthermore enables organic inspectors to also inspect **financial records**. Checking whether there are different bank accounts, which business activities are carried out and reviewing financial activities in the different accounts helps to detect falsified invoices or purchases of non-authorized inputs or products.

Organic farmers need to keep **records** that may be checked by competent authorities **for purposes other than compliance with the organic production rules**. A check of this documentation – if needed in cooperation with competent authorities- may be used to unveil duplicate record keeping.

Transport companies do not always pay specific attention to the organic quality of transported products. As a result, **transport documents** like CMRs (for road freight), bills of lading (for sea freight), air waybills (for air freight) and rail transport documents (for rail freight) may not contain the term “organic” or “in-conversion”. As regards fully packaged products, as long as the transport document can be undeniably linked with another document accompanying the goods during transport, there should be no suspicion. Such other documents may be a packing list and/or delivery note drawn up by the seller or shipper of the organic or “in-conversion” products.

International transport is mostly covered by insurance. **Incoterms**[67] are used to clarify the change of ownership of products that require transport. Such indications may be used in the traceability checks.

Cross border transport outside of the EU, is usually accompanied by additional phytosanitary checks. The result of such checks is a **phytosanitary certificate**. Countries that do not have export rules for organic products (e.g. the allowance of any necessary exceptions) for their import and/or export may fumigate each consignment entering and/or leaving their territory. Where there is doubt, the authenticity of the phytosanitary certificate may be checked by requiring the original version. Regarding trade in plants and plant products from non-EU countries, more information can be found on the European Commission's respective website.[68]

In the case of import of high-risk products (as defined in Article 8 of Regulation (EU) 2021/1698), in addition to the transport documents, the travel plan which provides an overview of the physical movements of the consignment and change of vehicle including location and time of departure and arrival) shall also be made available in TRACES and checked for coherence with the supplied transport documents.

The **Customs clearance documents** are relevant for EU importers, who must be in possession of an Economic Operators Registration and Identification (EORI) number. The European Commission provides more details about the Custom clearance documents on its website.[69]

Operators shall check the certificate of their supplier(s) and, where relevant, of their subcontractors.

The **Certificate of inspection** (COI) must be issued in TRACES by a recognised CA/CB. Although information relating to the number of packages referred to in box 13, the total gross weight in box 16, and the means of transport in box 17 are entered in TRACES, they may be changed after electronic signature of the COI by the CA/CB. Test results and commercial documents are also required before the COI is signed. They may be made available in TRACES, provided there is an updated version of the COI within 10 days from its original issuance and in any case before endorsement by the Competent Authority[70].

4.3 Cross- and Traceability Checks (including mass balances) (off-site and on-site)

Traceability and mass balance checks have a prominent importance and an essential role among investigation tools to reveal cases of intentional substitution or commingling. Both are often interlinked. The mass balance reconciliation cannot be carried out without reliable traceability information and of course all information used, and data lie in records and documentation kept and provided by the operator. Both inspection methods can be applied off-site or on-site; this mainly depends on the noncompliance history of the operator, the question whether suspicious products are still in stock and also its cooperation with the CA/CB. In the case of trading of organic products by operators who have no physical contact with the products, traceability checks and mass balance analysis are based on checking relevant commercial and financial documents only.

[67] International commercial terms. Eleven terms of sale accepted worldwide in assignment of costs and responsibilities between the buyer and the seller. Proposed, updated, and copyrighted by the International Chamber of Commerce (ICC), https://iccwbo.org/

[68] https://food.ec.europa.eu/plants/plant-health-and-biosecurity/trade-plants-plant-products-non-eu-countries_en

[69] https://trade.ec.europa.eu/access-to-markets/en/content/customs-clearance-documents-and-procedures

[70] Article 5 (3) Commission Delegated Regulation (EU) 2021/2306 of 21 October 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the official controls in respect of consignments of organic products and in-conversion products intended for import into the Union and on the certificate of inspection

Traceability checks or mass balance checks carried out during an official investigation may initiate a need to be further analysed and to carry out cross-checks along the supply chain in order to verify the organic product flow.

In the case of organic farmers, traceability checks may cover inputs used for the production (**pre-harvest traceability and mass balance**). Traceability and mass balance checks are interlinked as the source of information lies in the same records and documents for both assessments.

Table 4.2: Trace-back audit and mass balance of harvested crop to seed

Stage of production:	**Supporting records and documents:**
Sale	Purchase agreements, invoices, delivery notes and other transport documents, sales records in inventory
Storage	Storage inventory (logs of incoming/outgoing stocks)
Harvest	Harvest logs, field logs
Input application	Field logs, storage inventory of inputs
Sowing	Field logs, records on sowing, storage inventory of seeds
Purchase of seed	Invoice, seed label, organic certificate, authorization of seed derogation

Table 4.3: Trace-back audit of feed used for organic livestock

Stage of production:	**Supporting records and documents:**
Feeding and grazing	Daily feeding ratios and records of daily quantities, logs of grazing periods and livestock groups
Storage	Storage inventory (logs of incoming/outgoing stock)
Harvest and purchase of feed	Harvest logs, field logs, invoices, delivery notes, organic certificates, labels

Post-harvest traceability checks and mass balances concern organic products traded and/or prepared/processed. They go back to the raw materials purchased.

Table 4.4: Trace-back audit of processing operation

Stage of production:	**Supporting records and documents:**
Sale	Purchase agreements, invoices, delivery notes and other transport documents, sales records in inventory, labels
Packaging	Packaging logs, labels
Storage of products	Storage inventory (logs of incoming/outgoing stocks)

Production	Production records with dates, quantities, lot identification
Storage of ingredients and other materials	Storage inventory (logs of incoming/outgoing stock)
Purchase of ingredients	Invoices, labels, organic certificates, authorisation of derogation, receiving logs

In the case of organic farmers, mass balance checks are sometimes difficult. It is essential that production data - as the first input for these checks - is compared with yield estimation data which was conducted by the inspector at the previous inspection or alternatively by the operators themselves and received by the control body as a production plan. Yield levels similar to the level in conventional production should always be a concern. Region-specific information may exist at country level – at agricultural chambers, agricultural universities or governmental agencies. Germany has established a handbook which delivers useful information for mass balance checks in organic farm production and organic processing activities (KTBL, 2021[71]).

4.4 Inspection visits (on site)

In the scenario of an official investigation, inspectors are expected to approach the operator's production system as a whole and not only zooming-in into the suspicious lot or production run. The aim is to identify systematic failures and/or falsification of records and other indicators used to evaluate compliance.

The primary goal of on-site visits is to check the plausibility of the production process of the organic product under suspicion. Preferably, the product should be cultivated/produced. The inspector should have the technical competence to judge whether the records match reality. Obtaining sufficient yields to export without using any inputs is not feasible. Calculating a rough nitrogen balance, comparing the amount of nitrogen lost at harvest with the amount of nitrogen supplied by amounts of authorised manure helps to identify unexplainable nitrogen deficiencies which could be an indication of the prohibited use of urea and other non-authorised N-fertilisers.

Table 4.5: Nitrogen balance for ginger production

N-output with harvested ginger	- 320 kg N/ha*a
N-input with approved manure and fertilisers	+ 42 kg N/ha*a
Deficit	**- 278 kg N/ha*a**

A similar situation might occur with plant protection products. The production of varieties of crops which are sensitive to being attacked by pests and diseases without corresponding inputs being used to control this risk, requires a convincing technical explanation. An inspection of the seed storage or a visit to the field shortly after sowing may indicate the use of treated seeds, but also the complete absence of any stock of seeds needs to be explained. In larger farms, tractor tracks on organic fields may be there because of non-registered applications. At the time of sowing/planting and even harvesting, land preparation activities could confirm herbicide (and/or nematicide) application(s). In

[71] KTBL, 2021: Kennzahlen für die Kontrolle im Ökologischen Landbau

conventional farming in the EU, there are more possibilities for pre-emergence herbicide applications than post-emergence. In third countries, the situation might be different.

In holdings with organic and in-conversion production units in any combination with non-organic production units, the equipment should be clearly separated and labelled/identified. Equipment used for the application of plant protection products may be divided into two categories: vertical downward spraying (e.g. for vegetables) and non-vertical downward spraying (e.g. for grapes or in orchards). EU Member States may impose additional rules on spraying equipment like e.g. technical control (as for vehicles), spray drift reducing knobs, surface water protecting buffer zones. The absence of authorised equipment shall be considered an indicator for relying on non-declared subcontractors. Aerial spraying by subcontractors is a classical risk for the use of prohibited pesticides, for example in banana production.

Pesticide storage rooms shall always be visited, and rooms under lock and the key not being accessible are a clear indicator for potential nonconformities. Despite strict rules about accessibility to such rooms, an organic farmer may not refuse access to an inspector to such a room.

In the context of holdings with organic and conventional production, plant protection products are sometimes stored in the same room and administered by the same person. This is not recommended and increases risk. A clear and effective separation[72] has to ensure that it is possible at any time to identify products for organic production. In addition, a register of products in stock shall be kept.

For official investigations, inspectors must carefully prepare themselves before the visit:

- Conduct a review of previous non-compliances and check the operator's follow up: theory and practice.
- Refresh themselves of the particularities of the operator's organic activity: parallel production? Subcontractors (aerial spraying)? contract farming? land ownership? type of crops? client portfolio[73]?
- Define of a strategy (= which questions to ask and in which order) is recommended to make operators admit that they have used prohibited products or substances
- Unannounced visits are recommended.
- Plan for enough time that day in case the operator does not show much willingness to cooperate.
- The use of a team of inspectors, preferably of diverse competences, is a good approach, in particular in larger companies. This is also a measure to avoid corruption.

During the on-site inspection visit,

- Immediately at the beginning, it should be verified whether photos can be taken. In most cases, the operator will confirm.
- Focus on open and technical questions (why? when? how? …)
- Note should be taken, and attention paid to not being misled by the operator: not answering, postponing the answer, answering vaguely, answering in a contradictory way to the same question.
- Focusing on non-compliances that may be easily corrected after the inspection (e.g. missing records) shall be avoided.

[72] Article 9 (7)-(10) Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

[73] Experience shows that bigger retailer companies impose more and more strict criteria on products to be delivered than local small scale and local buyers e.g. at farm gate.

- Several people present should be interviewed. If interesting information is obtained, the operator or his representative is confronted with the information obtained from staff. Observe non-verbal communication.

Relevant items must be verified, comparing the situation on site with records and other information. Bins should be checked for used packaging of prohibited plant protection products, seeds or fertilisers, and a detailed review of the bookkeeping of the current accounting cycle made. Collecting **objective evidence** during an official investigation requires not only the attention of the inspector to identify indicators of non-compliance that are present, but also to recognise a problematic situation, the absence of certain aspects that are typical for organic production. In this regard, identify the missing items in Figure 4.1.

Figure 4.1: Organic almond production in a non-EU country

The EU regulation imposes the application of preventive and precautionary measures on all operators. The implementation of such measures needs to be in place and able to be confirmed by practical data at any time.

Collecting objective evidence is a continuous activity of the inspector: it starts during the opening meeting, discussion of the impact of changes, checking documentary evidence, but especially during the physical examination of the operator's production or preparation units. Taking along a device to take pictures and some (handwritten or otherwise recorded) notes is strongly recommended.

Oral statements provided by the operator himself or by staff can only be used as evidence in case such statements are repeated (as citations) in the inspection report, signed by the operator's legal representative. Visual observations of "present" indicators of non-compliances are best photo-

graphed. Pictures taken during the inspection can be used as evidence of non-compliance for subsequent certification decisions. Such pictures may show products, locations, equipment (labelled or unlabelled) confirming unauthorised presence, which is different from unauthorised use, whilst both are prohibited. Documents (production records, cleaning records, technical specifications, …) can also be photographed.

In case of additional sampling, additional pictures of the lot/production run represented by the new sample are always useful. Pictures taken during the inspection can also be used as evidence by adding the pictures to the inspection report, signed by the operator's representative. Visual observations of "absent" indicators (absence of preventive measures like e.g. monitoring tools (sticky traps in orchards or greenhouses, distracting devices (pheromone traps), biodiversity increasing measures like flower strips) of non-compliance are more difficult to capture and to be used as evidence. Such observations are best described in the inspection report and illustrated by pictures.

Indirect evidence is also possible by referencing the original document which is kept by the operator, e.g. in cases where taking pictures or photocopying is not authorised by the operator. This could be the case in processing units when operators insist that inspectors cannot have hard or digital copies of the internal documents like recipes, whilst allowing the inspector to verify the content of such confidential information.

The spraying equipment (type, maintenance, capacity, width of spraying beam, pressure applied, ground speed during application, type of spraying knobs etc.) and the circumstances under which they are used, have a major influence on the efficient and effective use of plant protection production products. High speed and small droplets leaving the spraying equipment increase the likelihood for spray drift (or environmental contamination). It is useful to verify this in mixed farms, and where possible, at the neighbours.

4.5 Sampling and Analysis

Rombach et al., 2020[56] explain details about sampling in organic production. It's important to be aware that an agricultural solid product is not entirely homogeneous. In the case of certified products that contain prohibited substances, additional sampling and testing of unprocessed (raw) agricultural products of the same lot as in the certified product is preferred. The lot should not be mixed (1 supplier, 1 lot number). If this is not feasible, raw materials that are as closely related to the raw materials used in the certified product under investigation should be selected (e.g. mix containing multiple lot numbers from one supplier).

In the case of mixed farms or parallel production, sampling of inputs and remaining substances in equipment (atomizer tank or knapsack sprayer) are very effective to demonstrate use and/or ineffective separation between organic and non-organic production.

Sampling as indicated by Benzing et al.[74] is useful to distinguish between application and spray drift. Two samples need to be taken at the border and the centre of the field affected.

In the case of suspicion of application, picking leaves from inside the canopy delivers the same/very comparable results compared to picking leaves from the outer parts of the canopy. This is not the case in the case of presence due to spray drift, where the residue may only be found on the outer canopy. In the case of testing of leaves, test methods with a flexible scope may offer an accredited testing result.

[74] Benzing, A., Piepho, HP., Malik, W.A. *et al.* Appropriate sampling methods and statistics can tell apart fraud from pesticide drift in organic farming. *Sci Rep* 11, 14776 (2021). https://doi.org/10.1038/s41598-021-93624-8

In the case of heterogeneous products (by appearance) of the same lot number, the inspector shall split such lots into at least two "sublots" and describe the division (or new identification). After that, separate samples shall be taken from each of the "sublots" for separate analysis.

The sampling needs to be representative for the product or lot under suspicion.

When sampling is delegated, the party carrying out sampling shall be ISO / IEC 17025 accredited and respect the requirements as regards sampling.

The selection of the laboratory depends on various factors (see Chapter 2).

Laboratories for analysing samples taken by CA/CB in the context of official controls should be "designated laboratories"[75]. Competent authorities make available lists of such laboratories in the EU. For testing commissioned by compliant CA/CB operating in Third Countries, the conditions of Article 12 (6) of Regulation (EU) 2021/1698 apply.

4.6 Exchange of information

The main parties for exchange of information during an official investigation are the competent authority, the CA/CB, the laboratory and the operator.

4.6.1 Exchange of information with competent authorities

In the EU, a CA/CB is legally[76] obliged to inform the competent authority of each case of suspicion of non-compliance that affects the integrity of organic products. In practice, this means that this exchange of information is expected to take place at the start of the official investigation. It could also happen that the competent authority informs the CA/CB about the presence of a product or substance not authorised for use in organic production[77] or about a suspicion of non-compliance affecting organic integrity[78]. In both cases, after substantiation (see Chapter 5) an official investigation shall be started, and the products concerned shall be blocked. Competent authorities shall[79] take measures and establish documented procedures to enable such exchange of information.

4.6.2 Exchange of information with laboratories

In case the laboratory report shows the presence of prohibited products or substances, and a cross-border-case is likely, the laboratory shall provide a copy of its report in English.

4.6.3 Exchange of information with operators

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 in a product that is

[75] Article 37 of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products

[76] Article 9(2) of Commission Implementing Regulation (EU) 2021/279 of 22 February 2021 laying down detailed rules for the implementation of Regulation (EU) 2018/848 of the European Parliament and of the Council on controls and other measures ensuring traceability and compliance in organic production and the labelling of organic products

[77] Article 29(1) of Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

[78] Article 41(1) of Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

[79] Article 9(6) Commission Implementing Regulation (EU) 2021/279 of 22 February 2021 laying down detailed rules for the implementation of Regulation (EU) 2018/848 of the European Parliament and of the Council on controls and other measures ensuring traceability and compliance in organic production and the labelling of organic products

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, 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 (see Chapter 6.1). Where the suspicion has been substantiated or where it cannot be eliminated, the operator shall exchange information about this situation and make available, at least the elements listed in Regulation (EU) 2021/279 Article 1(2)[80]. But where the suspicion has been eliminated by the operator, the operator is legally not obliged to immediately exchange information about this situation. The validity of the decisions will be checked during the inspections of the CA/CB of this operator.

In December 2021, the French competent authority (INAO) created a 6-page instruction (in French) about suspicion and how French organic operators have to act.[81]

4.6.4 Sequence of handing over official investigation to another CA/CB and requesting information

A CA/CB that receives information about suspicion of non-compliance first starts up an investigation of its own operator[82]. At the end of this investigation, if the CA/CB cannot determine the source and cause of the presence, the CA/CB informs the relevant CA/CBs of the involved supplier(s). Upon receipt of (substantiated) information from another CA/CB as regards presence of non-authorised products or substances, the receiving CA/CB starts an investigation at the level of the operator(s) with which it has a certification agreement. This investigation shall be started up without questioning the result of the initiating CA/CB (see Chapter 6.4).

4.7 Change of certification body during official investigations

Every operator has the right to change from one certification body to another. However, when such a change is motivated by trying to hide nonconformities or to avoid the "severity and intensity" of an official investigation, it is not good practice to allow as CA/CB such a change "overnight". Good practice to prevent a too rapid change of certification body and subsequent continuation by another certification is to enforce in contracts only to allow operators a change of certification body with sufficient prior notice e.g. latest by 30 September to be effective from the next 1st of January.

[80] 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) the sampling sheet detailing the time, place and method used to take the sample; (e) any information about any previous suspicion with regard to the specific non-authorised product or substance; (f) every other relevant document to clarify the case.

[81] INAO Note d'information à l'attention des opérateurs certifiés en AB Mesures à prendre en cas de soupçon de manquement aux règles de la production biologique V.0 of 16 December 2021
https://www.inao.gouv.fr/content/download/4005/34979/version/1/file/Note%20mesures%20%C3%A0%20prendre%20en%20cas%20de%20soup%C3%A7on%20par%20les%20op%C3%A9rateurs.pdf

[82] In accordance with Article 2 of Commission Implementing Regulation (EU) 2021/279 of 22 February 2021 laying down detailed rules for the implementation of Regulation (EU) 2018/848 of the European Parliament and of the Council on controls and other measures ensuring traceability and compliance in organic production and the labelling of organic products

Table 4.6: Overview of websites from different countries to consult the authorised use of plant protection products in conventional production

Austria	https://psmregister.baes.gv.at/psmregister/;jsessionid=_7m2aB3DHDsdOC_EnG5RiQlxoB4zVYcotfP0tn-UW3fuFo95dlfc!-2064823541
Belgium	https://fytoweb.be/en
Bulgaria	https://bfsa.egov.bg/wps/wcm/connect/bfsa.egov.bg19113/b22d08ee-2597-4c74-ad2c-89f6d8823036/HERB%2BDES_6_.pdf?MOD=AJPERES&CVID=oDfIRFv https://bfsa.egov.bg/wps/wcm/connect/bfsa.egov.bg19113/97cbf10e-8b75-48cb-8585-87f69edf1cf3/Fungicide_6.pdf?MOD=AJPERES&CVID=oDfIEYy https://bfsa.egov.bg/wps/wcm/connect/bfsa.egov.bg19113/6ea04d85-a55e-48c3-b95a-53c961173947/Ins%2Bakar_6.pdf?MOD=AJPERES&CVID=oDfIWVg
Croatia	http://fis.mps.hr/TrazilicaSZB/Default.aspx?lan=en-Us
Republic of Cyprus	http://www.moa.gov.cy/moa/da/da.nsf/permission_protected_table_el/permission_protected_table_el?openform
Czech Republic	http://eagri.cz/public/app/eagriapp/POR/
Denmark	https://mst.dk/kemi/database-for-bekaempelsesmidler/bmd/
Estonia	https://portaal.agri.ee/avalik/#/taimekaitse/taimekaitsevahendid-otsing/en
Finland	https://www.kemidigi.fi/kasvinsuojeluaineet/haku
France	https://ephy.anses.fr/
Germany	http://psm-zulassung.bvl.bund.de/psm/jsp/
Greece	http://www.minagric.gr/index.php/en/farmer-menu-2/plantprotection-menu/plantprotproducts-menu
Hungary	https://novenyvedoszer.nebih.gov.hu/Engedelykereso/kereso
Ireland	http://www.pcs.agriculture.gov.ie/products/
Italy	https://www.sian.it/mimfFitoPub/ricercaInizialeFito.get
	https://www.fitosanitari.salute.gov.it/fitosanitariws_new/FitosanitariServlet
Latvia	http://www.vaad.gov.lv/sakums/registri/augu-aizsardziba.aspx
Lithuania	http://www.vatzum.lt/lt/veikla/veiklos-sritys/augalu-apsaugos-produktu-registravimas/#raap
Luxembourg	https://saturn.etat.lu/tapes/
Malta	https://mccaa.org.mt/Section/Content?contentId=1158
Netherlands	https://pesticidesdatabase.ctgb.nl/
	https://www.ctbg.nl/

Poland	https://www.gov.pl/web/rolnictwo/rejestr-rodkow-ochrony-roslin
	https://www.ior.poznan.pl/2045,plant-protection-product-database
Portugal	https://sifito.dgav.pt/Account/Login?ReturnUrl=%2F
Romania	https://www.madr.ro/omologare-produse-de-protectie-a-plantelor/lista-produselor-de-protectie-a-plantelor-omologate.html
Slovakia	http://pripravky.uksup.sk/pripravok/search
Slovenia	http://spletni2.furs.gov.si/FFS/REGSR/EN/index.htm
Spain	https://servicio.mapa.gob.es/regfiweb
Sweden	https://apps.kemi.se/BkmRegistret/Kemi.Spider.Web.External/
Turkey	https://bku.tarimorman.gov.tr/

CHAPTER 5: A SYSTEMATIC APPROACH FOR OFFICIAL INVESTIGATION

Jochen Neuendorff[83], *Nicolas Verlet*[84]

5.1 Introduction

Organic production must adhere to strict production rules, but organic products are not defined by their chemical properties. Organic production does not take place under a glass bell but is subject to the same general environmental impacts as conventional production - which might sometimes be the source of contamination of organic products. Therefore, organic products that contain traces of residues may be labelled as organic if its production process and the operator are in compliance with the EU organic regulation. In particular, operators must not have used any non-authorised substances, have not mixed organic and conventional products, and have taken all necessary precautionary measures to prevent contamination.

