FROM THE INVESTIGATION BIBLE.....

www.anti-fraud-initiative.org

..... TO THE 10 COMMANDMENTS

Thou shalt....

I. Keep in mind the key elements of the compromise.

II. Check if the information is substantiated.

III. Be prepared, think before acting!

IV. Establish hypotheses (probable, possible, excluded), the standard list for sources is a support.

V. Determine the intensity of the investigation: to go or not to go on-site?

VI. Apply the most effective investigation techniques.

VII. Conclude with an acceptable degree of uncertainty by focusing on use and specific follow-up of the case.

VIII. Address recurring contamination cases.

IX. Cooperate effectively, report properly, conclude and follow-up timely, with a special attention to OFIS.

X. Supervise operator's practices and expertise for eliminating suspicion at his level.

I. KEEP IN MIND THE KEY ELEMENTS OF THE COMPROMISE.

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

- An organic product may not necessarily be free of residues.
- When a control body or competent authority receives substantiated information about the presence of non-authorised products or substances indicating 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 an organic product if the operator has used non-authorised substances or products (“commingling”), or if he has not taken the necessary precautionary measures.

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

- Determine the source and cause is critical to put in place proportionate and appropriate precautionary measures to avoid risk of contamination.
- The assessment of all possible sources and causes can be a lengthy and expensive process.
- The regulation establishes the obligation to carry out an official investigation but gives several options for investigation techniques to comply with this obligation.
- Right balance to be found between determining the source and the cause and the associated costs, proportionality should be taken into account
- The corner stone of this balance: **a systematic approach for investigation**.

II. CHECK IF THE INFORMATION IS SUBSTANTIATED.

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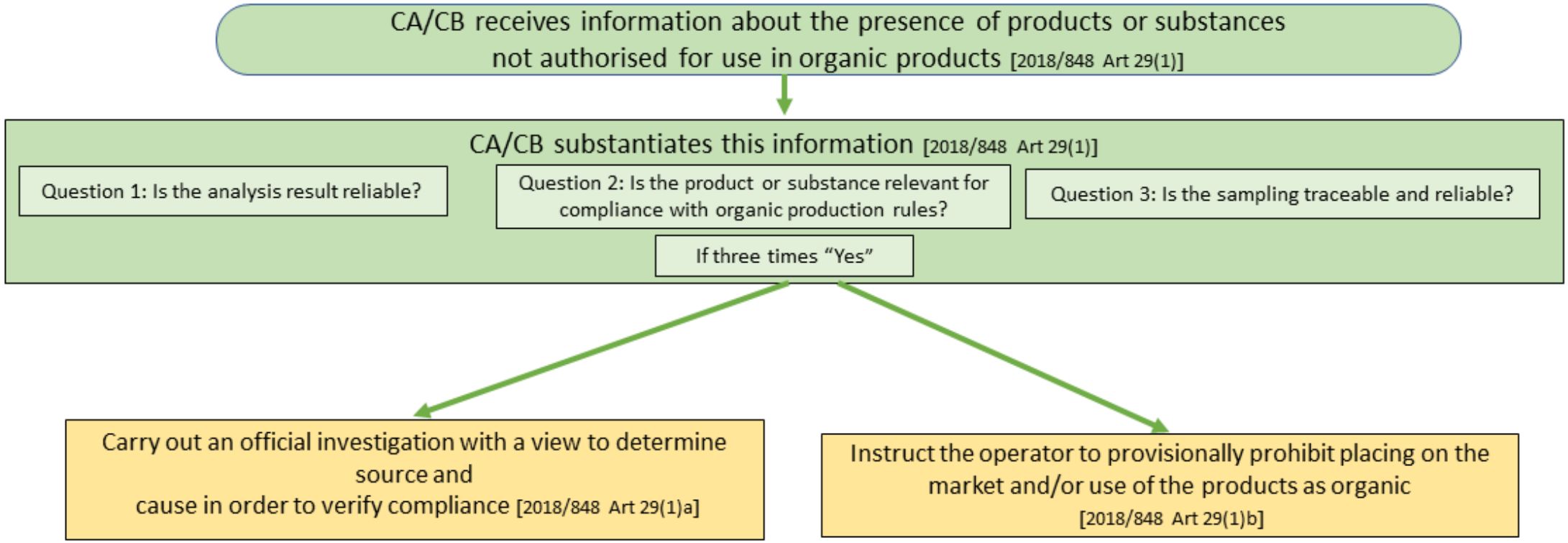
Vade Mecum
Chapter 2, § 5.2., 6.2.3



II. CHECK IF THE INFORMATION IS SUBSTANTIATED.	Vade Mecum Chapter 2, § 5.2., 6.2.3

- The task of substantiation is the primary responsibility of the CA/CB.
- Reliable sampling record and analysis report by accredited laboratories.
- Quantifiable residue (as a general rule, above the limit of quantification – LOQ), type of substance is more relevant than the concentration.
- Processing factors support the understanding of enrichment or dilution process, but cannot be used to invalidate lab result above LOQ.

III. BE PREPARED, THINK BEFORE ACTING!

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The documentary check: collecting and analysing of the information.

- Information about the sampling
- The product analysed (fresh, dried, processed….)
- Information about the sampling
- The active substance
- Evaluation of the operator file
- Records
- Traceability checks
- Regional context

The assessment of all possible sources and causes is lengthy and expensive. The connection of all the relevant information provided by the documentary check may considerably limit the number of hypotheses to be considered.