If a control authority, control body or competent authority receives substantiated information regarding the presence of non-authorised products or substances, it must immediately conduct an official investigation to determine the source and cause of the contamination. However, implementing this new provision has faced certain obstacles. The search for all possible sources and causes can be a lengthy and expensive process, in particular if several operators are involved, during which the products concerned must be blocked. There is a risk that the investigation could conclude that source and cause cannot be determined, or that a "drift" or "natural presence" is the most probable cause, without the assurance that effective investigation techniques have been utilised, particularly to eliminate the possible use of prohibited inputs or mixing with non-organic products. Therefore, finding the right balance between cost and efficiency is crucial. This is the main objective of an effective and efficient systematic approach to official investigations.

5.2 Substantiation of information

The starting point of the official investigation is “substantiated” information about the presence of non-authorised products or substances. The notion of “substantiated” has been added to Article 29 of the Regulation (EU) 2018/848 to clarify that it is not required to act on mere suspicions of contamination followed by an in-depth investigation only to finally conclude that the initial information concerning the presence was unreliable. One cannot speak of a “substantiated suspicion” until evidence like the analytical findings, for example, prove to be legitimate in terms of being correct, robust, and relevant within the meaning of the EU organic regulation.

A question arises: what criteria must information meet to be considered “substantiated”? Figure 5.1 displays the elements to be taken into account.

First and foremost, the analysis report delivered to the control authority or body (CA/CB) must be reliable. The laboratory conducting the analysis must be accredited to ISO/IEC 17025, which is the international standard for laboratory accreditation in the field of testing and calibration, specifying requirements for the competence, impartiality, and harmonised working methodology of laboratories (see Chapter 2). The analytical result should preferably be quantifiable, meaning above the limit of quantification (LOQ). However, more important than the concentration of the substance is the type of substance found by the laboratory. For pesticides, it needs to be evaluated whether the active

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This article exclusively reflects the personal opinions of both authors.

ingredient found is used in conventional production for the crop in question. It is worth noting that many modern pesticides break down quickly, so even trace levels may indicate non-authorised use or the addition of conventional products to an organic batch. Further information on how to evaluate analytical reports can be found in Chapter 4.

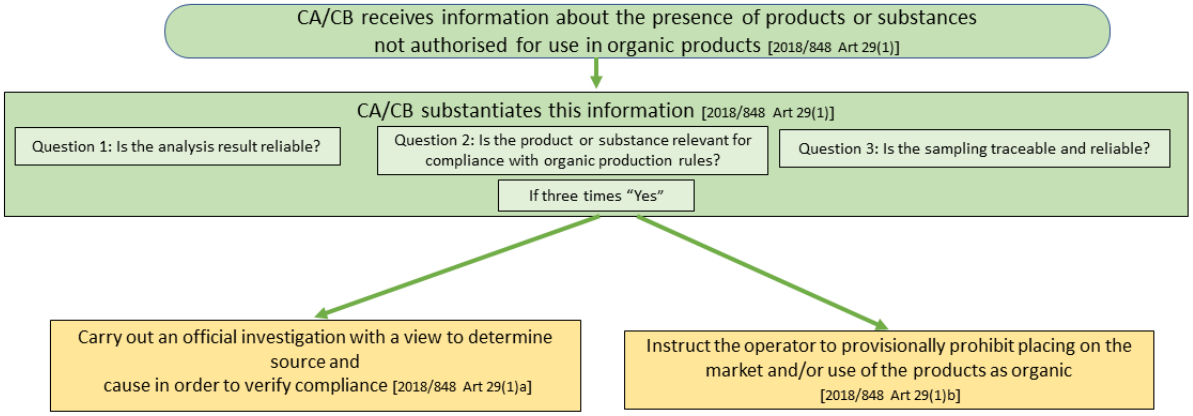

Figure 5.1: Substantiation of information on the detection of prohibited substances and materials

Analysis reports might need to be exchanged internationally. For these cases, it is useful to request a report in the English language from the laboratory.

It is important for the control authority (CA) or control body (CB) to carefully evaluate analysis reports. Simply relying on evaluations of analysis results by accredited laboratories is not adequate to enable informed decisions about follow-up measures in a CA/CB. Some basic principles need to be observed during such evaluations: The use of the 50% default value for enforcement decisions, as proposed in document Nº SANTE/11312/2021v2[20] cannot be applied to individual analysis results in organic production, because no specific threshold exists. Thresholds or "orientation values" from private guidelines can be used in the organic industry for contracting purposes but are not useful for the evaluation of lab results by CA/CB. Processing factors[85] support a good understanding of enrichment or dilution processes during elaboration/processing activities but cannot be used to invalidate a laboratory result above the limit of quantification (LOQ). The risk of the presence of residues due to the use of indirect analytical methods (CS_2 considered as dithiocarbamates, 2-chloroethanol considered as ETO, etc.) should be considered.

A sampling report that includes a detailed description of the sampling procedure and objective evidence such as pictures of labels, photos, or copies of documents is crucial for an accurate interpretation of the analysis results. It is important to note that deficiencies in sampling are the most significant source of error in the interpretation of analytical results [56] [86]. Therefore, it is essential to exclude any risks of contamination during the sampling process. Samples should be labelled properly and sealed to ensure their integrity. It is good practice for accredited laboratories to attach a picture of the sampling bag or container that arrived at the lab to the laboratory analytical report. This picture

[85] Scholz, R., van Donkersgoed, G., Herrmann, M., Kittelmann, A., von Schledorn, M., Graven, C., Mahieu, K., van der Velde-Koerts, T., Anagnostopoulos, C., Bempelou, E., Michalski, B. 2018: Database of processing techniques and processing factors compatible with the EFSA food classification and description system FoodEx 2. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1510

[86] Meyer, V. 2019: Sampling: The Ghost in Front of the Laboratory Door. LCGC North Am. 37, 768-774. https://www.chromatographyonline.com/view/sampling-ghost-front-laboratory-door

on the analysis report makes it possible to determine whether the conditions mentioned at the beginning of this paragraph have been met.

Finally, it should be evaluated whether the substance or product detected by the laboratory is subject to the authorisation proviso according to Article 9 (3) and Article 24 of the EU organic regulation. These substances or products include:

- active substances in plant protection products
- fertilisers, soil conditioners, and nutrients
- food ingredients
- food additives
- feed material
- feed additives
- processing aids
- products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production
- products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding
- products for cleaning and disinfection in processing and storage facilities.

Three conditions must thus be met to before information received qualifies as "substantiated": a non-authorised product or substance must be present in the organic product, illustrated by a report from an accredited laboratory. The sample must be fully traceable back to an organic product/lot and cross-contamination and exchange of the sample excluded. The presence must lead to the assumption that the organic product was not produced or processed following the production rules laid down in the EU organic regulation. Once these three criteria are met, an official investigation must be initiated immediately, and the products concerned must be blocked for further sales with organic labels. Sometimes, an additional sample is taken, and the result is negative - no contamination is found. How to deal with such a case? A direct comparison of these two lab results is scientifically not valid. If sampling is done at different times, by different people and thus differently implemented sampling procedures, the samples need to be considered separately and need to be evaluated in detail to make an informed decision[87].

The task of substantiation is the primary responsibility of the CA/CB, which is the first to receive the analysis result and associated documentation.

5.3 Official investigations to conclude on the source and the cause of contamination

"*The official investigation shall conclude on the source and cause of the presence of non-authorised products or substances*"[88]. The key objective must be kept in mind: to establish that an operator in the organic control system did not use non-authorised products or substances and has taken the appropriate and proportionate precautionary measures to avoid the risk of contamination, taking into account the shelf life of the product concerned. The official investigation is based on the current state-of-scientific knowledge. It is not necessary to investigate every possible source with the same intensity. Instead, the official investigation should focus on possible cases of non-compliance to verify whether the conditions set out in Article 29(2) of Regulation (EU) 2018/848 are met. Otherwise, the control system according to the EU organic regulation would be weakened.

[87] Hughes, M., 2022: Food Safety: tackling unexpected lab sample results. https://www.foodmanufacture.co.uk/Article/2022/01/11/Food-safety-how-do-I-deal-with-unexpected-lab-sample-results

[88] Article 2(3) of Regulation (EU) 2021/279.

„**Immediate**“ official investigation (Art. 29 1a) of Regulation (EU) 2018/848

Control bodies, control authorities, and competent authorities sometimes initiate or continue official investigations years after an accredited laboratory detects a contamination. This can even happen when the shelf life of the organic lot in question has already expired, and the operator may have left the organic control system. To ensure an effective and efficient evaluation of potential non-conformities, the legal provision mandates that an official investigation shall be launched "immediately". Delaying an investigation for years makes it difficult to identify the source and cause of contamination. Therefore, quick action from all parties involved is necessary.

5.4 How to mitigate the risk of weakening the control system? List possible sources and causes of contamination, and rank them by probability establishing hypotheses

When evaluating substantiated information in a CA/CB, it is important to rank hypotheses based on several factors. These factors include the non-compliance history of the operator, the type of activity and the structure of the operator and its risk classification, the type of substances identified, and the concentration of the non-authorised substance or product. Once these elements have been considered, it is appropriate to classify possible sources and causes, using the list referred to in Table 3.1 of Chapter 3, into three categories: "Probable", "Possible", and "Excluded"[89].

5.5 How to conduct a good official investigation? The need to determine the intensity of the official investigation

The intensity of an official investigation should be based on three different categories of risk as illustrated in Figure 5.2.

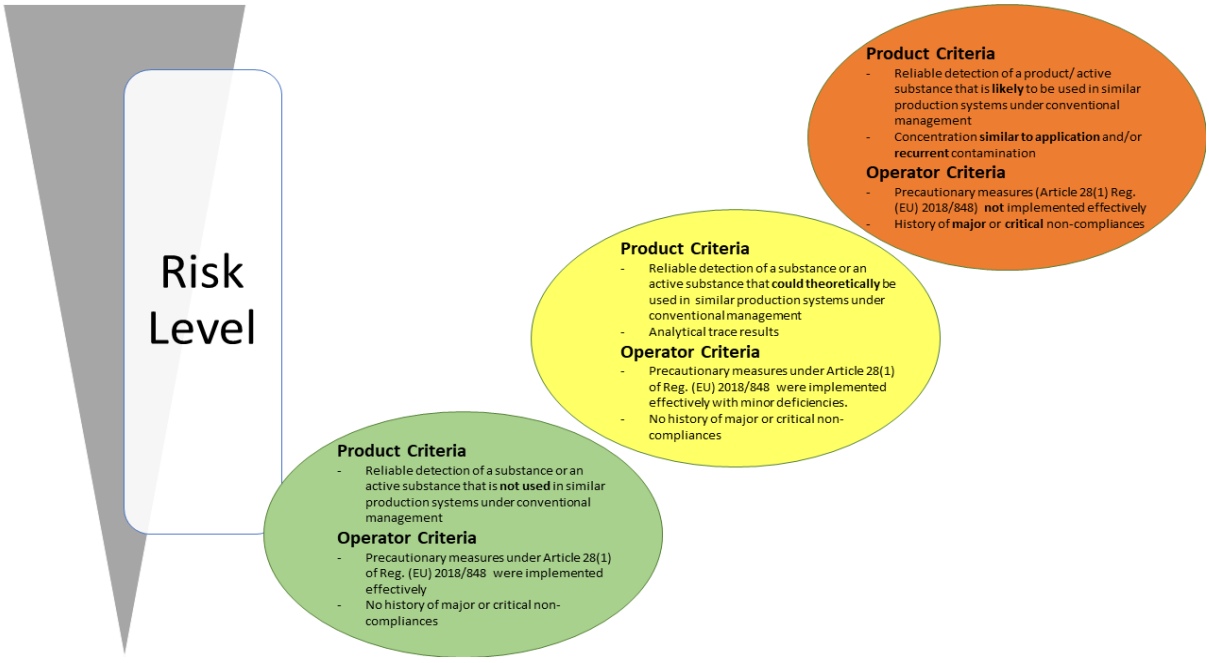

Figure 5.2: Risk analysis to determine the intensity of an official investigation

[89] By “excluded” hypothesis, we mean either a hypothesis not applicable to the type of activity or production system of the operator or a highly improbable hypothesis that can a priori be excluded from the scope of the investigation.

The risk analysis relies on criteria concerning the type and concentration of the product and/or substance analysed by the laboratory and the certification history of the operator[90], in particular, their implementation of precautionary measures as stated in Article 28 (1) of Reg. (EU) 2018/848, as well as the type and number of non-compliances that were identified by the CA/CB during previous inspections.

The output of the risk analysis determines the approach to and the intensity of an official investigation.

High-risk cases (red) are situations where contamination occurs with products or substances typically used in the conventional production of the same crop or product. An application-like concentration should trigger immediate action. A high-risk case also exists when the results of previous inspections show significant deficiencies in the precautionary approach and/or relevant critical and significant nonconformities have been found during previous inspections. Not all criteria need always be met. In the case of high risk, the official investigation should typically include a short-term on-site visit, preferably unannounced. During this on-site visit, amongst other activities the operator's facilities are checked for the presence of the product or substance in question, interviews with employees are conducted, input suppliers and external subcontractors are visited, and additional samples may be taken if considered to be useful. This depends on the degradation rate (LD_{50}) of the product or substance found before.

If the risk is assessed as medium (yellow in Figure 5.2.), the CA/CB typically has received an analytical report with traces of substances or products that could theoretically be used in similar conventional production systems but are more atypical there. The operator in question was not found to be conspicuous to the CA/CB up to date. Typically, the operator is required to provide additional information along with a documentary analysis internally the CA/CB. The information provided by the operator must include any relevant information that can clarify the case. If the investigation cannot be concluded based on the documents provided by the operator, a short-term, additional on-site visit must be conducted to ensure the completion of the investigation. On the occasion of the next annual inspection, the case is reviewed by the inspector on-site.

In the case of low risk (green), the evaluation is done in a CA/CB based on a documentary review. On the occasion of the next annual inspection, the case is reviewed by the inspector on-site.

5.6 Forensic approach to the case to select appropriate investigation techniques

Each official investigation needs to be designed individually, in a forensic way and shall apply the most effective and efficient inspection methods and techniques for the specific case. The scope is limited to sources and causes that have been assessed as "probable" or "possible" (see paragraph 5.3). A systematic approach that involves ranking the possible sources and causes (see Chapter 3) and selecting the best-suited investigation tools from the ones mentioned in Chapter 4 is necessary. As defined in Chapter 3, the hypotheses are grouped into 5 categories (use, commingling, cross-contamination, environmental contamination, and natural presence). CA/CB shall then intelligently choose effective and efficient investigation techniques (as illustrated in Figure 5.3[91] and Chapter 4) to complete the official investigation as quickly as possible and obtain factual results that clarify the suspect case.

[90] Hirschauer, N. 2004: A model-based approach to moral hazard in food chains. Agrarwirtschaft 53, 192-205. https://www.agrar.hu-berlin.de/de/institut/departments/daoe/abl/publikationen/dokumente/literatur/AWMoralHazardEndfassung160704

[91] Novak, C. 2023: Fraud in organic: Which investigation tools are successful? Conference of the Anti-Fraud-Initiative (AFI), Brussels. https://www.organic-integrity.org/fileadmin/afi/docs/afi15/Novak_AFI-Conference_09-02-2023.pdf

Figure 5.3: The Investigation Toolbox[91]

5.7 What degree of certainty in determining a source and a cause must be achieved?

As a general requirement, the investigation must conclude on the source and cause, but it must primarily provide solid evidence regarding the possibility of "use" and "commingling". If the preliminary analysis identifies these hypotheses as the most likely, the investigation methods should focus on all relevant investigation approaches to reach a high degree of certainty.

In case the analysis suggests that there are other hypotheses more likely than use or commingling, this high probability alone is not enough to conclude the investigation. Since the possibility of use or commingling exists, even if it is not the most likely hypothesis, it should be demonstrated that adequate and proportionate investigation methods have been used also to eliminate the possibility of use or commingling. For example, evidence that an active substance of a prohibited pesticide has been used by a conventional neighbouring farmer combined with a suitable sampling technique[74] is suitable to confirm drift. If the case is considered low risk, this can be done on a documentary basis and factual elements from previous audit reports (history of non-compliance, traceability, mass balance, etc.).

The principle of proportionality should play a role in the investigation to determine the possible sources and causes. As a reminder, *"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. They could include any method and technique for official controls which is considered appropriate to efficiently eliminate or confirm, without any unnecessary delay, any suspicion of non-compliance with this Regulation, 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.*[92]*".*

In any case the conclusion of an official investigation shall be based on factual elements, taking into account all possible sources and showing that the pertinent investigation methods have been implemented. However, the principle of proportionality may lead to a conclusion on the most probable source with a certain degree of uncertainty, especially since:

- the conclusion may be based on similar cases for which an in-depth investigation was carried out,

[92] Whereas (69) of Regulation (EU) 2018/848:

- the operator does not have a specific history of non-compliance linked to contamination,
- it is not a recurring case (except in cases where recurrence is considered unavoidable).

In addition, this relative degree of uncertainty should be mitigated by taking the finding to subsequent controls, thus confirming the initial conclusion.

5.8 Recurring contamination cases

Recurrence of contamination cases is a vital signal that must be considered. This recurrence can happen either in an individual context, such as recurrent cases originating from the same operator, or in a regional context, such as the recurrence of similar cases at different operators in the same region.

In the first case, the recurrence can be either a signal of intentional use, a structural deficiency concerning insufficient precautionary measures or may result from the product matrix (see Chapter 4). In the second case, the recurrence may reflect a regional context that increases the incentive to use non-authorised substances or techniques. This can be due to a lack of available labour, encouraging the use of glyphosate, severe sanitary conditions that can be resolved for example by ethylene oxide treatment, commingling with conventional products to compensate for a bad crop, and so on. These factors need to be considered during an official investigation of a recurrent case, and plausible explanations belong to the investigation result. Recurrent cases also serve as an input to the risk analysis leading for example to an increased unannounced inspection frequency, a more frequent calculation of mass balances or traceability checks, and more frequent and targeted sampling.

There is a type of recurrence that is different from the examples mentioned above. This type concerns cases where contamination is inevitable, and the operator cannot take any measures to prevent it. This particularly applies to sources listed under the "natural presence" category in Chapter 3. These sources include substances that are naturally metabolised by the plant or result from processing methods such as drying, distillation, or transfer of substances from the soil (known as "heritage chemicals" resulting from treatments carried out before the conversion period began). To the extent that an in-depth investigation was initially carried out for a similar initial case, and concluded on an unavoidable natural presence based on factual elements (soil analysis, scientific evidence, no use or commingling), a subsequent “recurrent” case may be eliminated by carrying out an official investigation with reduced intensity under the following conditions:

- The context prevailing for the recurrent case is identical to previous contaminations (production system, absence of non-compliances that could cast doubt on the results of the initial investigation).
- The level of contamination is similar or even lower (except for factually justified conditions)
- The official investigation may be finalised based on a documentary examination, making it possible to verify without delay whether the conditions listed above are met and to conclude on the source and cause.

5.9 Perishable organic products

Perishable products pose a unique challenge. According to Article 29(1) (b) of the Regulation (EU) 2018/848, CA or CB shall temporarily prohibit the sale of organic products until the official investigation is complete. This can have significant economic consequences since the investigation may take longer than the product's shelf life. The EU Organic Regulation does not provide for any specific measure apart from the general principle of proportionality applying to the official investigation: “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[93]".

It is important to note that the fact that goods are perishable should not be used as an excuse to conduct a superficial investigation that fails to identify the source or cause of contamination. It is crucial to prioritise a thorough investigation to ensure a rapid conclusion. To ensure efficient investigation of contamination cases, CA/CB should proactively inform relevant operators regarding the records required. They should also familiarise themselves with the operator's documentation and traceability systems before such incidents occur. This can be done during the annual inspection and should be included in the description according to Article 39(1) d) of the EU Organic Regulation. When it comes to fresh fruits or vegetables labelled individually or packed, decisions regarding the need for complicated mass balances or traceability checks should be made on a case-by-case basis, depending on the risk involved. In the event of a contamination case, an option is to inform all CA/CB responsible for the different operators in the supply chain simultaneously to save time.

5.10 A crucial element for official investigation: the timing and the duration

The investigation period, which encompasses the time between the receipt of substantiated information, official investigation, conclusion on the source and cause, and the decision regarding the marketing of the product, is an essential component for the control system to function effectively. Based on the experience gained from two years of implementing the new regulation, it is evident that there is ample room for improvement, which will benefit the organic sector as a whole.

Excessive delays in concluding official investigations must be avoided. It's important to consider the economic impact on operators when an organic product is provisionally blocked. This is intended to preserve consumer confidence but also has a wider impact. According to Article 29(1) of the EU Organic Regulation, it's not just the operator that is affected by a finding that is affected by the provisional blocking. It's the responsibility of the CA/CB to identify all operators concerned and block further sales of all lots potentially affected. As many cases involve imports from third countries, a consultation of the TRACES database can quickly identify all importers concerned by competent authorities. The CA/CB can then identify and take action at subsequent steps of the supply chain.

To reduce the duration of the investigation while maintaining or strengthening its effectiveness, three main elements need to be considered. Firstly, the scope of the investigation should be defined based on the most probable hypotheses, as outlined in Chapter 3. Secondly, appropriate investigation methods should be chosen from the toolbox in Chapter 4. Finally, the investigation should be concluded with a reasonable level of certainty, provided that the possibility of use or commingling has been conclusively eliminated. These elements are likely to help speed up the investigation process.

5.11 Exchange of information

Official investigations often involve multiple companies within an organic value chain located in different countries, and different CA/CBs as well. Unfortunately, instead of working together towards a common goal of clarifying an initial suspicion based on substantiated information, the parties involved sometimes try to avoid responsibility and accountability. Unsubstantiated statements such as "There is no suspicion of commingling or use of non-authorised substances" are not uncommon. Poor quality of questions and answers contributes to delays, such as when hypotheses on possible sources

[93]Article 29(1)(a) of Regulation (EU) 2018/848: see also whereas 69: "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."

of contamination or investigation techniques are not included in the information exchange, or when there are no clear conclusions on the determination of the source and cause of the case. This often leads to more questions and confusion. In addition, sometimes the CA/CB involved may even start to investigate the investigation process of the preceding CA/CB, resulting in a never-ending cycle of questions and answers back and forth.

CA/CB should share all relevant factual information to support an official investigation with other involved CA/CBs. Transparency and good collaboration are essential. Each CA/CB is responsible for its operator and must accept the conclusion of an official investigation carried out by another CA/CB, without challenging it by asking additional questions that are not directly linked to the case. CA/CB must specify the investigation's scope, the methods used, and the conclusions drawn from factual evidence. Slow communication should be avoided, particularly in the case of perishable goods. Good practices information gathering can be found in Chapter 4.

5.12 Concluding the official investigation: The source and the cause

The key question to determine the source is: “How did it happen?”, and to determine the cause: “Why did it happen?”. A list of all possible sources may be regrouped into five categories (see Chapter 3). The cause is linked to the reason (why), linked to the motive of the operator. This link is reflected in Article 1(b) of Regulation (EU) 2021/279, referring specifically to cause: “*Where there is a suspicion that the cause of the presence of non-authorized products or substances lies under the control of the operator, the operator shall examine any possible cause for the presence of non-authorized products or substances*”.

Official investigations are based on a systematic approach that includes the formulation of hypotheses on possible sources of contamination. The investigation should not only focus on meeting legal requirements but also on determining the cause of the problem. Determining the cause is important to evaluate whether the operator has put in place appropriate and proportionate measures to prevent contamination of organic products with non-authorised substances or products, as required by Article 29(2)(b) of Regulation 2018/848. Causes cannot be classified in categories and lists as sources, but they can be usefully grouped under a limited number of "root causes", such as the operator's intentionality, lack of knowledge of the EU Organic Regulation, absence or disregard of internal procedures and precautionary measures, among others.

The difference between a "source" and a "cause" does not mean that they should be investigated separately or one after the other (determining the source first, then the cause). In practice, investigating the source and the cause is done together in a systematic and holistic approach. However, to start the investigation process, it is essential to list all possible hypotheses of sources and rank them. This will help to determine the most relevant investigation techniques. As the investigation process progresses, the cause can be identified.

5.13 Concluding official investigations: Deciding on the status of the operator and the products concerned

The final decision-making process is described in Chapter 7.

CHAPTER 6.1: INVESTIGATIONS CONDUCTED BY THE OPERATOR

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

Alexander Beck[94], Janis Garancs[95], Bernard Lignon[96], Carmen Pfannkuchen[97]

6.1.1 Introduction

The Organic Regulation (EU) 2018/848 specifies the obligations and actions in the event of suspicion of non-compliance at operator level. Article 28 (2) focuses on how to react in the event of the presence of products and substances that are not authorised under the Organic Regulation.

According to the Article 28 (2), operators that suspect possible non-compliance with the Organic Regulation must carry out an assessment and decide whether the suspicion substantiates a non-compliance or not.

This chapter provides an overview of the regulations, followed by a process description and tools to support an effective implementation of the legal requirement.

6.1.2 Regulatory framework of Article 28 (2)

The requirements for handling a potential non-compliance under the Organic Regulation stipulate that operators are primarily responsible for assessing suspicious cases. The new EU Regulation (EU) 2018/848 strengthens the responsibility of operators for such cases and clarifies the division of responsibility between control bodies/control authorities and operators to the effect that operators must carry out an own assessment as a first step in case of own testing.

Articles 28 (1) and (2) of Regulation (EU) 2028/848 clarify the scope of the assessment. Products or substances not authorised for organic production within the scope of Article 9 of this regulation are relevant[98].

Article 28 (2) targets products that are intended to be “used or marketed” by the operator as organic or in-conversion products. Actions to be taken are focused on products in possession of the operator.

At this point it is important to clarify that the requirements under Article 28 (2) are to be considered in direct connection with Article 28 (1) "Precautionary measures".

It is important to emphasise that non-compliance with the requirements of Article 28 (1), i.e. the precautionary measures, is a characteristic for decertification of the product/process in accordance

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This article exclusively reflects the personal opinions of all authors.

[98] Neuendorff J., Wallau R., Dieter K., Beck A., Nizet T., 2022 >Interpreting Articles 28(2) and 29 of Regulation (EU) 2018/848 in accordance with the recognized principles of the EU organic legislation< European Food and Feed Law Review, Jahrgang 17 (2022) Ausgabe 5, S 343-353

with Article 29 (2). The implementation of precautionary measures should take place after a risk assessment. Best this Organic Control Point OCP concept is part of the HACCP and VACCP[99].

The self-control systems in accordance with Articles 27 and 28, in particular the precautionary measures established in a company/operation are subject to the review by the CA/CB. Its design includes all relevant aspects and its effective implementation by the operator must be **verified** by CA/CB during its inspections and is confirmed by the organic certificate.

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)[100], 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 implemented[101]). "Proportionality" must always be considered in the measures to be taken. [102] [103]

Step by Step procedure

Article 28 (2) introduces a step-by-step procedure. The CB/CA must verify the **procedure** set up in organic operations including the documentation of the case.

The **first step** is to check whether the **information received is correct and relevant, indicating a potential non-compliance**. **Second step:** If the information is correct and relevant the operator must identify and isolate the product until the case has been clarified[104]. The **third step** is to clarify **whether the "suspicion" can be confirmed and a non-compliance with the EU Organic Regulation is found or whether this can 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 (Article 28 (1)) under the control of the operator, or if there are indications of relevant previous non-compliance requests from the competent authorities, control bodies/authorities[105].

The implementation of Article 28 (2) point "b) check whether the suspicion can be substantiated" is explained in Regulation (EU) 2021/279 Article 1 (1). This list limits the operator's legally specified obligations. Once again, this concerns products in the possession of the operator.

If the assessment reveals that the suspicion is substantiated or cannot be eliminated, the operator must notify the CA/CB (Art. 28 (2) d)). The operator is obliged to cooperate in clarifying the suspect case (Article 28 (2) e).

If the investigation reveals that the "suspicion" of non-compliance with EU Organic Regulation is not substantiated or can be eliminated, the product can be further processed by the operator and placed on the market.

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[99] Beck A., Guhrke L., Milan M. 2022; Neues Bio-Recht – Vorsorgemaßnahmen treffen und Abweichungen rechtskonform handhaben< LMuR 2/2022, S. 93-97

[100] 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-authorized products or substances, including systematic identification of critical procedural steps;

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

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

[103] Beck A., Grube M.; 2022; > Der „Verdacht", der „begründete Verdacht" und „fundierte Information" im Zusammenhang mit einem Verstoß gegen die Vorgaben des Bio-Rechts< ZLR 6/2022, S.829-835

[104] 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…"

[105] Reg. (EU) 2018/848 Art. 29 (2)

The operator needs to follow its internal procedure verified by control bodies/authorities. Again, all cases must be carefully documented.

Information to the buyers

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) or an event that "affects the integrity of those products", the buyer of the product must be informed without undue delay if the products concerned are on the market.

Obligations to inform actors in the organic supply chain, regarding traceability, are limited to direct suppliers (see Article 1 (2) b) EU (Regulation) 2021/279) and customers (see Article 39 (1) d) iii) of Regulation (EU) 2018/848)

As the operator is obliged to inform the CA/CB without undue delay in the event of a substantiated suspicion of non-compliance, and because it is not easy for an operator to assess whether the "integrity" of a product has been "compromised" and also how to maintain "proportionality" when reporting to the supply chain, it is recommended to coordinate the required notification to customers with the CA/CB[106] [107].

6.1.3 Implementation in practice

The internal procedure for the event of a suspicion of non-compliance in accordance with the Article 28 (2) of Regulation (EU) 2018/848 must be appropriately defined within each company. The procedures implemented by operators must be verified by the control body/authorities as part of the certification process. The internal procedures set up by the operator must be appropriate to the size of the company and the type of production.

The following chapters propose elements of a procedure for assessing the presence of non-authorised substances in accordance with Article 28 (2)[108]. 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 regarding possible non-compliance with the Organic Regulation as plant protection substances.

Step 1: Verification of the information

In case information about a potential suspicion for a product owned or sold with references to "organic" occurs, the first step must be verification of whether the information is correct and relevant.

A) Identify and document the context.

For the documentation of the case, it is recommended to refer to the ANNEX of the Commission Implementing Regulation (EU) 2023/1195. The final structure of the documentation must be based on the specific operational situation.

[106] Beck A., Dieter K., Neuendorff J., Wallau R. 2024; Von der Notwendigkeit, Art. 29 der Verordnung (EU) 2018/848 verhältnismäßig anzuwenden ZLR 1/2024

[107] Schmidt H-P., Haccius M., 2022; EL 183. Zipfel/Rathke Kommentar Lebensmittelrecht, S 327 ff

[108] Partly based on: FiBL BLQ Guideline https://orgprints.org/id/eprint/43004/2/Guideline_FiBL_BLQ_Residue_Handling_Operators_Art27-28_ENG_final.pdf

IFOAM OE Guideline
https://www.organicseurope.bio/content/uploads/2023/05/IFOAMOE_REG_PositionPaper_Residues_22052023.pdf?dd

B) Verify whether the information available is correct and relevant.

1) Clarify whether the product or substance found is subject to the authorisation requirement under Article 9 (3) 1) of the Organic Regulation (Tool 1, see Table 6.1.2). If this is not the case, there is no need for action regarding Article 28 (2) Regulation (EU) 2018/848.

2) Check the relevance and correctness of the information.

   a) Is the analysis report reliable? (Tool 2, see Table 6.1.3
   b) Is the sampling reliable? (Tool 2)
   c) Exclude false positive results. (Tool 3, see Table 6.1.4)

3) Check if MRL is respected?
If the MRL is exceeded, the operator faces not only an organic but a food safety issue too. In this case the sanitary processes must be considered.

Follow up:

- ☐ If the findings confirm the correctness and relevance of the information, there is cause for "suspicion" according to Article 28 (2).
- ☐ If the finding/information turns out to be invalid or false positive and this situation is well documented, the products can be processed or traded as organic.

Step 2: Suspicion of non-compliance is confirmed

If the result is confirmed and a potential non-conformity could exist, there is a **suspicion of non-compliance under Article 28 (2)**. In this case, the product must be identified internally and **isolated** – if this has not already been done in Step 1. By doing so, it is recommended to respect the shelf-life of the product not least to avoid food waste as much as possible.

Step 3: Assessment of the case

The third step is to assess whether the products and substances found indicate **the use** of a non-authorised substance or product, **inadequate precautionary** measures, lack of action in response to **requests by CA/CB** and/or other non-compliances with the requirements of the EU Organic Regulation. The assessment initiated must be in reasonable proportion to the seriousness of the suspicion and the goods or processes behind it. For example, the durability of the product, the quantitative scope and the complexity of the case needs to be considered.

Chapter 5.4 of the Vade mecum is offering a concept respecting the risk level for justifying the "intensity" of the assessment/investigation to be carried out. This concept may be a helpful tool and can be adopted to the needs of operators.

Many situations require that suppliers of the products be informed about the suspicion and asked to comment. Involving the supplier's control bodies/authorities is advisable, depending on the case. Statements from suppliers and their control bodies/authorities 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. Tool 5 can be helpful.

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

Table 6.1.1: According to Art 1 (1) of Regulation (EU) 2021/279, at least the following must be checked

Mandatories actions		**Actions**
Does the information on the label of the organic product match with the information on the accompanying documents?	Yes / No	
Does the certificate provided by the supplier relate to the product actually purchased?	Yes / No	
In case bulk and Import, is the seal number, container, lot of the COI, correct?	Yes / No	
If one of the 3 questions above has to be answered with no: Check whether the supplier has delivered conventional goods instead of organic goods.		
Incoming goods		
Does the cause of the presence of non-authorised products or substances lie under your control?	Yes / No	If **Yes**: You shall examine all possible causes (Tool 4) If **No**: It makes sense to follow up with the supplier (Tool 5) In **addition**, Tool 4 can be used and in case a follow up with the control bodies/ authorities is recommended.
Are there contamination possibilities after receiving the goods?	Yes / No	If **Yes**: You shall examine all possible causes (Tool 4)

A sensible strategy for evaluating suspected contamination is to formulate relevant hypotheses on the source and cause of the contamination (see also Chapters 3.3 and 5.4).

The hypotheses derived theoretically or from practical experience on possible sources and causes should then be worked through, i.e. excluded, based on the hypothesis with the highest probability of occurrence. The hypothesis of a possible source and cause should be considered causes and sources regulated by the organic legislation (use of plant protection agents, commingling, precautionary measures) and not regulated (botanical contamination, spray drift). The hypothesis can be ruled out when precautions as agreed with CB/CA have been taken.

Steps to take:

- ☐ Establish hypothesis on possible sources and causes
- ☐ Test the hypotheses (true/likely or not)
- ☐ All hypotheses can be closed suspicion is eliminated
- ☐ One hypothesis of non-conformity cannot be eliminated suspicion is substantiated

For assessing the case Tool 4 (see Table 6.1.5) provides helpful guidance, strategies, and a set of initial questions.

Step 4: Conclusion and follow up

If the investigation shows that the “suspicion” is substantiated or cannot be eliminated, the operator reports the suspicion to the competent authority or the control bodies/authorities and provides all available information. (Article 27 d) and e) of Regulation (EU) 2018/848)

If the investigation process reveals that the “suspicion” can be eliminated or is not substantiated, the product can be processed and placed on the market as organic. The process must be documented. This documentation serves as verification of proper inspection and documents the arguments and facts by which the suspicion was eliminated (Article 28 (2) c) of Regulation (EU) 2018/848).

For taking this decision the operator should follow closely the procedure agreed with and verified by its CA/CB. It is recommended that the information and data of the supplier are included in the assessment. This decision must be technically and/or scientifically well justified. Depending on the company's internal competencies and the complexity of the case, scientific sources and, if necessary, external experts should be consulted for the assessment. Depending on the situation, an informal exchange with the one control body or authority is useful and recommended. Contamination with non-authorised substances in organic goods from third countries requires special care. In any case, the result of the assessment and the underlying reasoning must be documented in detail.

Tools supporting the internal procedure for assessing the presence of non-authorized substances in accordance with Article 28 (cf. Chapter 6.1.2)

Is the product or substance groups subject to the authorisation requirement Article 9 (3) and Article 24 (1) (2). More details to those substance and product groups can be found in Implementation Regulation (EU) 2021/1165.

Table 6.1.2: Substance in the scope of organic regulation (TOOL 1)

Is the product or substance a:	Yes / No
Active substances to be used in plant protection products?	
Fertilisers, soil conditioners and nutrients?	
Non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin?	
Feed additives and processing aids?	
Products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings, or installations used for animal production?	
Products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding?	
Products for cleaning and disinfection in processing and storage facilities?	
Food additives and processing aids?	
Non-organic agricultural ingredients to be used to produce processed organic food?	
Processing aids to produce yeast and yeast products?	
GMOs, products produced from GMOs, and products produced by GMOs (Art 11)?	
Raw materials used in organic food or feed treated with ionising radiation?	

Table 6.1.3: Verification of the information from laboratory (TOOL 2) cf. Chapter 2.4

Questions related to laboratory results that help verify their validity;	Yes / No
Can the laboratory result be traced back to the batch indicated on the lab result?	
Is any information about the sampling available?	
Does the sampling information technically meet the requirements (procedure and documentation, photo)?	
Is the sampling representative for the batch?	
Is it a random sample?	
Is a counter sample available? Second expert opinion in accordance with Art 35 of Reg 2017/625?	
Is the laboratory suitable for the relevant analysis?	
Is the reporting limit appropriate?	
Is the value reported above LOQ?	
Is the accuracy of the results, including fluctuation range, correctly reported?	
Is the laboratory accredited for the combination of sample (matrix) and method according to 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 considered 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 ®)?	

To exclude false positive results, proceed as follows:

Table 6.1.4: Exclusion of false positive results (TOOL 3)

● Analyse counter samples. (It is recommended to carry out 2 counter-analyses in 2 different accredited laboratories. If there are 2 negative results on the counter-analyses, the first result will be invalidated. If only one counter-analysis is positive, the first result will be confirmed.)
● 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.

Hypothesis could be built on following concept (see also Chapters 3 and 5):

Table 6.1.5: Assessment support (TOOL 4)

I.	*Is it the substance used for the production?*
II.	*Is commingling possible?* (in a large sense, covering the sale of conventional product as organic)
III.	*Cross-contamination/Contamination in the product chain* (within the scope on under the control of the operator) ⍰ Is there a possibility of contamination at the operator level, are there leaks in the precautionary measures?
IV.	*Is there environmental contamination possibly?* ⍰ Is there a possibility of contamination on farming level (open system)
V.	**Is natural presence a possible source?**

After formulation of the hypotheses, they should be ranked in order of their probability. The procedure should be established on the systematically agreed with the control body/authority of the operator.

The hypothesis should be tested, based on available Information - both internal and external (Literature, Expert opinions). And please check whether there are any expert opinions available from relevant organisations or authorities that could help classify the findings (For example: www.qm-votum.bio ; https://www.residues.fibl.org; https://www.authent.bio)

For different hypotheses different issues/tools can be used to figure out the facts:

Table 6.1.6: Different hypotheses on possible source and cause

I	**Is it the substance used for the production?**
1.	Does using the analysed active substance make sense for application in the crop or feed/food concerned, i.e., does its use make sense from an agronomic or technical point of view?
2.	Are there different possible uses/purposes for the active substance? What other sources of the active substance are possible? Can the substance be result of a chemical reaction while industrial processes (e.g. heating)
3.	Are several/additional substances detectable that make an application or a conventional origin probable?
4.	Are comparative data available on the specific product or process regarding the active substance found… a) in the supply chain? b) or within the company from the same or different origins?
5.	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?
6.	Which processing factors can be taken into account?

	(EFSA https://zenodo.org/record/1488653#.YNBWg0xCRPY // BFR https://www.bfr.bund.de/cm/343/bfr-datensammlung-zu-verarbeitungsfaktoren.pdf)
7.	What is the Maximum Residue Level (MRL) for the residue compared to the level of the finding? 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?
8.	Are there any further data and analysis results available from the supplier?
9.	….
II	**Is commingling possible?**
1.	Price differences organic/conventional for the product (incentive for fraud)
2.	Availability on the market /harvest situation (e.g. is there a lack of goods caused by crop failure, products are replaced)
3.	Cultivation structure at farm level. Information on organic ha available? Potential quantity of harvest calculated?
4.	Is traceability/transparency of the batch ensured? The data available?
5.	Commingling during transport excluded?
6.	Is it a product blend? (The homogeneity of the raw material is highly relevant regarding the evaluation and error analysis in the process) 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? e) Can possible impurities be assigned to one or more of the origins?
7.	…

III	**Cross-contamination? Contamination in the product chain**
1.	Leak in the precautionary measures – implementation documentation - in one operation? - of the supplier – if available?
2.	Are the production monitoring records present and correctly completed?
3.	Could a member of staff or an external member of staff have caused the contamination?
4.	Conventional goods present in the production plant, transportation and storage facilities involved? - Was there any confusion, mixing, etc. between conventional and organic production? - Have the identification and traceability rules been correctly applied? - Has the cleaning protocol between conventional and organic production been correctly observed and recorded? - Have storage conditions (protection, identification) been defined and respected? - Is contamination of used inputs excluded?
5.	Analysis of Raw Material upstream of production available?
6.	Is the substance in question present in the water used in your company?
7.	Is another source possible? Is the substance in question present in products used in your company (cleaning and disinfecting products, pest control products, etc.)?
8.	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?
9.	…
IV	**Is there environmental contamination possible?**
1.	What does Literature say about the presence of environmental contamination in nature? In the region contamination is assumed (product comes from, is stored, or processed)
2.	How is the persistence of the substance?
3.	Check cultivation structure and situation at farm level (open system) for possible contamination? Agreed precautions under the control of farmer established?
4.	Check possible contaminations at the food chain.
5.	…
V	**Is natural presence a possible source?**
1.	What does literature say on the natural occurrence of the substance?
2.	Contamination by botanical impurities?
3.	How much of the natural occurring substance can be typically found in the specific crop?
4.	…

Table 6.1.7: Example for Questions to a supplier (TOOL 5)

Linked to the feedback of the supplier:
Is the supplier a European supplier or producer?
Has the supplier done an examination and gave a statement that there is no substantiated suspicion?
Has the supplier done an examination and gave a statement that there is no substantiated suspicion? The assessment was based on this questionnaire?
Linked to the information's of the supply chain:
Are there conventional crops in the neighbourhood? (If YES, which conventional crops? / Which distance?)
Is there a risk during harvest? How is the harvest performed?
Is there a pre-cleaning / cleaning at agricultural level? / Is there a risk for contaminations?
Which kind of measures are taken to avoid contamination from conventional products?
How are the goods packed? (f. e. single use material, material used several times only for organic, material used several times also for conventional)
How was the cleanliness of the container/truck checked prior loading?
Were the goods transported in a container? *(fumigation possible?)*
How is the product stored? (bulk, BB, bag, container)
What pest control measures are carried out in the warehouse?
What is the warehouse like?
….

Concluding remarks

The provisions of Article 28 provide the opportunity to assess at operator level a suspicion of non-compliance, and therefore, if the suspicion is eliminated, to be able to place their products on the market as organic without having to initiate an official investigation. On the other hand, these provisions give operators a responsibility which must be assumed with the greatest seriousness.

Operators are the first links in the investigation chain. It's a heavy responsibility, but one that will be lightened by the use of this Vade mecum, the aim of which is to support and encourage companies to assume this responsibility in a professional manner. The quality of their work will have a threefold benefit:

- to avoid unnecessarily overburdening CBs with administrative tasks in cases where doubts can be raised directly at operator level. CBs will be able to concentrate on the really contentious cases
- to share any initial information gathered informally with their CBs, who will then be able to draw conclusions to their investigations more rapidly. This should limit the needless destruction of organic foodstuffs finally recognised as compliant.
- to be part of a continuous improvement process in collaboration with CBs/CAs which can be promoted to consumers.

This chapter presented the methodological elements and practical tools for implementing Article 28 in a rigorous and effective manner, consistent with the systematic approach and the "investigation toolbox" developed in the Vade mecum for the conduct of official investigations, particularly in Chapters 3, 4 and 5. Some conditions are to be met for implementing them in an adequate manner:

- The procedures set up and implemented by the operator should be verified by its CB/CA.
- Reliable relationships with CB/CA as well as with professional associations and experts should be established.
- The operator should have the competence and capacities to efficiently manage the self-control system established in the company (see § 6.1.2)
- Qualified staff should be available for implementing the internal procedures in place to carry out in the event of a suspicion of non-compliance.
- The investigation process and its outcome should be carefully documented (see § 6.1.3), and should be reviewed and supervised by the CB/CA.
- If the contamination has an external origin (i.e. outside the responsibility of the operator), the operator can build up its assessment on strong and sustainable commercial links with its suppliers.
- Special attention is needed in the case of imports from third countries especially when the food chain is unknown.
- Any suspicion remaining doubt which cannot be eliminated fully or with high probability should lead to an information of the CB/CA.

CHAPTER 6.2: INVESTIGATIONS CARRIED OUT BY THE CONTROL BODIES

Sergiy Galashevskyy[109], Samanta Rosi Bellière[110]

6.2.1 Introduction

In the specific case of suspicion of non-compliance due to the presence of non-authorised products or substances, the investigation shall determine the source and the cause of the presence of such products or substances, in order to ensure that operators comply with the requirements for organic production and, in particular, have not used products or substances that are not authorised for use in organic production. In addition, the investigation should ensure that those operators have taken proportionate and appropriate precautionary measures to avoid the contamination of organic production with such products and substances[111].

During the investigation carried out by control authorities (CA) / control bodies (CB), the evidence for all possible origins of the presence of the residue is collected. Such an investigation needs to be tailored to the individual case, taking into account specific aspects such as the organic production activity (e.g. farm/processing/trade), the product, the detected plant protection product or non-agricultural ingredients or processing aids etc. and the context; it may include also traceability of the lot, observations in the field (e.g. absence of weeds in case of suspected herbicide application), additional sampling of foliage, soil, equipment or crops, literature review for environmental behaviour of the substance that might lead to technically unavoidable contamination, alternative sources for the presence of the residue (e.g. natural occurrence), and concentration or dilution factors in case of processed food (see Chapter 4 and 5)[112].

While the graphs in Chapter 5 (Figure 5.1. Substantiation of information on the detection of non-authorised substances and materials) and Chapter 7 (Figure 7.1 Flowchart of an official investigation) show an overview of the key elements of the investigation process, in this chapter, we will go through the whole investigation workflow process (see below Figure 6.2.1) starting from preparation for possible investigation and ending with the follow up with the operator concerned about the outcomes of the investigation. It is intended to be a procedural section, based on the requirements of EU Organic Regulation, as well as providing valuable interpretations by the EU Commission, with some data from scientists and researchers, and the good practices of different CB, including the authors who have had many years of experience (both in EU and Third Countries).

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This article exclusively reflects the personal opinions of both authors.

[111] Whereas n. 68 and 69 of Regulation (EU) 2018/848.

[112] Schleiffer M, Speiser B, FIBL, 2022: Presence of pesticides in the environment, transition into organic food, and implications for quality assurance along the European organic food chain. A review.

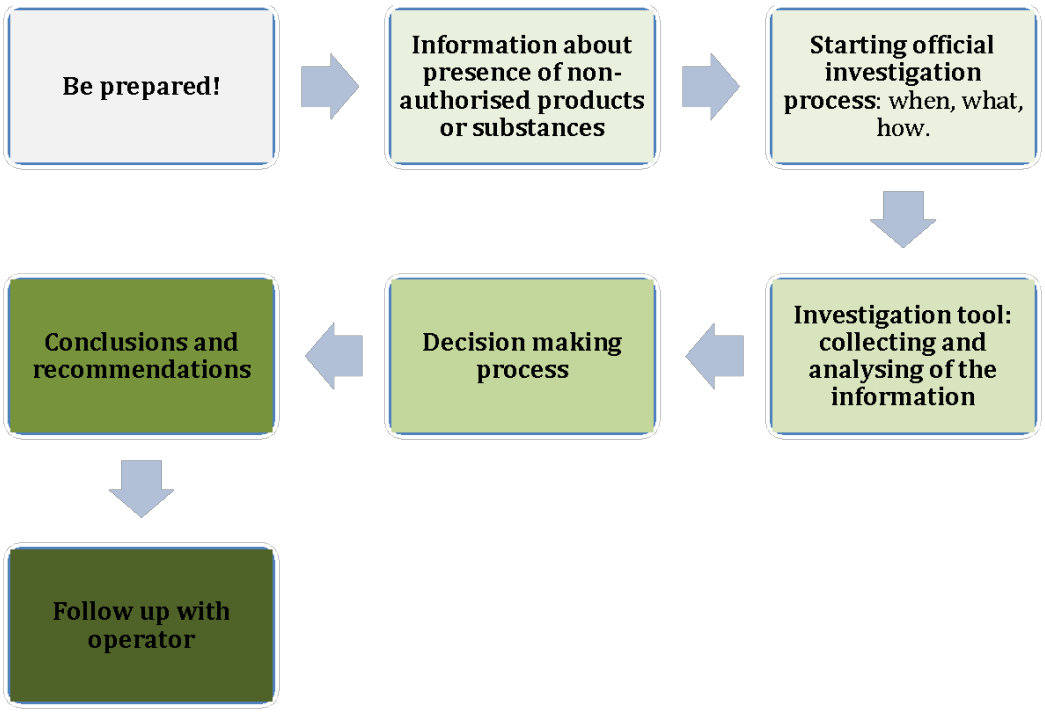

Figure 6.2.1: Investigation workflow

6.2.2. Be prepared!

In order to be efficient and effective whenever there is a need for investigation, control authorities (CA) / control bodies (CB) should proactively think in advance and be ready for possible investigations.

This might be achieved by:

Appropriate documentation for certified operators

- Description of the operator production unit (Operator Profile, Operator Management Plan, with description of risks and corresponding proportionate and appropriate precautionary measures implemented by the operator[113]; geo-location of the production units and premises[114])
- Inspection reports/records[115], including the verification of precautionary measures implemented by the operator and notes with inspector observation about farming practices, e.g. indicators of application of preventive measures like presence of sticky traps, natural predators, biodiversity stimulating factors, characteristics of the variety concerned, agronomic practices (sowing/planting distance), monitoring practices (tensiometers to measure stress due to lack of water), indicators of disease/pests on the plant.
- Records about previous non-conformities/sanctions of operators for the last 3 years
- Photo-reports of crops, storage/processing units, labels, sampling process, consignments, transport, seed etc; it might help to have photos with dates and GPS data.
- If applicable, sampling reports, with notes of the inspector about possible risks and other useful information: e.g. risk of spray drift or any other pollution, map showing neighbouring

[113] Regulation (EU) 2018/848, Article 28.1

[114] Regulation (EU) 2021/1698, Article 11.1

[115] Regulation (EU) 2018/848 Article 38, Regulation (EU) 2021/1698, Article 11

crops and wind direction[116]; identification of sampling points/spots; lot/batch identification etc.
- If applicable, laboratory reports.

It is also useful, especially for CBs from Third Countries, to store control samples (for their shelf life) in an adequate place and conservation conditions (especially relevant for export consignments/lots from Third Countries);

Organisational measures

- Development of an internal procedure (e.g. investigation procedure) which clearly indicates and defines responsibilities (defined responsible person/roles for investigation).
- Suitable resources in place, including inspectors, in order to carry out, in addition to the office activity, inspection and sampling activity over a short period. As best practice, it might be useful to have more than one person responsible for the investigation.
- Competent personnel for implementing official investigations who continuously increase their competence. As best practice, it might be useful to exchange experiences between investigation experts/teams, to invite external experts, to consult conventional business etc. It is important that the evaluation of residue findings requires a high level of competence.

Third Country CA/CB

According to Article 16 of Regulation (EU) 2021/1698 and Article 3 of Regulation (EU) 2021/2306, CA/CB have to carry out, before the consignment leaves the third country of export or of origin:

- systematic documentary checks, and
- physical checks, as appropriate according to a risk assessment (including high-risk products as defined in Article 8 of Regulation (EU) 2021/1698 and according to the EU document for additional control measures in TC[117]).

- Documentary checks:

  - traceability of the products and ingredients:
  - For products involved in the EU additional control measures, where there is a complex supply chain a transparent flow chart must be added to the documentation, unequivocally presenting both the flow of the goods and the financial flow. All actors of the supply chain should be certified and identified, including financial traders/agent (as soon as they own the product) or inspected, if any preparation is happening by subcontractors[118]. All operators involved in the supply chain and their respective Control Bodies should be mentioned.
  - the volume of the products included in the consignment is in line with the mass balance checks of the respective operators;
  - the relevant transport documents and commercial documents (including invoices) of the products;
  - all relevant documents, including the certificate of operators, records of the inspections, the production plan for the product concerned and records kept by the operators or the groups of operators, available transport documents, commercial and financial documents and any other documents deemed relevant by CA/CB.

[116] Overview report "Pesticide Residue Control in Organic Production", 2017 https://op.europa.eu/en/publication-detail/-/publication/0cc30f7a-4674-11e7-aea8-01aa75ed71a1

[117] Ref. Ares (2023) 8135116-29/11/2023

[118] Regulation (EU) 2021/1698, Article 10.2(b)

- Physical check of consignments

  - sampling of consignments: as a best practice, it might be useful to take samples "just before delivery" and/or "after last activity has been carried out (e.g. preparation)" and to keep such "control samples" to be analysed for further investigation, in case of substantiated information about residues will be reported.

- Travel Plan: for consignments made out of bulk organic products, the control bodies shall draw up a travel plan in TRACES, including all the premises to be used during the travel from the third country of origin or export to the European Union[119].

It can be a transparent flow chart that unequivocally presents the flow of the goods with quantities and lot numbers indicated, including premises and ways and means of transport to be used.

6.2.3. Information about presence of non-authorised products or substances

CA/CB shall immediately start the official investigation when[120]:

They receive 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* (e.g.: via OFIS, from Competent Authorities, other CA/CB, consumers/importers etc)

or ***have been informed by a certified operator*** *in accordance with point (d) of Article 28(2),*

or ***detect*** *such products or substances in an organic or an in-conversion product*

Once received the information, the following steps should be taken by the CA/CB (see also Chapter 5.2):

A) Check if the information received is substantiated and reliable, by verifying the following (not an exhaustive example):

   1) **Is the analysis result reliable?**
      i.e. is the laboratory ISO/IEC 17025 accredited?
      If not accredited it's up to the CA/CB to decide about investigation.
      The level of residues detected is >LOQ/LQ? For the cases when residue level >LOD< LOQ, the CA/CB shall decide case by case, depending on the substance and origin of information, whether or not to start an official investigation.
      Can the laboratory result be traced back to the affected batch/consignment/lot?
   2) **Is the product or substance relevant for compliance with organic production rules and is there a suspicion of a non-compliance?**
      Is the nature of the non-authorised substance in the sampled product related to the activities of the operator?
      (i.e. not relevant are heavy metals, mycotoxins, alkaloids, microbiology etc as they are not included in the scope of Organic Regulation)121
   3) **Is the sampling traceable and reliable?**
      i.e. is the sample origin tracked?
      Is the information available about who took the sample and when?

[119] Regulation (EU) 2021/1698, Article 16.5

[120] Regulation (EU) 2018/848, Article 29.1

[121] EU COM (COP, 01.04.2019): "Control Bodies first check whether the nature of the non-authorised substance in the product sampled can be related to the activities of the operator"

Chapter 5, Figure 5.1 provides further information. In case the detected residue level is > MRL, according to Regulation (EU) 2017/625, such cases shall be handed over or at least be dealt with as well by the competent food and feed safety authority. Nevertheless, this does not prevent the CA/CB from opening an official investigation to identify cause and source, to evaluate appropriate corrective actions and modification of existing precautionary measures to prevent such presence from occurring in future[122].

If the CA/CB decide that the received information is not substantiated, it still may plan some control measures with regard to the concerned operator, e.g. additional sampling during next inspection or additional unannounced inspection.

It has to be considered that if the information arrives from another CA/CB, such information is likely substantiated because each CA/CB is responsible for its operator and must accept the conclusion of an official investigation carried out by another CA/CB (see Chapter 5.10) if factually justified.

B) So, if information is substantiated indicating a potential non-compliance, the CA/CB decides either to conduct an unannounced inspection or inform the operator about the case. The CA/CB "*provisionally prohibits 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*"[123], if applicable, as in some cases, the affected products/lots are already sold and/or consumed;
C) CA/CB may request further information (e.g. traceability with supporting documents) and ask the operator to start its own investigation (not a compulsory step according to the regulation, but helpful) and provide results as soon as possible.

6.2.4. Starting the official investigation process: when, what, how

The official investigation shall aim at identifying the source and cause of the presence of the non-authorised products or substances. While carrying out the official investigation, the control authorities (CA) / control bodies (CB) may apply all methods and techniques that are foreseen by the Official Control Regulation (EU) 2017/625.

The control bodies "*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 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*[124].

[122] Approach to investigation and residues and contaminants discussed in the RESCUE network

[123] Regulation (EU) 2018/848, Article 29.1(b)

[124] Regulation (EU) 2018/848, Recital 69, Article 29.1(a)

As already explained in Chapter 5, time is a crucial element. According to the EU Commission "*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***"[125].

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

Regarding the methods, CA/CB could use for their official investigations "***any method and technique** for official controls which is considered appropriate **to efficiently eliminate or confirm**, without any unnecessary delay, any suspicion of non-compliance with this Regulation, 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*"[126].

*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*[127].

What CA/CB shall determine at a minimum during an official investigation, is listed in Article 2.1 of Regulation (EU) 2021/279:

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 pre- harvest 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.

In case the CA/CB have no traceability of the affected product available, a **mass-balance/traceability check is the priority.** During an investigation, a CA/CB should be able to provide a complete traceability of the product under investigation (see details in Chapter 4.3).

The control authorities (CA) / control bodies (CB) decide how to carry out the official investigation choosing among:

A) only a documentary review (off-site) where all the data needed is already available ("*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*[128]"). OR

[125] Ref Ares (2022) 7959596, 17.11.2022

[126] Whereas n. 69 of Regulation (EU) 2018/848.

[127] Regulation (EU) 2021/279, Article 2.2

[128] Whereas n. 69 of Regulation (EU) 2018/848.

B) physical check / on-the spot inspection (announced or unannounced), incl. document checks, if there is a need to:

- check original documentation and records;
- take a sample (if no product in stock or the product has been harvested, soil samples and/or dust particles in the storage facility should be considered), see Chapter 4.4 for details about sampling strategies and techniques;
- verify on the spot whether precautionary measures are adequate;
- interview with personnel;
- others (Chapter 4.4 provides important details how an efficient onsite inspection can be organised.)

Chapter 5.5 explains how to choose the most appropriate intensity of the official investigation according to the different risk levels of a combination of Product / Operator criteria.

The control authorities (CA) / control bodies (CB) consider the need to exchange information with other control bodies/ authorities in cases where the product itself/ingredients of the product have been produced by other operators, certified by another CA/CB:

- as soon as possible, start an information exchange with the control bodies/authorities of the other operators involved in the chain (one step back) to inform them about an ongoing investigation. In this primary information exchange, it's important to state that the control bodies/authorities will update them about the result of the investigation[129].
- If, based on the investigation result it is possible to exclude the possibility that the contamination took place at the level of the operator under investigation, then the CA/CB updates the control bodies/authorities of the supplier/s without delay, to allow the "upstream" CA/CB to carry out a detailed investigation in a reasonable timeframe[130].

Proper communication between the CA/CB improves the understanding of the pesticide residue related questions and contributes to the effectiveness of the controls[131].

6.2.5. Investigation tool: collecting and analysing of the information

While checking information for its substantiality, CA/CB should verify information about sampling, testing and detected substances.

As best practice, control bodies may use an investigation workflow document/report for efficient investigation, collecting information and record keeping. Below are some topics of the investigation workflow to be considered:

- **information about the sampling**
  The aim is to check substantiality of incoming information and to evaluate and exclude possible mistakes during sampling and sample transportation:
  - What is represented by the sample? Is the sample representative of the sampled object?
  - Was the sampling competent? (with reference to Regulation (EU) 691/2013, Commission Directive 2002/63 for sampling of a lot/consignment)

[129] Regulation (EU) 2018/848, Article 43.2, 43.3, Regulation (EU) 2021/279, Article 9(2)

[130] Regulation (EU) 2018/848, Articles 43.2, 43.3, Regulation (EU) 2021/279, Article 9(2); Regulation (EU) 2021/1698, Article 21(4,6)

[131] DG Health and Food Safety, 2017 "Overview report Pesticide Residue Control in Organic Production" DG Health and Food Safety

- **information about the analyses**

The aim is to check substantiality of incoming information and to evaluate and exclude possible mistakes by the laboratory:

- laboratory accredited (ISO/IEC 17025:2005)? accreditation of method/matrix?
- LOQ for the residue exceeded?
- MRL for the residue exceeded?

- **information about the detected substance (see Chapter 4.2.2 for details)**
  The aim is to check substantiality of incoming information and to evaluate the detected substance, in particular:

  - *the type, name, quantity and other relevant information of the present non-authorised products or substances*[132], e.g.:

    - scope and period for possible use (in conventional agriculture)
    - active substance, metabolite or something else
    - volatility? water solubility?
    - systemic or contact?
    - banned or still authorised for use in conventional production in country concerned and in the EU?
    - persistence (degradation rate: DT_{50}, DT_{90} [133])

Some other questions that might help to understand the nature or origin of the detected substance:

- 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[134]?
- Can the substance be naturally occurring or be authorised for use in organic[135]?
- What other sources of the active substance are possible?
- Are several/additional substances detectable that make a deliberate application or a conventional origin probable?
- Can the substance persist in the soil for a long period?
- Can the substance be present due to environmental contamination and/or spray drift (transported by air, water or being transferred by handling in the food)?
- Can the substance be used in combination with other active substances (in the same PPP) or in a spraying program?

[132] Regulation (EU) 2021/279, Article 2.1 (c)

[133] PPT COM's expectations in terms of PES RES approach, 20.04.21

[134] According to the Relana Position Paper 19-01 version 2019/04/12 "Sources of contamination of samples for analyses": *"Several substances legally classified as pesticides are so-called „multiple source" compounds, for example they are deliberately used for other purposes, such as biocides, disinfectants, repellents, or additives in pesticide or fertiliser formulations. It can be repellents against mosquitoes, veterinary biocides and drugs, cleansers, disinfectants, wood preservatives, cosmetics, packing materials, even lab gloves etc.``*

[135] In the 2021 EU report on pesticide residues, it is emphasised that *"most of the quantified substances are often present in samples flagged as organic, either because they are authorised for use (e.g. copper compounds), they naturally occur (e.g. bromide ion, dithiocarbonates), they occur as degradation product of a sanitisation processed (e.g. chlorate) or are persistent contaminants of already banned substances (e.g. DDT (RD))"*.

- **information about the sampled/analysed product (see Chapter 4.2.1 for details), in particular:**

  - the name of product;
  - the type and characteristic of the product, e.g. fresh/dried/frozen product, raw material or processed, mono or multi-ingredient, green mass/leaves, soil, inputs etc.;
  - *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 pre-harvest or post-harvest*[136]*;*
  - if green mass/leaves, then the stage of plant development should be indicated where possible;
  - processing ratio for sampled product (drying or concentration factor), to be considered, but not directly implemented (see Chapter 5.2);
  - *lot identification, if applicable;*
  - *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*[137]*;*
  - the quantity of products affected to be determined;
  - if any other products are affected?[138]

  Some other questions that might help to understand the origin of contamination:
  - 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? 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 contamination due to the "post-harvest" activities 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, fumigation of containers, disinfection...)
    c) equipment and installation for storage (usually subject to treatments with insecticides for pest control, either on empty equipment and installation or on the non-organic food managed at the same facilities)
    d) cross contamination between treated non-organic and organic products (adequate precautionary measures for identification, segregation and cleaning have been adopted)

  - Is the product where the presence of the residue has been detected a high-risk product[139]?
  - Are any other samples or analyses available for the concerned product? What are the results of those analyses (if any)?

[136] Regulation (EU) 2021/279, Article 2.1 (d)

[137] Regulation (EU) 2021/279, Article 2.1 (a) (b)

[138] EU COM, COP, 01.04.2019, PPT "Article 29 (a) & (b)

[139] Regulation (EU) 2021/1698, Article 8, Ref. Ares (2023) 8135116-29/11/2023

- Are control samples available? What are the results of those analyses (if any)?
- Have other samples been taken and analysed? What are the results of those analyses (if any)?[140]

- **Information about the operator (see Chapter 4.2.3 for details), in particular:**

  - Have the operators identified been involved in other non-compliance/suspicion of non-compliance/other problematic cases in the last 3 years?
  - Does the operator have only organic activities?
  - What is the risk category for the operator according to the CA/CB risk assessment?
  - Are other operators in the supply chain affected?[141]
  - Are there further results of previous official investigations on the organic or in-conversion products concerned[142] (e.g. OFIS cases etc.).
  - Have the operators concerned been submitted to a specific control?[143]

Some other information, if available, that might help to identify possible hypothesis about source and the cause of contamination:

- Verification of the possible use of the relevant product/substance by the operator
- 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. Precautionary measures need to be adequate and implemented effectively. An important point in this context is the question whether the operator uses subcontractors to apply inputs and how it is ensured that these subcontractors arrive with clean equipment?
- Verification of possible drift, both long range and short range have to be taken into consideration. In the case of short range, it's important to investigate to distinguish short range drift from non-authorised pesticide application. If the crop is still in the field, it's important to do an appropriate sampling activity, taking samples at different distances from the potential source of contamination: one close to the possible source of spray drift and the other one at the centre of the organic field[144].

The operator may prepare results of his own investigation, that can be taken into consideration among the inputs for the investigation. It would be appropriate to receive them before making the decision.

6.2.6. Decision making process

The steps for the decision-making process have been identified as follows:

[140] Regulation (EU) 2021/1698, Annex III

[141] Regulation (EU) 2021/279, Article 2.1 (e)

[142] Regulation (EU) 2021/279, Article 2.1 (f)

[143] Regulation (EU) 2021/1698, Annex III

[144] [74], A., Piepho, HP., Malik, W.A. et al. Appropriate sampling methods and statistics can tell apart fraud from pesticide drift in organic farming. Sci Rep 11, 14776 (2021). https://doi.org/10.1038/s41598-021-93624-8: *"In most cases, comparing pesticide residues in leaf samples from field margins close to a possible source of spray-drift, to samples from the centre of the organic field, allows to distinguish the effects of spray-drift from deliberate pesticide use by the organic farm. The method works even in regions with extremely intensive pesticide use and aerial spraying by conventional neighbours."*

A) The CA/CB control authorities (CA) / control bodies (CB) evaluate all the available information (inputs) and formulate a hypothesis (see also Chapters 3.2.1-3.2.2 and 5.3-5.4).

For example, based on source and cause, possible hypothesis might be:

- non-authorised substance (pesticide, fertiliser, ...) has been applied in the field
- organic products were mixed with conventional products ("partial commingling")
- contamination from the operator's equipment (during harvesting or processing)
- environmental contamination by heritage chemicals in soil[145][146]
- natural presence of the substance in crops or environment[28]
- substance formed during authorised processes (e.g. use of authorised inputs)[28]

B) The CA/CB qualifies each hypothesis, if necessary, as "probable", "possible", and "excluded", while checking probability, see also Chapter 5.4.
C) The CA/CB prioritises the hypotheses (some hypotheses to be excluded), paying special attention to the hypothesis of "use of non-authorised substances", as the first hypothesis to be checked.

Spray drift from neighbouring fields and other reasons for contamination are considered acceptable if sufficient precautionary measures are taken by the operator. According to the EU Commission *"a drift needs to be proven – not adequate buffer zones; sampling in the passage paths compared to sampling of the plant leaves or the soil around the plant"*[147].

There are so far no official criteria to decide on the adequacy of precautionary measures; the control bodies have to carry out a case-by-case assessment based on all elements available.

D) The CA/CB makes a decision based on the most likely (probable) hypothesis about the source and the cause of the presence of the non-authorised substance (see details in Chapter 5.7).

As best practice, the investigation process can be facilitated with specific investigation policies for the most common detected substances, encountered by control bodies; it may already have useful information about substance, possible hypothesis and previous CA/CB conclusions about this substance (examples of common substances: phosphonic acid/fosetyl, bromides, DEET, dithio-carbonates, glyphosate etc).

More reliable answers can be obtained with a case-by-case investigation, where evidence for all possible origins of pesticide residues is collected and the likelihood of unavoidable contamination and fraud are estimated [148].

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[145] EGTOP final report June 2022: 3.2.7 Comment on widespread environmental contamination:

"Organic agriculture has grown considerably and is increasingly confronted with environmental pollution and pollutant loads in different cycles organic farming is a part of.

Meeting the quality demands/expectations and compliance to the organic regulation is made more difficult by the presence of pollutants in many eco-systems and food cycles, as well as by the contamination from conventional cycles with substances banned in organic agriculture, e.g. by the possibility of drifting pesticides.

The proposed measures can reduce contaminations (in frequency and in amounts) but may not always completely eliminate them from the organic production chain. Under these circumstances, a certain level of contamination can be difficult to avoid in organic products".

[146] Presence of pesticides in the environment, transition into organic food, and implications for quality assurance along the European organic food chain. A review. 2022: *"Synthetic pesticides are widely present in all environmental compartments. They originate from applications in the region, in distant areas or from historical use. Transition into the food chain has been demonstrated by various studies. However, large uncertainties remain regarding the true pesticide contamination of the environment, their dynamics and the contamination risks for the food chain. Organic operators can take certain measures to reduce the risks of pesticide contamination of their products, but a certain extent of pesticide contamination is technically unavoidable."*

[147] Third country CA/CB EU COM meeting 2021

[148] Presence of pesticides in the environment, transition into organic food, and implications for quality assurance along the European organic food chain. A review. 2022

6.2.7. Conclusions and recommendations

All possible efforts have to be put into concluding the investigation. In extreme cases investigations may be concluded without the source and cause having been found, but then the approach has to be the following: investigations can be closed when: the source and the cause have been found or it can be concluded that the source and cause cannot be found (which is not the same as not having been able to find it so far) and it can be justified/proved that they cannot be found (i.e. this is not a matter of time but a matter of having exhausted all means of enquiry)[149].

The provision on the conclusion of the investigation as soon as possible constitutes merely an exhortation to carry out the investigation as quickly as possible, without delay".

The product concerned **shall not be marketed as an organic**[150] or in-conversion product or used in organic production where CA/CB, has established that the operator concerned:

A) has used products or substances not authorised for use in organic production;
B) has not taken the precautionary measures;
C) has not taken measures in response to relevant previous requests from the control bodies[151].

- **The conclusions of the control authorities (CA) / control bodies (CB**) should include:

  - the status of "the integrity of organic and in-conversion products", corresponding to the status of the related lot (possibly yield, unit, activity or operator)
  - information about "the source and the cause of the presence of non-authorised products or substances"
  - whether or not the operator has **used** products or substances not authorised for use in organic production
  - whether or not the operator has **implemented** appropriate precautionary measures (which were submitted to the CA/CB earlier)
  - whether or not the operator has **taken** measures in response to relevant previous requests from the competent authorities, control authorities or control bodies[152].

***"A non-conclusive investigation** on the source and the cause of the presence of non-authorised 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** [153]."*
Nevertheless, such investigation should be proportionate to the suspected non-compliance.

- **The CA/CB defines corrective measures/recommendations for the operator**, e.g. about preventive/precautionary measures, implementing organic risk management plan etc, if applicable
  The CA/CB communicates conclusions to the operator(s)
  It's important to remember the operator concerned shall be given an opportunity to comment on the results of the investigation[154].

[149] Ares (2022)7959596 17/11/2022

[150] According to Reg. EU 2018/848 Art. 29.5, there are Members States having in place rules providing for products that contain more than a certain level of products or substances not authorised for use in organic production not to be marketed as organic product

[151] Regulation (EU) 2018/848, Article 29.2

[152] Regulation (EU) 2021/279, Article 2.3

[153] Ares (2022)7959596 17/11/2022

[154] Regulation (EU) 2018/848, Article 29.3

- **The CA/CB communicates results of the investigation with other involved parties for external cases** (e.g. CA/CB of supplier/buyer, OFIS, competent authority) if applicable
- **The CA/CB evaluate the response from the operator** (if available):

  - if the operator does not agree with conclusions: the operator should provide additional information and/or appeal to CA/CB;
  - if the operator agrees, he informs CA/CB about measures to be taken/implemented (Action Plan) to any non-compliance

- **The CA/CB keeps a chronology and records of investigations** (for further investigations or control by authorities)
  The CA/CB shall keep records of the investigation it has carried out and control bodies shall draw up a final report for each official investigation[155].
  That final report shall contain:

  a) the records of the specific elements, e.g. which investigation methods/procedures have been used, outcomes of the investigation etc.
  b) the records of the information exchanged with the competent authority, other control authorities, control bodies and the Commission related to this official investigation[156].

6.2.8. Follow up with operator (see also Chapter 7.6)

Once the investigation has been concluded, CA/CB has to remember to implement follow up activities such as:

- reassess the risk of the operator (and the risk of the product, if applicable), based on the outcome of the investigation as it might be that the risk level of the operator has been increased and therefore the control plan would need to be readjusted accordingly
- check during the next physical control and/or documentary control what actions were taken regarding the operators and/or the products concerned, in particular:

  - check if the operator removed all references to organic/in conversion in case of decertification/downgrading;
  - verify if the operator took corrective measures as necessary to avoid future contamination[157];
  - verify if the operator informed in writing and without undue delay buyers of the products (if applicable) if non-compliance that affects the integrity of the products in question has been established[158].

6.2.9. Cases and investigation examples

1) **Imazamox in sunflower cake/seed (Ukraine)**

The CB detects Imazamox (0,023-0,027 mg/kg) in sunflower cake during physical check of consignment at the level of processor.

[155] Regulation (EU) 2021/279, Article 2.4

[156] Regulation (EU) 2018/848, Article 29.3

[157] Regulation (EU) 2018/848, Article 9.3

[158] Regulation (EU) 2018/848, Article 39(d)(III)

The processor does only organic activity, mixing/commingling and contamination is excluded due to well implemented precautionary measures.

The supplier of sunflower seeds is an agricultural producer. After checking documents, it was identified that the operator grew special hybrids of sunflower, which are resistant to imazamox and imazapyr, and designed for conventional technology, especially against *Orobanche Cumana* (parasitic weed). Also, an official assessment is available, that in the area where the operator is located, there is a problem with e.g. *Orobanche Cumana*.

Hypothesis of non-authorised use in the field was the most likely, as there was no reason for using such seeds in organic production, which requires the opposite - more resistant hybrids to the possible problem, e.g. *Orobanche Cumana*.

Table 6.2.1: Hypothesis on presence of imazamox in sunflower cake/seed

Hypothesis	**Arguments in favour**	**Arguments against**
Use of non-authorised substance (PPP) by agricultural producer (supplier of raw material)	- operator grew special hybrids of sunflower, which are resistant to imazamox and imazapyr, and designed for conventional technology; - in the area where operator located, there is a problem with e.g. *Orobanche Cumana* (parasitic weed)	
Spray drift of PPP from neighbour fields	- Low concentrations; - found only in cake, not in oil	- operator claimed he used buffer zones (harvested separately) to avoid drift
Commingling/mixing with non-organic during transportation/processing/storage		- only organic activity; - only organic products; separation is well organised
Cross-contamination during processing or transportation		- transport of processor/buyer; precautionary measures against contamination are well implemented
Laboratory false detection		- confirmed by re-analyses

Conclusions:

Source: Non-authorised substance

Cause: Non-authorised substance (pesticide) applied in the field

2) **Bromides in winter wheat (Ukraine)**

The CB received substantiated information (through OFIS system and from the CB of buyer/importer) about presence of bromides in the grain of winter wheat (15 mg/kg).

Table 6.2.2: Hypothesis on the presence of bromides in winter wheat

Hypothesis	**Arguments in favour**	**Arguments against**
Use of non-authorised substance (PPP) (soil treatment)		- use only for small-scale farms, mostly vegetables; - operator has no equipment for it; - very rare practice in the region.
Use of non-authorised substance (PPP) during cultivation (herbicides, desiccants)	- there are 2 products with bromide authorised in the region	- 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-authorised substances from neighbour fields		- was found in green mass of several crops of this operator, samples were taken far from possible drift
Non-authorised use by during storage (fumigation)		- was found in green mass of several crops of this operator; - would cause higher residues very rare practice; not authorised to be used in region
Cross-contamination during storage or transportation		- was found in green mass of several crops of this operator; - precautionary measures against contamination are well implemented
Natural presence of the substance in environment	- was found many times in different operators from this location/region - was found in green mass of several crops of this operator; - there is scientific research that confirms higher content of bromides in local soils	

Conclusion:

Source: Natural presence

Cause: Natural presence of the substance in environment (soil)

CHAPTER 6.3: INVESTIGATIONS CONDUCTED BY COMPETENT AUTHORITIES IN MEMBER STATES

6.3.1 Evaluation of the survey: "Systematic approach for official investigations"

Mathis Hartung[159]*, Nicolas Verlet*[160]

A "surveymonkey" survey was sent to the 27 EU Member States (MS) represented by the COP[161] delegates. Representatives of 21 Member States participated in this survey, representing 85 % of the entire EU area of organic production. The results are presented as graphs and as a summary of comments received for open-ended questions. All the data is presented anonymously, without referring to any individual Member State.

The survey did not aim to provide a detailed analysis of how Articles 28 and 29 of Regulation 2018/848 are implemented and supervised by the competent authorities of MS, nor to make any comment on current practices. The aim was to produce a first factual overview of the main elements which structure operator assessment and official investigations related to the presence of non-authorised products and substances. The information collected gives a first indication of current practices.

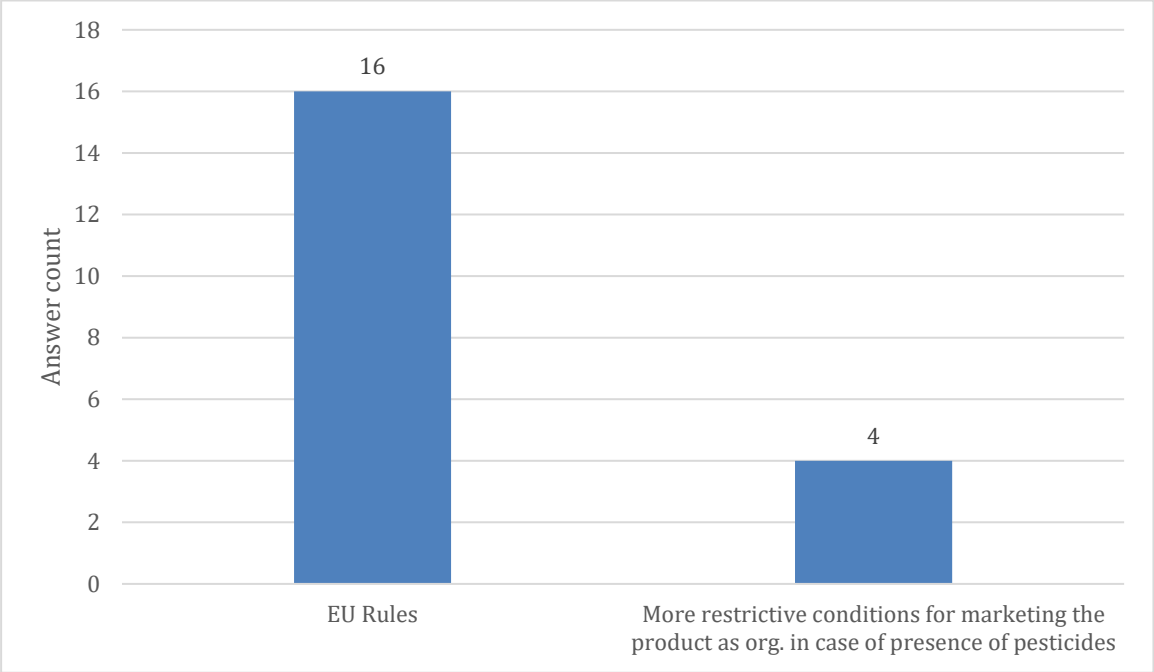

Figure 6.3.1: Regulatory framework for the implementation of Art. 28 and 29 in EU member states

The majority of participating MS apply the EU legal provisions of Article 28 and 29. Only four MS indicate a more restrictive framework as referred to in Article 29 (5), that means, they apply national

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This article exclusively reflects the personal opinions of both authors.

[161] Committee on Organic Production

thresholds in case of residue findings (Figure 22). One member state is a special case: one region applies stricter rules, the other one not. Thus, it was removed from the graph.

With regard to the implementation of Article 28 by Reg. (EU) 2018/848 by the operators, a slight majority of MS has no specific provisions concerning the application of Article 28 up to now (see Figure 23). Among the ten MS having put in place specific provisions, two have chosen legislative decrees, the remaining eight have used "soft legislation" (instructions, procedures, guidelines, etc.). As this was a survey for competent authorities, the result does not indicate that no approaches are in place.

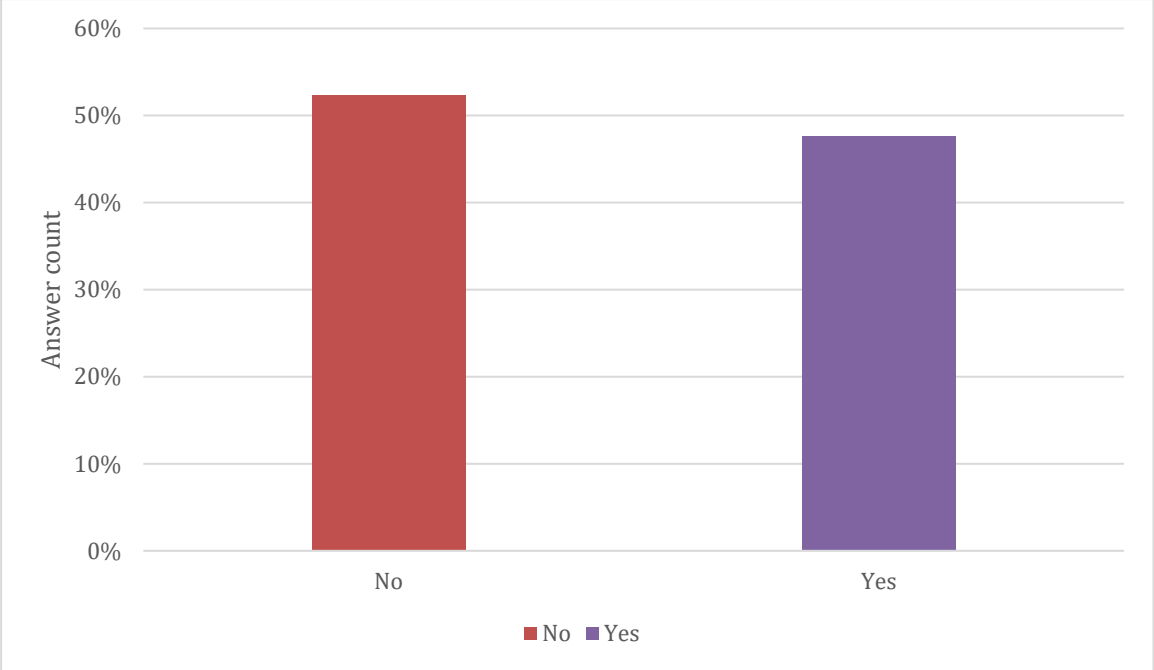

Figure 6.3.2: Provision in the EU member states with regard to the implementation of Art. 28

In one MS, a CB has established a guideline for operators on how to deal with Article 28 (2). In another MS, the development of some tools was supported by the "Federal Organic Farming Schemes"[162]. In several other MS, the competent authorities have indicated that either provisions are under consideration or specific discussions with operators and control bodies are underway. It might be an interesting option to identify "best practices" in the MS on how to deal with Article 28 (1) and (2) (see also Chapter 6.1). As the cases may vary significantly, the operator assessments need to adjust to their particularities, similar to official investigations. Nevertheless, the effectiveness of operator assessments should be evaluated during the annual inspections by CA/CB. Inspection reports should contain information how cases are assessed, and whether the approach is satisfactory.

[162] See https://orgprints.org

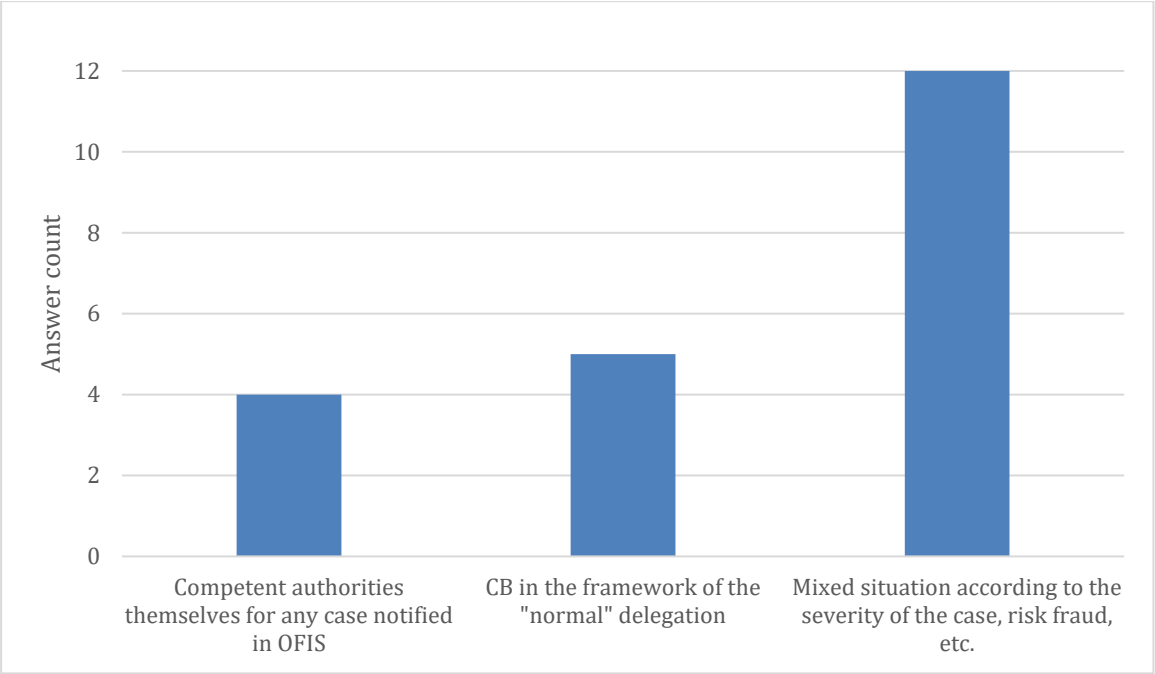

Figure 6.3.3: Actors in the control system conduction official investigations in the EU member states

The responsibilities for official investigations are displayed in Figure 6.3.3. Most MS involve competent authorities as well as CBs. In the vast majority of cases, CBs conduct the official investigation in the framework of their official delegation. The competent authority can be involved when it comes to analysis related to the control of imported consignments or in very few specific cases where a significant fraud case is alleged.

In most EU Member States, the results of official investigations are reported through two different channels, depending on whether it is a national case, or whether the case is international.

On the national level, all competent authorities are aware that suspect cases according to Article 29 (1) must be reported by operators and CA/CB with high priority. The procedures vary. As an example, one MS reports that any positive result of analysis must be reported by the CBs to a dedicated mailbox managed by the competent authority. Another one uses a specific software tool for national residue cases. No information could be obtained about how MS ensure an “equal level playing field” for operators which notify or how actively other operators are tackled for not submitting information on suspect cases. It also remained unclear how suspect cases potentially concerning several operators are dealt with on a national level.

On the international level, the OFIS system is used for reporting purposes. As there are guidelines from the European Commission, the procedure is described. MS reported as a problem that in the case of cross-border sales the information that an official investigation has already been conducted in one MS does not always arrive in another MS so that the reopening of cases which were already closed is avoided.

All MS competent authorities are aware of the reporting obligations at the end of an official investigation. The methodology for this varies. It might be useful to identify best practices.

6.3.2 Approaches from Bavaria

Christian Novak and Monika Simon[163]

6.3.2.1 Control and certification system in Germany

Based on the federal structure, 16 regional authorities (RCA) and 1 central authority (CCA) are competent and responsible for enforcing the legal framework in the Federal Republic of Germany. The state-supervised control system in Germany consists of 19 approved and accredited private control bodies (CB) supervised by the RCA on site (witness audits). The Federal Office for Agriculture and Food (BLE) is responsible for the nationwide approval and the office audits of private control bodies.

In principle, the regional competent authorities are responsible for the implementation of organic legislation. They delegate inspection tasks to approved private control bodies. The control bodies require a private legal contract with operators which wish to be certified for an organic activity and carry out on-site inspections as well as certification. A report to the competent authority is mandatory in cases of violations of the EU Organic Regulation such as suspected and established non-compliance.

The Bavarian state research centre for agriculture (LfL) as competent authority in Bavaria

The Bavarian State Research Centre for Agriculture (LfL) is the regional competent authority for Bavaria. With an area of 70,541.57 square kilometres Bavaria is the largest federal state in Germany. At present, 15 private control bodies carry out the organic inspections for over 17,000 organic operators in Bavaria. The LfL delegates certain tasks to the control bodies in accordance with the “State Regulation on the Bavarian State Centre for Agriculture (LfLV)" and the control bodies are obliged to inform the LfL in cases of suspicion and non-conformities. In addition to supervising the control bodies, the LfL is responsible for initiating administrative offence proceedings and taking measures in accordance with Article 29 (1) b), Article 41 (1) b) and Article 42.

National and regional legislative framework

- Organic Farming Act (ÖLG)[164]

The ÖLG is a law enacted by the Federal Republic of Germany to ensure a harmonised implementation of the EU Organic Regulation. In particular, the ÖLG serves to introduce a nationwide procedure for the approval of control bodies for the inspection of organic operations. It also creates a system of penalties and administrative offences for violations of the EU Organic Regulation. This act contains certain enforcement tasks in organic farming in Germany and improves the effectiveness of the implementation of EU Organic Regulation.

- Organic Farming Act Implementation Regulation (ÖLG-DV)[165]

The ÖLG-DVO was published in August 2023, and it contains detailed specifications for the approval of private control bodies in organic production. This legal act defines the requirements for control bodies to carry out official inspections, the specific procedure for the approval of certification bodies and the qualification of inspectors. It contains the common catalogue of measures for cases of suspected non-compliance and established non-compliance to be applied in Germany.

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This article exclusively reflects the personal opinions of both authors.

[164] Öko-Landbaugesetz (ÖLG) of 7.12.2008 (BGBl. I S. 2358), last modified on 17. August 2023 (BGBl. 2023 I Nr. 219).

[165] Öko-Landbaugesetz-Durchführungsverordnung (ÖLG-DV) of 26. Juli 2023 (BGBl. 2023 I Nr. 206).

- Bavarian Agricultural and Forestry Jurisdiction and Enforcement Act (ZuVLFG)[166]

The Bavarian state research centre for agriculture (LfL) is dedicated as a regional competent authority (RCA) regarding ÖLG, Regulation (EU) 2018/848 and Regulation (EU) 2017/625 in Article 13 of this regulation.

- State Regulation on the Bavarian State Centre for Agriculture (LfLV)[167]

With § 4 of this regulation the LfL delegates certain tasks to the private control bodies approved to operate in Bavaria. This regulation determines additional possibilities for intervention and supervision for the LfL.

Sources of suspicion

- Most cases under Article 28, Article 29 and Article 41 are reported to the regional competent authority in Bavaria through five channels as part of investigations by a control body responsible for a specific organic operator in Bavaria
- complaints by consumers or competitors about a specific (organic) operator in Bavaria
- information by other control bodies and / or authorities about a specific (organic) operator in Bavaria
- notification by the concerned operators themselves
- as part of its own investigations by the RCA

In all these cases and if not already done, the operators' responsible control body will be immediately informed by the LfL. In accordance with Regulation (EU) 2018/848, the control body initiates the corresponding official investigation and constantly coordinates with the competent authority in Bavaria.

Whenever a control body suspects an infringement pursuant to Article 28 (2) c), it informs the LfL immediately, in order that the authority can take the provisional measures in accordance with Article 29 (1) b), Article 41 (1) b) and Article 42 of Regulation (EU) 2018/848.

Useful elements

Apart from these fixed requirements, there are other additional approaches in Bavaria that could lead to a clear result and that have proved to be quite successful in the past. What we find helpful in our daily work to face and investigate residue and other cases:

- Complementary approach

To improve the quality of investigation results and to get a better understanding of a specific situation, complementary strategies are necessary. This means on the one hand cross-system communication and investigation involving other potentially responsible authorities (e. g. competent authorities for food or feed safety, food, fraud, plant protection, and animal welfare) and on the other hand using the complete toolbox of investigation methods to get the whole picture of the individual case.

Besides the regular sampling and analysis and the usual document checks, it is mainly the on-site inspection that provides the most valuable clues and insights. Here, production details in the investigated operator that could be a possible cause of contamination can be more easily uncovered. For example, are there recognisable tracks in the field allowing the conclusion that unauthorised use of pesticides has taken place here? Are the crops in the field exceptionally "clean" (almost no other

[166] Land- und forstwirtschaftliches Zuständigkeits- und Vollzugsgesetz (ZuVLFG) vom 23. Dezember 2022 (GVBl. S. 695, BayRS 7801-1-L).

[167] Verordnung über die Bayerische Landesanstalt für Landwirtschaft (LfLV) of 12. November 2002 (GVBl. S. 652, BayRS 7801-9-L).

plant species) and does the operator have the appropriate technical equipment that makes the operator's statements appear plausible? Is separating goods in storage as clear and effective in practice as in theory? A key element of this tool is the adequate training and experience of inspectors. Only then it is possible to focus on certain food production processes and understand possible sources of contamination.

Another important investigation tool in suspicious cases is serious cooperation between the control bodies along the value chain. Cross-checks to be carried out for this purpose should be applied consistently and continuously.

- Precautionary measures (Article 28 of Regulation (EU) 2018/848)

As part of the on-site inspection, the concept for precautionary measures is of course one of the operator's most important documents for investigating the processes of the operator for possible non conformities. The concept serves to identify the operator's compliance and the implementation documentation can provide initial indications of possible negligence or even fraudulent intent.

- Holistic approach

In each case asking a lot of questions (where, what, why, how much… e.g.) can be a very useful method to distinguish patterns, intentional practices, or fraud from „chaotic" operators, lack of knowledge, etc. This approach differs significantly from the fixed procedural paths of authorities and is intended to supplement these with holistic points of view.

- Case-by-case evaluation

In general, each case is different and should be considered separately and individually. In the event of suspicion, the necessary information must therefore be collected and submitted each time, even if it may seem redundant in certain cases. However, it is important to have consistency in the case analysis and to follow a clear line in the processing of cases to prevent unpredictability.

6.3.2.2 Conclusion

All in all, the current legal framework offers a well-equipped "toolbox" for conducting appropriate official investigations in the federal state of Bavaria. Provided that the roles of the control bodies and authorities are clearly defined, the investigating parties can rely on several complementary instruments to conduct their official investigations, and hence they do not have to focus on a single element such as residues when treating an individual case. Key elements of this complementary approach are (amongst others) a close collaborative attitude with other regional competent authorities (e.g., food safety and food fraud authorities), including a timely and efficient information exchange, as well as a sound background knowledge on CB's and CA's side to enable the necessary holistic view in each single case of suspicion of non-compliance.

6.3.3 Approaches from Denmark

Robert Lind[168]

6.3.3.1 Organic control and certification system in Denmark

The Ministry of Food, Agriculture and Fisheries of Denmark is a one string system, meaning the official public control system and the competent authority is one integrated system, also responsible for the organic controls and certification. The ministry is both competent authority and control authority (CA), and no delegations of controls take place. The Danish Agricultural Agency (DAA) is responsible for the primary sector (organic farmers) and the Danish Veterinary and Food Administration (DFVA) is responsible for the organic food operators. Public Laboratories are also a part of the overall ministerial control system.

In Denmark there is no additional organic legislation in place relevant for the follow-up when residues of non-authorised substances (e.g. pesticides) are present in organic or in-conversion products and a suspicion of a non-compliance has arisen. The legal basis is the basic level formed by the provisions of the European Organic Regulation (EU) 2018/848 and its implementing and delegated regulations together with the European official Control Regulation (EU) 2017/625 and horizontal legislation.

The authorities have specific guidelines and manuals for organic inspectors for handling pesticide residues in organic production, both for investigations and for the follow-up on measures and sanctions. These are only for internal use and not available to the public.

Denmark has no action levels for initiating investigation or accepting organic status or not.

All confirmed findings of residues will, as a starting point, give rise to possible suspicion but shall be substantiated (Article 28 (2)).

Organic controls and official investigations (Article 29 (1) a) and Regulation (EU) 2021/279 Article 2) are integrated in the overall public control system for food. This also implies that measures and sanctions for organic is part of the bigger horizontal system and will follow these overall national practices in the official control system according to Regulation (EU) 2017/625. Denmark is not applying a common catalogue of measures for cases of suspected and established non-compliance to be applied in its territory identical to the proposed catalogue by the organic Regulation (EU) 2021/279 Article 8.

6.3.3.2 Sources of suspicion

Suspicions under Article 28 and Article 41 are mostly notified to the competent authority in Denmark in the following ways:

- Operators own analysis of organic products purchased from supplier or farmer (primary production) discovers signs of pesticides (wind drift)
- Organic inspection at the farm discovers suspicious field conditions (e.g. no weeds, spraying trails, very high yield etc.)
- Organic inspection sampling (authorities sampling and analysis program of organic products, annual sampling program Danish Technical University)

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This article exclusively reflects the personal opinions of the author.

- Information received from CB´s from another EU member state where organic products from Danish suppliers are found with residues (via OFIS)

Such findings trigger official investigations by Danish authorities (if substantiated)

- Information from CB´s of another country where organic products have been delivered/sold to a Danish company as a client, having residues (normally via OFIS). Already status is ”not organic” or “suspicion awaiting result of investigation in another country”.
- Other types of information might also lead to an official investigation (whistleblowers etc.)

For the competent authorities (CA) in Denmark the starting point is that all confirmed findings of residues linked with a potential nonconformity will give rise to possible suspicion.

6.3.3.3 Substantiated suspicion by the organic operator

In Denmark it has been a discussion point whether all cases of suspicion should be reported immediately to the competent authorities or the organic operator according to Article 28 would have the room for carrying out its own initial investigations in order to determine if the suspicion could be substantiated. If the operator clarifies that the suspicion is not substantiated, it is a must that the relevant documentation is kept on file by the operator in order to be available for the subsequent annual organic inspection. It can be stressed that the authorities might not agree on the evaluation and decision made by the operator. By involving the authority, the decision is more valid and joint. This is the approach by the DVFA in Denmark.

In Denmark it could be acceptable for the organic operator to clarify whether the suspicion is substantiated. The examples below give some indications of possible removal of the suspicion.

Example 1: Organic liquorice extract from an EU country. The liquorice extract contains phthalimide but no Folpet residues. Documentation was provided by the Danish organic operator to the authority in form of a written declaration from the suppliers control body on the specific operator, specific case and residue findings. This documentation can be accepted as the end of suspicion and no further official investigation will be conducted and no OFIS case will be started.

Example 2: Phosphonic acid. Declarations from CB are only accepted if they refer to specific findings on specific operators producing the organic product. A general statement from the CB that all residues of phosphonic acid is of background contamination or natural origin would not be acknowledged.

6.3.3.4 Official investigations

Whenever an operator finds a substantiated suspicion of a non-compliance to Article 28 (2) c), the CA must be informed immediately, in order that the authority can take measures in accordance with Article 29 (1) b), Article 41 (1) b) and Article 42 of Regulation (EU) 2018/848. This implies blocking of the organic products at the premises of the operator. Further blocking downstream will be decided by the CA if not already done by the operator. Proportionality has to be taken into account at this level, and the decision is based on the likelihood of breach of the organic integrity of the products covered by the suspicion. The obligation to inform the buyers that there is a suspicion the product might not be organic mostly has the same consequence as the information would be if the product is definitely not organic (Article 41 (1) b and Article 39 (1) d iii).). In real life and due to private contracts between the operators, the organic status is lost even though the investigations are ongoing, and the conclusion is not finally decided.

In Denmark, the Danish Technical University (DTU)[169] can be used for initial evaluation of the likelihood of potential active use of the residue involved. The DTU database contains all samples covered by the national pesticide-programme for many years. A typical evaluation is based on type of pesticide, residue level found and product type. The database covers many conventional products (fruits and vegetables) where the information is clear on levels when active use has taken place. If the same levels are found in the organic version this would speak for active use.

The methodology of the official investigation is outlined in Article 14 of Regulation (EU) 2021/625 as well as in Article 2 of Regulation (EU) 2021/279 and will include all the relevant hypotheses which will be conducted in parallel. A suspicion at the premises of a national organic operator will most often result in a physical inspection whether an organic farmer or a food processor. If physical activities have been carried out, all possible reasons must be investigated to determine if the source and cause is at the operator level.

The initial task is to secure full overview of the case at the operator mainly via documentation

- organic status of the involved lot/batch by invoice, delivery documents, Certificate of Inspection if imported
- organic certified supplier and check of organic certificates including subcontractors
- mass balance and traceability backwards/forward in the chain, assess if organic output is reliable

The physical investigation involves additional clarification and documentation

- if processing takes place: production files and registration of the relevant batches etc.
- storage facilities, conventional alternatives in the company, likelihood of commingling
- cleaning of production equipment and registration if conventional production takes place
- if proportionate precautionary measures have been followed, for example established by the operator and indicated in the organic report (Article 28 (1))
- where relevant, if organic, their own checking programme and relevant HACCP procedures are followed

The preliminary conclusion of the case is to be drawn up by the CA, as well as a systemisation of relevant documentation suitable for upload in the OFIS.

Additional pesticide analysis is mostly not used but might be Imposed on the operator for future measures if risk is considered to be increased.

6.3.3.5 Conclusion of the investigation and decision taken - product status and operator

Every case is individual - different aspects need to be considered and balanced for the final decision (Article 41 (2) of Regulation (EU) 2018/848).

As CA, the investigations concerning only national operators are simple ones if the source and cause can be deducted from evidence found at organic operators already inspected by the Danish CA.

If the conclusion is that the source and cause is not at the national operator level, this information is filed and passed on in OFIS for further investigations upstream in the chain.

[169] The Danish technical University, in collaboration with the Danish veterinary And Food Administration (DFVA) annually publishes reports on the results of this Danish pesticide control. In general, the program covers appr. 2500 samples pr. Year and uses a health-risk-based approach, with some samples chosen based on suspicion and others randomly selected. The products chosen for sampling is also based on historical data on pesticide presence and exceedance of Maximum Residue Limits (MRLs), market trends, and consumption data from DTU on the Danish population.
The annual reports are on this website (only in Danish): https://www.food.dtu.dk/publikationer/kemikaliepaavirkninger/pesticider-i-kosten

Decision making on organic status or not based on information received from abroad, both within EU and outside EU is more complex and requires robust and systematic descriptions of the hypothesis and the actual investigations carried out. Ideally the CA/CB delivers the final conclusion of the organic status. However, situations occur where insufficient documentation on official investigations are submitted that does not support the conclusions made by the CA/CB. This emphasises the need for good quality investigation work and documentation.

When the final decision in Denmark has to be taken based on investigations outside Denmark, it is a "holistic decision" where all relevant factors are taken into account.

In a nutshell, the conclusions from the CA/CB of the investigated products and operators are decisive for the organic status. Lack of sufficient investigations or obvious bad research may make this invalid for a national decision and make the suspicion upheld. In principle, a conclusion on "still organic" could be changed if an obvious hypothesis in the investigation of the source and cause remains unanswered. In Denmark the pesticide database of the Danish Technical University may be used for reference in such cases.

6.3.3.6 Proportionality in case of withdrawal from the market

When the final conclusion from the investigation is leading to the product not being organic, the official decision is also on the withdrawal from the market and to what extent it must be done along the distribution chain, both nationally and internationally, where the latter is handled via OFIS information to or from other countries. The decision of withdrawal is to be taken by competent authorities at national level and must be proportionate according to basic national legal principles for public administration.

There is no fixed rule or percentages in the regulation or national guidelines for the extent of the withdrawal. No case is identical, and it is always a case-specific evaluation of proportionality.

For single products, for example raisins deemed non-organic, the decision is simple and straightforward: it will be withdrawn from the market including the retail level.

Cases where one single ingredient of a composite product is affected, for example raisins in muesli which are only a minor part of the organic product, less than 5%, will most likely only be blocked at wholesale level. To evaluate the proportionality an indication could be that the EU-regulation[170] has the possibility of using up to 5% non-organic ingredients, if approved, and still use the EU-organic logo.

A balanced decision involves the number of traders/retailers involved, the amounts of affected goods, the possibility of repacking or relabelling the prepacked products, the risk of food waste, time and cost for organic operators and other possible criteria. The EU-Commission tends not to approve such 5% rules of thumbs and has in a letter explained their interpretation[171], but also acknowledged that the final decision is left to the national competent authority.

In cases where organic consignments have been blocked for a longer time along the chain due to lengthy investigations, there is frequently no need for a decision by the authorities.

Operators themselves downgrade the product to conventional immediately due to protection of their company brand or due to "business contracts" with retail chains; implying immediate downgrading

[170] (EU) Organic Regulation 2018/848 article 30 (5) a) (ii):" at least 95 % of the agricultural ingredients of the product by weight are organic; and."

[171] Letter from EU-Commission ARES (2023) 5532609 dated 10/08/2023 Case #1 on acceptable level similar to use of 5 % non-organic ingredients.

even though the suspicion is not fully investigated. Another straightforward reason is the shelf life of the goods might be exceeded.

6.3.3.7 Fraud suspicion

As an integrated part of the competent authority in Denmark a special task force focusing on food fraud can be assigned to inspections in food companies.

The Food Inspection Task Force unit does not have a specific focus on organic food companies.

Although normal organic inspection is done by one inspector, the Task Force works in teams of 2-10 inspectors on the inspection or investigation of suspicious operators. In Denmark, over the years, only very few cases have given reason to a specific fraud suspicion on organic operators. If suspicion of fraud arises during regular inspections, *The Food Inspection Task Force* unit can be involved for further handling and substantiation of the suspicion of food fraud. Signs of fraud could be a systematic lack of documentation for organic status or a lack of traceability of organic products etc.

In very specific cases, the Task force also has the possibility to cooperate with the police and Tax Agency in joint actions. *The Task Force* has not so far been involved in organic pesticide residues investigations.

Fraud cases will also be reported in other horizontal EU-Systems i.e. RASFF[172] or Food Fraud Network and handled there, but this will not exclude reporting in OFIS as well, even though there is an element of double counting. Bigger fraud cases will normally be handed over to the Police for criminal investigations.

As organic inspection is integrated with other horizontal control tasks and also farmer subsidy schemes, information on suspicious situations related to organic production might be transferred internally within the CA and might in special cases lead to fraud suspicion.

[172] Rapid Alert System for Food and Feed (RASFF) – EU-Commission

6.3.4 Approaches from France

Olivier Catrou[173]

6.3.4.1 The control and certification system for organic production in France

In France, the competent authorities for the implementation of organic regulations are:

- Institut National de l'Origine et de la Qualité[174] (INAO),
- Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes[175] (DGCCRF)
- In addition, for the control of imports of organic products: Direction Générales des Douanes et des Droits Indirects[176] (DGDDI); Direction Générale de l'Alimentation[177] (DGAL).

A coordination protocol is in place to guarantee effective and efficient coordination and cooperation between the different competent French authorities.

6.3.4.2 National Framework for Organic Agriculture

General organisation of controls

- Controls of operators before placing on the market are carried out by control bodies approved by INAO and accredited by the French accreditation body, COFRAC according to the NF EN ISO/CEI 17065 standard.
- Regarding controls of products placed on the market**,** DGCCRF verifies the accuracy of information on marketed products of any origin (French, EU and third countries) regarding the labelling referring to organic production. In addition, DGCCRF is carrying out a plan to control pesticide residues on organic products; in this context, products are targeted based on non-compliance detected in previous years and information regarding risks of fraud identified for a combination of country/product.
- Controls of imported products are the responsibility of DGDDI and DGAL.

The role of INAO

INAO is a public administrative establishment of the State responsible for the implementation of legislative and regulatory provisions relating to the 5 quality schemes: AOP[178], IGP[179], STG[180], Label rouge and Organic Agriculture.

Regarding agriculture, INAO is in charge of:

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This article exclusively reflects the personal opinions of all authors.

[174] National Institute of Origin and Quality

[175] Directorate General for Competition, Consumption and Fraud Repression

[176] General Directorate of Customs and Indirect Duties

[177] General Directorate of Food

[178] Appellations d'Origine Protégées – Protected Designations of Orgine

[179] Indications Géographiques Protégées – Protected Geographical Indications

[180] Spécialités Traditionnelles Garanties – Traditional Specialities Guaranteed

- implementing tools to ensure uniform application of the law
- supervising the control bodies, according to Article 40(1) of Regulation (EU) 2018/848.

Since 2022, controls have been carried out on the basis of common control provisions (DCC)) applicable by all CBs. Shortcomings noted by the CBs during inspections are dealt with in accordance with the provisions of the national catalogue of measures to be applied in the event of non-compliances, established by the INAO and supplemented by specific provisions for each CB for the sectors covered by French specifications for organic farming.

The provisions applicable in France provide for at least one physical inspection per year per operator. In addition, the CBs implement a risk analysis to guide the selection of operators who should be subject to additional control visits and unannounced inspections and from whom samples must be taken (except for cases of suspicion or fraud).

The role of DGCCRF

The DGCCRF carries out an annual control plan for the organic farming sector which pursues two objectives:

- on the one hand, detect possible dysfunctions in the organic sector among operators (producers, processors, importers, distributors);
- on the other hand, prevent false claims referring to organic and nonconformities regarding the labelling.

These controls are decided at national level, based on a risk analysis taking into account the infractions detected on products and operators in the previous years. In addition, certain sectors could be targeted more specifically (e.g.: importers putting organic products on the market, particularly via websites, without being certified).

Retailers are the most targeted operators (around ¾ of the operators), being considered as a high-risk category when they are exempted from certification[181]; catering falls within the scope of controls.

Specificities of regions are taken into account; all regions and a large number of departments being covered. Between 1000 and 2000 operators are subject to inspection; the percentage of non-conformities with follow-up is approximately 20%, mainly regarding the certification obligation (conditions for exemption not met), and labelling issues.

The detection of non-authorised substances (pesticides, non-compliant additives) occurs in a much lower proportion.

6.3.4.3 Implementation of investigations by control bodies in France

CBs should carry out controls according to the common control provisions, which includes an annex detailing the analytical strategy. Each CB must apply the analytical strategy aimed, in addition to the physical and documentary checks carried out on site, to determine if the operators have used non-authorised products or substances, have implemented production techniques not compliant with the organic regulations, and to detect any possibility of contamination with non-authorised substances or commingling with conventional products.

The analytical strategy brings together several components:

1) the frequency of samples,
2) the nature of the substances to be considered,
3) the period of sampling
4) the sampling methods, collection and storage of samples,

[181] According to Article 35(8) of (EU) Regulation 218/848

5) the analytical methods to be implemented by the laboratories,
6) evaluation of analysis results

The annex details the provisions to be implemented by any control body for each of the points listed above.

The interpretation of analysis results in the event of detection of non-authorised substances is based on the following principles:

An investigation must be carried out by the CB with the participation of the operator:

- Each time an analysis result reveals the presence of non-authorised products or substances.
- For products/substances for which a concentration limit or conditions of use have been established in Regulation (EU) 2018/848;

This investigation can take several forms

- The evaluation of the result of the analysis by the CB, and/or
- A documented investigation with the operator or the CB of the supplier, and/or
- A field inspection carried out by the CB.

The purpose of the investigation is to determine the source and cause of the contamination and to decide on the certification status of the product (marketed as organic or downgraded as conventional), of the contaminated area (to impose a conversion period) and of the operator (suspension or withdrawal of the certification), if applicable.

The CB must report the cases where the source and the cause of the contamination have not been determined and specify the reason.

In the event of the presence of non-authorised products or substances, the CB immediately informs the operator concerned, in writing, sends him the analysis report and carries out an investigation.

In the event of a substantial/proven doubt, the CB asks the operator to block the batches concerned, pending a decision relating to certification for a period determined by the CB. The CB may request that the blocking be extended to other batches/products as soon as evidence/factual elements such as the history of the operator's file, the nature of the products, the type of substances identified, the information provided by the inspector in the report. The blocking period may be extended by the CB if the operator does not provide the required elements for the investigation.

The operator may, within 15 days of notification, request that the second sample be analysed by a laboratory accredited by INAO and referenced by its OC, and which may be different from the laboratory which proceeded to the first analysis.

Following the result of the investigation, the CB must take a decision.

Case of pesticides

The CB evaluates all results of the analysis reports received. In any case, if the analysis report reveals the presence of a single substance not authorised in organic agriculture, at a concentration greater than or equal to 0.02 mg/kg without taking into account the uncertainty of the measurement (= value of reference) a substantiated/proven doubt exists, and the CB must ask the operator to block the batches concerned. This reference value is reduced to the limit of quantification (without taking into account the uncertainty of the measurement), in the following cases:

- Sampling in the event of suspicion of non-compliant practice or cross-contamination,
- Collection from a risky operator,

- Collection following an alert received,
- Substance found is a herbicide (localised), or an insecticide on a matrix taken post-harvest
- Presence of several substances
- Substance degrades very quickly (case of phosphine)
- Complex matrix (complex or multi-ingredient processed products).

The CB must provide a justification if it decides not to block batches despite the presence of a non-authorised substance above the reference value. If the source or cause cannot be identified, but there is a suspicion of a non-compliance, the CB must carry out a more in-depth examination and in particular increase the intensity of the inspection, in particular in the presence of the following elements:

- Concentration levels comparable to those detected in conventional products
- Repeated non-compliance identified by the same operator
- Recommended improvement measures not implemented
- Multiple residues
- Other indicators of misconduct.

CHAPTER 6.4: INFORMATION EXCHANGES, INCLUDING CROSS-BORDER COMMUNICATION (OFIS)

Roberto Maresca[182]*, Nicolas Verlet*[183]

6.4.1 Introduction

Part of the content of this chapter is sourced from the EOCC[184] Task Force OFIS. However, the information of this chapter reflects only the considerations of the authors.

The purpose of this chapter is to analyse the process of the exchange of information regarding the investigation put in place by involved control authorities/control bodies (CA/CB) and competent authorities, including the EU Commission, in case of substantiated suspicion of non-compliance of organic products. This kind of exchange of information occurs electronically via the Organic Farming Information System (OFIS).

6.4.2 The history and purpose of the OFIS system

The history of this system dates back to 2008; at that time, OFIS (Organic Farming Information System) was intended to be used as a platform to let Member States and Control Bodies provide specific information. The Article 94.1 of Regulation (EC) 889/08 introduced a "*computer system enabling electronic exchanges of documents and information made available by the Commission (DG Agriculture and Rural Development) for information other than statistical information*". This system was designed to allow the exchange or publication of various types of information involving Member States and European and non-European control bodies, all under the aegis and supervision of the European Commission. The Commission used the same portal to communicate some of the data with common interest, making them public and therefore available to all citizens.

The same reference to "*a computer system that enables the electronic exchange of documents and information*" was included in the new Regulation (EU) 2018/848, applying, among others, to the information and documents regarding the authorisation of non-organic ingredients for processed organic food; the exemptions granted following catastrophic circumstances etc. The OFIS portal is also used by the CA/CB to carry out controls in third countries, to submit their annual report, as well as for new CA/CB to send their request for recognition to certify operators in third countries in compliance with the Regulation (EU) 2018/848.

OFIS plays an important role in the exchange of information related to the presence of non-authorised substances and to the outcome of the official investigations as referred to in Article 29 of the Regulation (EU) 2018/848. As a general rule, competent authorities shall immediately share information with other competent authorities as well as with the Commission in OFIS, any suspicion of non-compliance that affects the integrity of organic products[185]. In addition, the competent authorities shall document the results of the official investigations and the measures taken to avoid the presence

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[184] European Organic Certifiers Council

[185] Article 43(1) of Regulation (EU) 2018/848

of non-authorised substances; Member States shall make such information available to other Member States and to the Commission via OFIS[186].

The recent legislation has defined new requirements for managing the exchange of information in two secondary regulations that specify in detail the methods of exchanging information in case of the loss of organic integrity of products; the Regulation (EU) 2021/279, in its Article 9, defines the way to exchange information with the Commission and other Member States while the Regulation (EU) 2021/1698 (Article 21(2)) clarifies the exchange of information between control authority and control bodies in third countries on one side and Commission and Member States in EU on the other side. The provisions of these two regulations are further detailed in paragraph 6.4.3. below.

Member States are also asked to provide to the Commission on a yearly basis the information on detected non-compliances and the enforcement of measures according to their national catalogue of measures. This annual report from Member States is to be submitted on the basis of the information required by the standard model form available in the Annex of the Regulation (EU) 2021/1935 and transferred directly to the OFIS system by the Member States.

6.4.3 The OFIS notification process

In this paragraph the process and steps of the exchange of information of the OFIS Notifications will be described. First of all, it is appropriate to divide the types of notifications into two categories. Those involving an organic product whose integrity was found to be compromised in Member State "A" and coming from another Member State "B" are called OFIS-INEU (OFIS Irregularity Notifications European Union). The exchange of information relating to OFIS-INEU notifications involves only the competent authorities of the Member States and the Commission.

OFIS Notifications involving products coming from third countries are identified as OFIS-INTC (OFIS Irregularity Notifications Third Countries) and provide for the exchange of information between the competent authorities of the Member States, the Commission and the CA/CB in third countries.

6.4.3.1 Flow of information (process) in case of notification involving products from EU origin (INEU)

Article 9 of Regulation (EU) 2021/279

When a Member State “A” detects a suspected or established non-compliance which affects the integrity of organic or in-conversion products coming from another Member State “B”, the notifying Member State “A” shall notify the Commission and the relevant notified Member State “B”. The notification is provided via OFIS by entering the information on the appropriate online form developed on the basis of Annex II part 1 of the Regulation (EU) 2021/279. Although OFIS notifications are always notified by the competent authorities of the Member States, in the vast majority of cases the information relating to suspected or established non-compliances is provided by the CA/CB in the EU by Member States.

This transfer of information requires an effort on the part of the competent authority which will have to evaluate the completeness and punctuality of the information provided before proceeding with sending the notification. The notified Member State has 30 days starting from the notification date to inform about the actions and measures taken, including the results of the official investigation, specifying if it is the final result (and as such which actions were taken to prevent the repetition of the case) or an intermediate result but already providing details of the investigation conducted so far and the related measures. Once the OFIS notification is received, the notified Member State needs to

[186] Id. Article 29(6); Article 1 of Regulation (EU) 2023/1195

involve the CA/CB (there may be several) that certified the product before it was sold to the notifying Member State. An in-depth but also rapid exchange of information between the various entities involved is therefore necessary in order to reach a timely closure of the case within the timescales established by the legislation.

Once all the information of the investigation carried out is collected, the notified Member State provides all the information by filling in the on-line form available on OFIS, designed according to the template in Annex II part 2 of Regulation (EU) 2021/279. The notifying Member State can finally evaluate the content of the reply and decide whether to accept the outcomes or if any other information or clarification is needed. This aspect highlights the importance of providing an effective reply to the OFIS notification itself, provided that the information coming from the notifying part is complete and timely enough to allow an effective investigation by the notified part.

6.4.3.2 Flow of information (process) in case of Notification involving products from non-EU origin (INTC)

Article 9 of Regulation (EU) 2021/279 + Article 21 of Regulation (EU) 2021/1698

When an EU Member State detects a suspected or established non-compliance which affects the integrity of organic or in-conversion products imported from a third country, the notifying Member State shall notify the Commission by entering the information on the appropriate online form in the OFIS system, developed on the basis of Annex II part 1 of the Regulation (EU) 2021/279. Also in this case, as explained for the OFIS-INEU the issue might be raised by a CA/CB designated by an EU Member State. It is essential that all relevant information is included so that an effective and rapid official investigation can be conducted.

In general, when the product was exported from an EU recognised, equivalent third country, the authority of this third country is notified on OFIS and will be in charge of the official investigation.

If the certification is delegated to EU-recognised CA/CB operating in third countries, they will be notified and will provide the outcomes of the investigation. It might be that the product involved in the notification was covered by a COI issued by a specific CA/CB, and that in the meantime the exporter changed the CA/CB. In this context, it is important to mention that contracts with operators in third countries should not be terminated immediately, even during official investigations (see Chapter 5). It is important that clear deadlines for contract terminations are complied with. In exceptional cases, the CA/CB which has issued the COI should be notified. It is the responsibility of this CA/CB to collect all the information of the investigation carried out on the product involved – if needed asking for the cooperation of the actual CA/CB of the exporter at the time of the OFIS notification – and to reply to the notification.

Once receiving a notification from a member state, the Commission in turn notifies the CA/CB in the third country, transferring the information uploaded. The notified party then needs to start the official investigation and provide within 30 days the actions and measures taken, including the results of the official investigation, specifying if it is the final result – and as such which actions were taken to prevent the repetition of the case - or an intermediate result but already providing details of the investigation conducted so far and the related measures and information if the notified control body does not certify the whole supply chain. As within the EU, it often happens that in third countries the notified CA/CB does not certify the whole supply chain of that specific product, but rather the exporter of the involved product. In these cases, it is therefore necessary first of all for the exporter's CA/CB to verify whether there may have been non-conformities at the level of its controlled operator and then, if no such non-conformities emerge, reconstruct the entire supply chain and then contact the CA/CB of the different operators involved asking to carry out their relevant part of investigation and provide the outcomes and the actions and measures taken, in order to reply to the notification.

The exchange of information can certainly represent a bottleneck for the continuation of the investigations. It should also be underlined that the notified CA/CB, on which the burden of the final response falls, does not have any particular tools to "force" the other Control Bodies to collaborate quickly except to inform the EU-Commission about lack of responses. Once the notified CA/CB has provided all the information by filling in the on-line form available on OFIS, the notifying member state can finally evaluate the content of the reply and decide whether to accept the outcomes or if any other information or clarification is needed. It is therefore essential that the outcomes of the official investigations are factually reported in a complete way.

6.4.4 Challenges

As explained in Chapter 5, the exchange of information involves several actors whose contribution is fundamental to making the entire process quick and effective. In this paragraph we will delve into the major challenges that the parties involved in this process have to face.

6.4.4.1 Challenges for notifying EU member states

Before issuing an OFIS irregularity notification, it is important to provide detailed information regarding the irregularity raised, including dates, times, and locations. Additionally, all relevant evidence or supporting documentation to help the recipient to understand the nature and severity of the irregularity shall be included. It is important to clearly outline the consequences or potential impact of the irregularity. Effective communication and transparency are key in issuing such notifications to ensure prompt resolution and compliance.

The notifying party has the task of verifying that an in-depth verification has been conducted to exclude that any contamination indicating a nonconformity may have occurred at a level of the supply chain placed under the authority of the notifying member state and of stating the results of such investigations in the OFIS notification form.

Among others, the traceability documents must be attached to an OFIS notification to allow the unique identification of the product involved, in order to trace back correctly and unequivocally the organic operators who managed such product (and obviously also the CA/CB of these operators).

6.4.4.2 Challenges for the notified part

To provide the reply to the notification and present the results of the investigations carried out, the notified party must collect the evidence and prepare a clear and complete response within the appropriate time frame (30 days). In the case of OFIS INEU it is the notified Member State that is responsible for the reply and therefore it is relatively easier to find the information from the delegated control authorities/bodies of the operators involved. The issue might become complicated when, in the case of OFIS INTC, the reply should require an exchange of information between different CA/CB.

In any case, here below are the major challenges regarding specific aspects of the reply to the OFIS Notification that can still be improved.

The notified party should describe the investigation methods implemented to determine the source and cause of the contamination as it is not always possible to identify how the investigation was conducted.

It may happen that the decisions taken following the investigations conducted are missing from the OFIS responses, and it is therefore unclear whether the product has been destructed, has lost or maintained its organic status, whether it is blocked and so on.

There should be a description regarding how the investigation measures were implemented, if operators only provided documents, if they were subjected to specific controls, and if any decision was taken about the certification status of the operators.

CA/CB should take appropriate measures to avoid recurrences of the case that originated the notification. The description of those measures should be correctly indicated in the OFIS Notification reply form. Vice versa, the reply should provide the reasons why it was not considered appropriate to take any measures.

During the entire certification process, which also includes investigation of suspect cases, evidence is fundamental to support the decisions taken, in order to be comprehensive and comprehensible, the notifications as well as the replies shall be supported only by the documents useful for understanding the case, avoiding uploading those that do not complete or add anything to what already was explained.

6.4.4.3 The role of the EU Commission

As already mentioned, having access to all the information related to the OFIS notification cases, the EU Commission is in the position to evaluate and analyse the management of them. In particular, these data provide a complete overall vision of any critical issues relating not only to the activities of Control Bodies/Authorities, Competent Authorities and operators, but can also reveal problems relating to the most recurring non-permitted substances, as well as indicating which products/ product categories to pay attention to. OFIS is therefore a cornerstone for the effectiveness of the EU organic control system.

Information and data related to OFIS Notification cases are often shared by the Commission with Member States during the meetings of the Committee on Organic Agriculture. This flow of information is key for reinforcing control measures to deal with identified risks, non-compliances, and possible fraudulent practices and to anticipate and prevent critical situations by highlighting recurrent cases, and abnormal contamination deserving rapid and specific attention. It could be envisaged that part of the information shared with competent authorities could also be disclosed in a consolidated structure and in an anonymous form to the CA/CB within and outside the EU, which would have the opportunity to use the same to make it more effective the control activity.

As far as known, the OFIS System does not allow the “cancellation” of those notifications which are later evaluated as unsubstantiated or redundant (as they are linked to other notifications for the same product lot) which in any case are included in the history and statistics of the system. There might be space for improvement to somehow put them out of the overall evaluation from the EU Commission, in order to have data as reliable as possible.

Finally, all parties involved should consider the OFIS notifications as a priority task. Speed is the main issue regarding the efficiency of the system. Closing an OFIS case should be a matter of months if not weeks, rather than years!

CHAPTER 7: DECISION MAKING

Nicolas Verlet[187]*, Jochen Neuendorff*[188]*, Bernhard Speiser*[189]

7.1 Introduction

The previous chapters have discussed the decision-making processes that stakeholders must undertake in their respective activities. For many, it involves implementing a specific decision-making process as part of their internal processes (such as precautionary measures for the operator, investigation methods for the control body, etc.).

The following decisions need to be made during an official investigation according to Article 29 of the Regulation (EU) 2018/848 (see Figure 7.1.):

- Deciding whether to launch an official investigation and instructing the operator provisionally not to place the products concerned as organic on the market
- Deciding on the source and the cause of a non-authorised product or substance
- Deciding on the product status (organic or conventional) at the end of the official investigation
- Deciding on the operator's certification status at the end of the official investigation (including the option of certificate suspension or withdrawal)
- Deciding on the follow-up to the investigation, including documentation (preferably through a database[190]) and revision of the risk classification of the operator.

All decisions taken shall be supported by robust evidence collected during the official investigation, according to the systematic approach detailed in Chapter 5. As reflected in recital 69 of Regulation (EU) 2018/848[191], the investigation should include any appropriate methods and techniques for official controls, as well as being proportionate to the suspected non-compliance.

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[190] Check out the Knowledge Base: Pesticide Residues on Organic Products for an example of a joint approach. https://www.resi.bio

[191] *"In order to ensure a harmonised approach across the Union as regards the measures to be taken in the case of suspicion of non-compliance, especially where such suspicion arises due to the presence of non-authorised products and substances in organic or in-conversion products, and to avoid uncertainties for operators, competent authorities, or, where appropriate, control authorities or control bodies, should carry out an official investigation in accordance with Regulation (EU) 2017/625 in order to verify compliance with the requirements for organic production. In the specific case of suspicion of non-compliance due to the presence of non-authorised products or substances, the investigation should determine the source and the cause of the presence of such products or substances, in order to ensure that operators comply with the requirements for organic production and, in particular, have not used products or substances that are not authorised for use in organic production, and to ensure that those operators have taken proportionate and appropriate precautionary measures to avoid the contamination of organic production with such products and substances. 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. They could include any method and technique for official controls which is considered appropriate to efficiently eliminate or confirm, without any unnecessary delay, any suspicion of non-compliance with this Regulation, 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."*

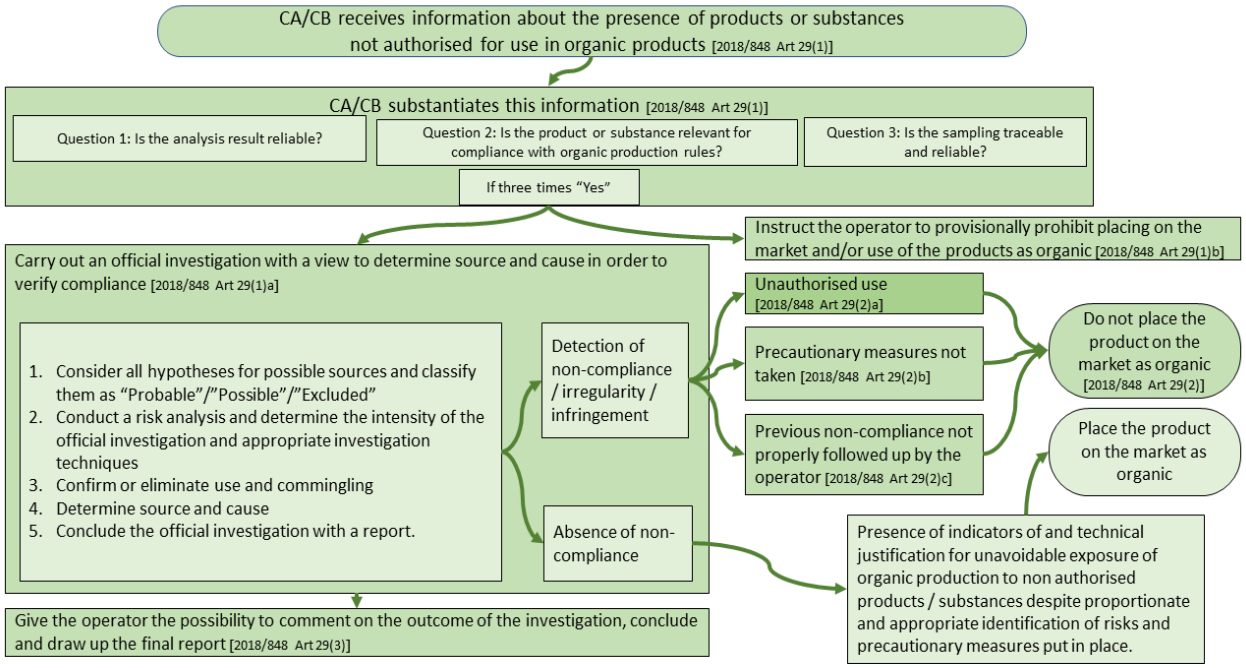

Figure 7.1: Flowchart of an official investigation as referred to in chapter 5.

7.2 Decision to start an official investigation and to provisionally block a product/batch

If there is "substantiated information" about the presence of non-authorised products or substances, an official investigation must be initiated. The criteria for the "substantiation" of information are mentioned and explained in detail in Chapter 5.2.

It is the legal obligation of the control authority (CA) or control body (CB) to "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." This decision must follow the provisions of Article 29 (1) (b) of Regulation (EU) 2018/848, in compliance with the administrative law of the EU Member State concerned. In this context, it should be noted that the controls under the EU Organic Regulation are official controls under Regulation (EU) 2017/625 and that the organic control bodies act only as "delegated bodies" of these competent authorities according to Chapter III of this Regulation. The decision must take into account that other batches of the same product are still placed on the market by several operators, also ones not directly involved in the specific case.

Whether or not to widen the provisional blocking to other operators in the EU is a case-to-case decision that should take into account the argument of consumer protection and the principle of proportionality, as well as the suspected source and cause for the residue.

7.3 Decision to conclude on the source and cause of the presence of non-authorised substances

When the official investigation has been conducted, using the techniques and methods identified in the forensic profiling of the specific case (see Chapter 5.5 and Chapter 4) with the clear aim to identify or to eliminate possible nonconformities, in particular the use of non-authorised substances or commingling, a decision shall be taken on the source and cause of the presence of non-authorised products or substances (see Chapter 3).

This decision shall be justified by a logical sequence of technical arguments based on factual evidence identified during the official investigation and on actual state-of-the-art scientific knowledge.

A situation rarely arises where no source or cause can be identified. This typically happens when operators involved are no longer a part of the organic control system, making it impossible to conduct an official investigation. In cases where fraud is suspected, the CB involved should notify the relevant authorities in such cases.

The decision to conclude on the source and the cause – an example

Four active ingredients of prohibited plant protection products (PPP) above the limit of quantification have been identified in a fresh vegetable originating in a Third Country. Mass balances and traceability checks at the different operators involved in import and trading activities in the EU do not reveal nonconformities.

During the unannounced visit to the producer in the corresponding Third Country, the CB detects two empty bins of PPP, one with an active ingredient corresponding to one identified in the fresh vegetable. It is the PPP with the longest LD_{50}. The CB inspector decides to sample the water in the pesticide sprayer and later the laboratory results of this sample also confirm the presence of the same active PPP ingredient.

The CB decision on the source and the cause is the use of non-authorised substances in the field,

7.4 Decision to be taken on the product status and the operator certification status

The decision on product status (organic or non-organic) and operator certification are closely linked and should be decided together. Article 29 (2) of Regulation (EU) 2018/848 as well as Article 2 (3) of Regulation (EU) 2021/279 detail what shall be the output of an official investigation. CA/CB must decide on the organic integrity of the batch(es) concerned, whether the operator has used products or substances not authorised for use in organic production, has not taken the precautionary measures agreed previously with the CA/CB responsible for this operator or has not taken measures in response to relevant previous requests from the competent authorities, CA or CB.

7.4.1 Decision on how the product concerned can be labeled

If one or more non-conformities affecting the organic integrity[192] of the batch(es) concerned have been identified at the end of the official investigation, and/or the conditions of Article 29 (2) have not been respected and/or other relevant major or critical non-conformities were identified with a clear relation to the batch(es), the references to organic production must be removed. Useful references to support such decisions can be found in the national catalogues of measures according to Article 41 (4) of Regulation (EU) 2018/848 for the EU member states or in Annex IV of Regulation (EU) 2021/1698 for CB operating in Third Countries. Of course, these decisions must also be taken in compliance with the administrative law of the EU Member State concerned if they are taken in an EU member state.

[192] Article 3 (74) of Reg. (EU) 2018/848: 'integrity of organic or in-conversion products' means the fact that the product does not exhibit non-compliance which:

a) in any stage of production, preparation and distribution affects the organic or in-conversion characteristics of the product; or

(b) is repetitive or intentional;

7.4.2 Decision to be taken on the certification status of the operator

It is even more important to decide on the certification status of the operator(s) involved in a case as a follow-up to the investigation than to decide on the certification status of the batch(es) concerned. This is a crucial step to prevent recurring cases.

If the official investigation reveals non-compliances, these need to be classified as minor, major or critical. Based on this classification, the decision is to be taken whether the certificate of the operator will be maintained, suspended, or withdrawn. Of course, the justification for this decision shall also be documented. Again, the national catalogues of measures according to Article 41 (4) of Regulation (EU) 2018/848 for the EU member states and Annex IV of Regulation (EU) 2021/1698 for CA/CB operating in Third Countries deliver clear references.

The competent authorities may delegate to control bodies the official control tasks[193] which are necessary to conduct an official investigation and to take the decisions above mentioned. The scope of the investigation carried out by a control body is limited to the assessment of the compliance with the EU organic regulation, and, in case of suspicion of fraud, the control body may not be able to implement the most appropriate methods to confirm or eliminate this suspicion. However, if there is any suspicion of fraud, it is required to report the case to the appropriate authority, including the EU Commission if the case has an international aspect. The CB will then assist these official institutions during their investigation if required.

7.5 Decision on the follow-up of the investigation (documentation, risk assessment of the operator, and future inspections)

The follow-up of an official investigation is a key element, often neglected. It shall be used to reinforce the control system and to avoid the presence of non-authorised products and substances in organic products.

To start with, it is essential to record the findings of the official investigations. Article 2 (3) of Regulation (EU) 2021/279 provides the legal basis for this. The purpose of this documentation is to identify the sources of the problem more accurately in the future and to enable prompt action in case of similar incidents. It is recommended to maintain this documentation in an electronic database for easy access and management[4].

As a next step, the CB ought to review the risk classification of the operator in accordance with Article 38(2) of Regulation (EU) 2018/848. This evaluation will help decide whether the present risk classification is suitable or needs to be adjusted for conducting risk-oriented inspections or sampling more frequently in the future.

It is important to take into account the findings of the official investigation when preparing for future inspection visits. In particular, considering the degree of uncertainty achieved in determining a source and a cause referred to in Chapter 5.6., the following inspection visit should include some specific checks (additional sampling, cross checks, focus on traceability….) which may mitigate in an efficient and effective manner, the (unavoidable but acceptable) remaining uncertainty on the conclusion of the official investigation provided that the possibility of use or commingling has been eliminated on the basis of robust evidence. These inspections must include an assessment of the adequacy of the precautionary measures in place as required by Article 28(1) of the concerned operator, as well as the implementation of procedures for assessing cases as outlined in Article 28 (2).

[193] Article 40(1) of Regulation (EU) 2018/848

POSTSCRIPT

Editorial Board

The Vade mecum on official investigation in organic products first of all addresses what we could call the "constituent elements" of an official investigation which shall be carried out in the event of the presence of a non-authorised products or substances in an organic product: the laboratory analysis which constitutes the starting point in most cases, the possible sources and causes of the contamination and the toolbox of investigation techniques available to determine these sources and causes. These elements have been put into context to propose a structured and systematic approach for official investigation, leading to the conclusions which must be taken as a result of the investigation. Finally, this systematic approach has been tested in reality through the practical experience of operators, control bodies and competent authorities.

We highlight the technical and operational nature of the Vade mecum. The professional experience and competence of the authors and contributors, as individual experts, contributes to meet this objective. It has been a collective work based on intensive and fruitful exchange between the authors, and the members of the steering committee, but also more broadly with many interlocutors from all parts of the organic sector. This collective and informal dynamic benefited from the AntiFraud Initiative (AFI)[194] experience, based on the AFI conference[195] on 24th and 25th January 2024 where the objective and content of the Vade mecum was presented and a fruitful exchange with the participants took place.

The content is primarily aimed at those directly involved in the conduct of official investigations. We have nevertheless sought to present the technical content in a clear and accessible manner to all people more widely involved in the organic sector.

The Vade mecum has no legal or regulatory character and its implementation in practice is not mandatory. The operational dimension can only be achieved if the stakeholders see added value for their individual situation, but also some benefit for the organic sector as a whole. If this is the case, by sharing a common ground, voluntarily implementing a similar approach and best practice, this initiative may lead to an enhanced harmonisation of investigation practices and decision-making even if we are aware that the Vade mecum is far from having covered all open issues and bottlenecks.

We thank Jan Deane for the English proofreading of this document.

We would like to thank the Federal German Ministry of Agriculture for its financial support through the German Federal Organic Farming Scheme.

[194] Initiated in 2007 by Bo van Elzakker, Beate Huber and Jochen Neuendorff.

[195] https://www.organic-integrity.org/meetings/afi-16-2024

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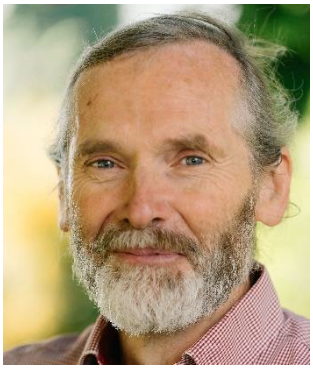
[196] Shrivastava A. and & V.B. Gupta, 2011: Methods for the determination of limit of detection and limit of quantitation of the analytical methods. Chron. Young Sci 2011;2:21-5

ANNEX I: ON THE AUTHORS

Lea Bauer* studied agricultural engineering and environmental management at Szent István University, Gödöllő, then oenology and wine management at Corvinus University in Budapest. She is working as a Regulation Consultant for IFOAM Organics Europe. Her expertise related to EU Organic Regulation and horizontal legislation in the field of agriculture and food has been gained during her involvement in the work of different IFOAM structures and her previous job at the control body, Biokontroll Hungária being in the position of Head of International Department. She gained experience in organic certification, national and international accreditations, quality management, and standard setting.

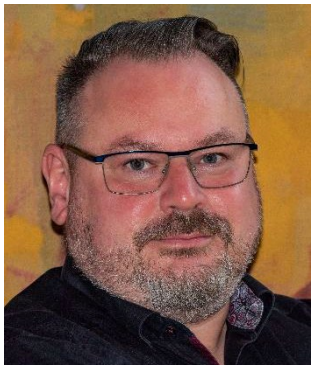


Dr. Alexander Beck* is an active farmer who studied food science and economics and holds a doctorate in food technology. Since 1990 he has been working on guidelines and legislation for organic food. His work also focuses on food quality and operational quality assurance. Over the last few decades, he has held multiple positions in national and international private and state bodies. He is the current managing director of AÖL e.V. and BLQ GmbH.

Samanta Rosi Bellière studied agricultural science and took a Master in organic and biodynamic agriculture.
She worked for 20 years for an Italian certification body as a competent inspector and responsible of the organic certification system, dealing especially with import from Third Countries and residue cases.
In 2023 she started to work as an assessor for IOAS, an international accreditation body, and she is also involved in different training activities, such as BTSF Organic.

Olivier Catrou has a background as Master of sciences in agronomy. He has been working in INAO (Institut National de l'Origine et de la Qualité for the past 10 years as Member of the Board - Manager of services in charge of organic agriculture and the economy Implementation of community regulations. He supported ministerial departments for the revision of the EU legislation and managed the National Committee for Organic Agriculture. He previously had different management posts in the French Ministry of Agriculture.

Rosi Fritz holds a degree in Nutritional Sciences (Ökotrophologie) and is currently responsible for quality management at Ulrich Walter GmbH in Germany. Since 1992 she has been working in various companies of the food industry in the fields of quality assurance, quality management, and food law. At Ulrich Walter GmbH Rosi Fritz has been responsible for the implementation of the organic regulation across all company activities, including the import of products from third countries. She ensures compliance with organic legal regulations. She has also been involved in the investigation of individual quality and compliance cases, as well as conducting risk analyses relating to various substances and organic production sectors.



Dr. Norbert Fuchsbauer is a state approved food chemist. After twelve years of experience gained in the field of pesticide residue and contaminants analysis at laboratories of Chemisches Institut Burkon, Nürnberg, and Aquaopta GmbH, Nürnberg, he started as Head of laboratory at HiPP-Werk Georg Hipp OHG, Pfaffenhofen. Later being a coordinator for raw materials and their analysis for five years at the Department of Quality Assurance with a key focus on the evaluation of analytical results of pesticide residues in 2020 he became European Affairs Manager at Food Safety HiPP GmbH & Co. Vertrieb KG and engaged in dealing with Multiple-Source-Substances.

Sergiy Galashevskyy* has a Master's degree in Agronomy and Business Administration. He has been working for Organic Standard Ltd, a Ukrainian certification body, for 17 years, first as an inspector, then as a head of certification department, and for the last 15 years - as a general manager. Sergiy has many years of experience in organic certification, as well as in evaluation and investigation of residue cases. He has been a Board member of the European Organic Certifiers Council (EOCC) since 2017 and a member of the official working group for implementation of organic legislation in Ukraine.

Janis Garancs, current COO of Alojas, is and has been for the last twenty years one of the key developers of the Latvian Food Industry. He has a master's in chemistry and 25 years' experience in the starch industry. He held senior positions in R&D, sales, production, general management, and he successfully initiated the production of sustainable legumes proteins in the Baltics. Janis's experience, capabilities and innovation acumen are contributing in putting Alojas on the map of the world production leaders of sustainable ingredients solutions.

Christine Gonzalez is an agroecologist, with several years of experience as a residue officer at an international control body. Since 2022 she handles organic supply chain topics at Martin Bauer GmbH & Co. KG and focus primarily on preventing fraud and evaluating residue findings in organic raw materials. She is conducting root cause analysis in the origins of diverse botanical supply chains and has gained experience in the work with large-scale cultivation structures, small holders but also wild collection in many different countries. In addition, she contributes to several associations like AöL. OPTA and BÖLW.

Mathis Hartung has a master's degree in molecular food technology and works as an inspector and reviewer for the German control body Resource Protection Ltd. (GfRS) since 2022.

Dr. Philipp Peter Könen is a German food chemist. He studied food chemistry at the University of Bonn. After graduating in 2017, he began his doctoral thesis in Professor Wüst's working group at the University of Bonn on sesquiterpene analysis in grapes and wines using multidimensional gas chromatography, which he successfully completed in 2021. In 2022 he achieved the title "state-certified food chemist" from the North Rhine-Westphalia Office of Nature, Environment and Consumer Protection (LANUV). Since October 2022 he has been working as a scientific assessor and chemical analyst at the Labor Dr. Lippert GmbH focusing on residue analysis in fresh fruits and vegetables.

Dr. Felix Lippert studied agricultural sciences in Stuttgart-Hohenheim before becoming head of post-harvest physiology at the Institute of Fruit and Vegetable Crops at the University of Bonn. He is still a member of the agricultural faculty there, where he supervised numerous theses. Over the last 20 years, he has developed a group of companies offering services in the fresh fruit and vegetable category, including Labor Dr. Lippert GmbH. This has a strong research focus and endeavours to combine agronomic knowledge with analytical expertise in contaminants and plant protection products.

Bernard Lignon is currently working for SYNABIO (the French organic processors' association) as a Regulatory and Quality Officer since July 1st, 2019. Member of the working group of IGOP (IFOAM's organic processors' group) and of the IFOAM Europe Board. Member of the CNAB (Comité National de l'Agriculture Biologique) in France.
Synabio is managing pesticides contamination issues (analysis database: SECURBIO (more than 15,000 results/redaction of the guide" building and managing its monitoring analytical pesticides plan in organic products"/RASFF analysis).

Robert Lind is Master of Business Administration and was employed at the Department of Marketing, Copenhagen Business School engaging in research on consumer behaviour in organic products. Since 2002, he is working in the Organic Unit in the Danish Veterinary and Food Administration under The Ministry of Food, Agriculture and Fisheries. He represents Denmark in the Committee on Organic Production under the EU-Commission (DG Agri). He has participated in the development of several national strategies for organic production as well as their implementation. He is one of the creators of the Danish Organic Cuisine Label in 2009 (Gold, silver, bronze for restaurants)

Julie Marchand is quality and certification manager in aromatic and medicinal herbs, spices and teas, 100% Organic, with 12 years of experience.
She has expertise in the management of product analyses, particularly pesticides residues on dry products, as well as organic product certification, and other certifications such as quality assurance, fair trade or corporate responsibility certifications. Deeply involved in investigations to raise doubts about fraud, with the search for understanding the mechanisms of environmental contamination.

Roberto Maresca studied Biological Sciences at the University Federico II in Naples and underwent professional training on agri-food quality. Since 2011, he has held various positions at CCPB srl, gaining extensive knowledge of organic certification. He has been Scheme Manager for International certification and private standards such as NOP, JAS, COR, Bio Brazil, Bio Korea, KRAV, Naturland, and Bio Suisse. Actually, he is the Scheme Manager for EU Regulation 2018/848 certification for Italian operators, also involved in inspection activities and European projects. He is a Board Member of EOCC and the coordinator of the EOCC Task Force OFIS.

Jochen Neuendorff* is agronomist and managing director of the control body Resource Protection Ltd. (GfRS) (www.sicher.bio) since 1989. In addition to audits and inspections according to credible sustainability standards with a main focus on organic production, he is involved in research and development projects. Since 1998, he has also been a Lead Assessor and Technical Expert for accreditation bodies and has evaluated certification bodies in Africa, Asia, Europe and Latin America. He coordinates the EOCC task force Official investigations. As transparency and credibility are particularly important to him, he was a founder of the Anti-Fraud Initiative in 2007.

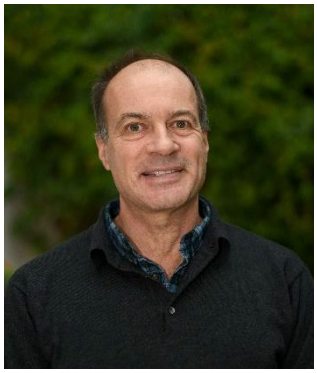
Tom Nizet* is a bio-engineer (biochemistry and industrial micro-biology) (1997, KULeuven, BE) and since 2019 the managing director of Authent GmbH who is supporting the development of quality management in organic certification worldwide. During his career, he worked for Certisys (2005 – 2019) and EOCC, implementing EU and USA Organic Regulations and handling pesticide residue cases in organic products. In 2023, he passed the national (BE) tests to operate as a consultant for pesticide use by conventional farmers (P3 licence). Tom is EOCC Task Force Residues coordinator.

Christian Novak is head of the responsible department at the Bavarian competent authority LfL. As an engineer in agriculture, he has a sound practical expertise in organic farming and his working experience includes both the German market and several third countries.

Engaged in the organic movement since the 80s, **Roberto Pinton*** is qualified as a technical-economic expert for food distribution, and supports companies, organisations and CBs on food regulations and quality schemes. He served for two terms as a board member in IFOAM Organics Europe, for 15 years as technical manager of an Italian association of organic processors and traders, on behalf of which for nine years he was a member of the committee for safeguarding impartiality in a CB. He is in his third term as a member of the agri-food committee in the national accreditation body appointed by the Italian government.

Carmen Pfannkuchen has a degree in food technology. She works in quality assurance and management at Midsona Deutschland GmbH. She has many years of experience in quality control of organic products. Midsona Deutschland GmbH works with both EU and imported products, which means that she is experienced in evaluating residues in EU and non-EU organic products.

Monika Simon has a background as an engineer and teacher in horticulture and agricultural economics. Currently she works at the Bavarian competent authority LfL especially in the range of processed organic products, trade, and import. She is involved in the observation and investigation of individual residue cases.



Dr. Bernhard Speiser* is a biologist employed at the Research Institute of Organic Agriculture FiBL in Frick, Switzerland. During his career at FiBL, he carried out research projects in organic plant protection, namely on control of slugs, grapevine downy mildew and potato late blight. In 1999, he joined the FiBL inputs evaluation team. Since 2009, he is also a member of the FiBL residues working group and has been involved in the investigation of individual residue cases, as well as risk analyses relating to individual substances or organic production sectors.

Nicolas Verlet* has a background as an agronomist and a PhD in economics. He ran a lavender and dairy farm for 10 years, then was involved in work on essential oils in the French Ministry of Agriculture. He joined the European Commission (DG AGRI) in 1995, in charge of the Neighbourhood Policy and the negotiation of bilateral agreements. He was posted to the EU Support Group for Ukraine for 4 years. From 2017, he led the work on the organic reform and drafting of the secondary legislation as Head of the organic unit. Now retired, he works as consultant in the organic sector.

Rodolphe Vidal has a technical and university background focused on plant improvement, plant physiology and ecology. His professional career led him to investigate the agri-food industry, which allowed him to better understand and grasp the complexity of food systems. Today, after twelve years at the French Organic Food and Farming institute, he coordinates the department that is interested in evaluating all dimensions of the qualities of organic products from agricultural raw materials up to the plate, including consumer expectations regarding organic products.

Laurence Vido is a graduate engineer in organic and analytical chemistry. She joined ECOCERT France in 2007 and was in charge of residue cases. She moved to ECOCERT SA as Global Analysis Manager in 2009, where she enriched her knowledge on contaminants, developed several tools to manage the interpretation of residue cases, the management of investigation and the reporting of residue cases on OFIS, while continuing to handle pesticides residues cases on organic products. She is also involved on different EOCC Task **Forces (OFIS**, Residues and Official investigations).

***Members of the Editorial Board**