IV. ESTABLISH HYPOTHESES (PROBABLE, POSSIBLE, EXCLUDED), USING THE STANDARD LIST FOR SOURCES.

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A proposal for a standard approach on sources and causes

- Every residue has a "source"
- The term source describes the technical and physical aspects of a residue case.
- The investigation to determine the source addresses the question "***How did it happen***?"
- A standardised and exhaustive list of potential sources in a prerequisite for an harmonised systematic approach to official investigation.
- The systematic approach distinguishes five categories of sources
  - Use
  - Commingling
  - Cross-contamination
  - Environmental contamination
  - Natural presence

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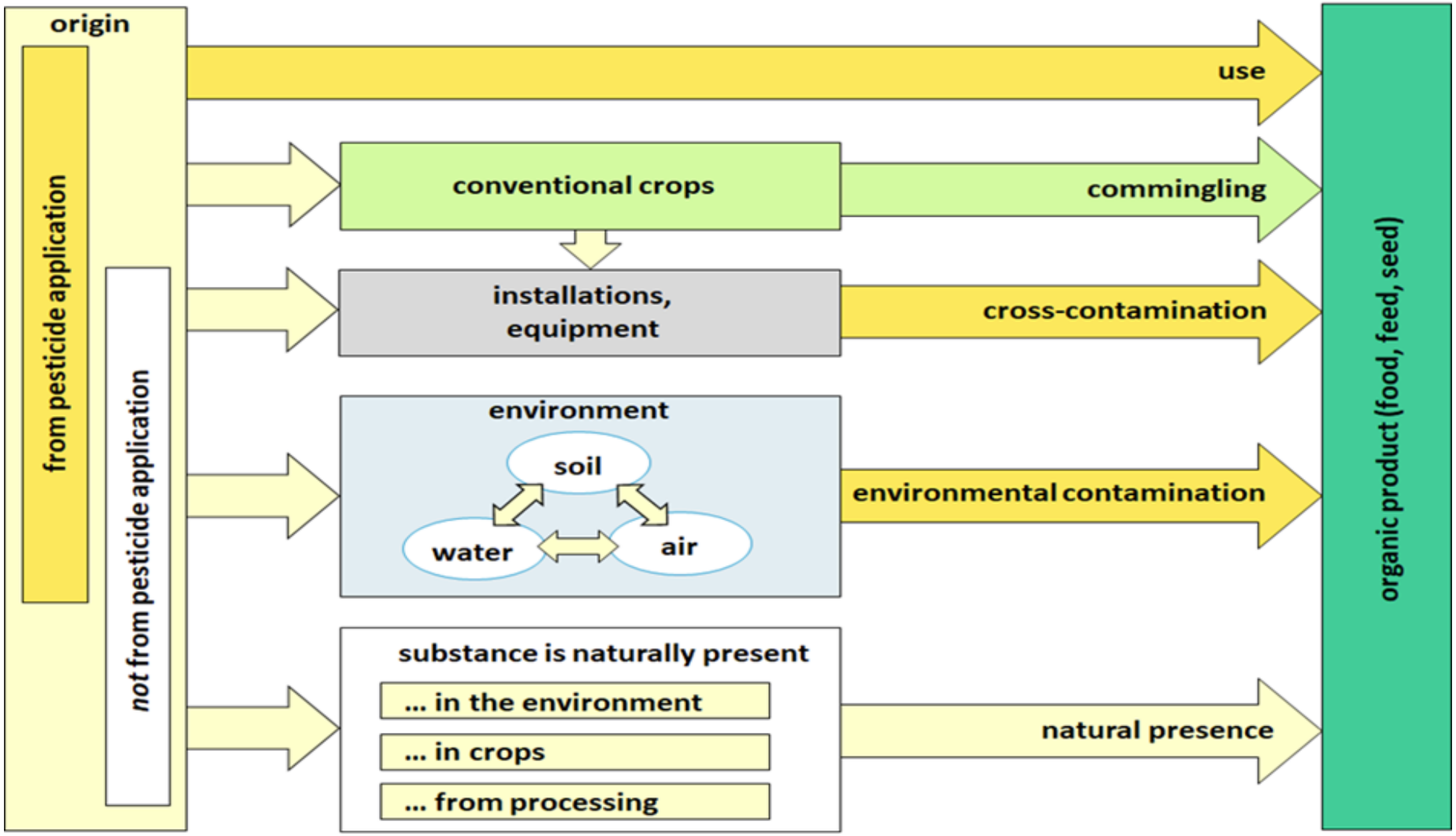

IV. ESTABLISH HYPOTHESES (PROBABLE, POSSIBLE, EXCLUDED), USING THE STANDARD LIST FOR SOURCES.		Vade Mecum: Chapter 3, § 5.4, 6.2.6
1	**Source no 1: Use of non-authorized substance**	
1.1	Non-authorised substance (pesticide, fertiliser, ...) applied in the field	
1.2	Use of treated seeds or seedlings	
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)	

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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	

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- Every residue has at least one "cause".
- The term causes describes the organisational and motivational aspects of a residue case (process established by the operator, behaviour of staff…).
- The investigation of causes addresses the question "***why did it happen?"*** and indirectly, how such residue cases can be avoided in the future.
- As a result of human behaviour, it is impossible to list all possible causes, only to classify them in "root causes", for example:
  - Intentional
  - Insufficient precautionary measures
  - Neglect of precautionary measures
  - Lack of knowledge
  - External factors (not under the operator's control)

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Ranking of hypotheses

The operational objective of the documentary check and all the factors analysed is to classify possible sources, using the standard list into three categories:

- Probable: concerns the most probable hypothesis regarding the source of contamination. If the probability can be established with sufficient certainty by the documentary check, the official investigation may be closed and conclude on the source. Otherwise, the investigation will implement the most relevant investigation techniques aimed at confirming this hypothesis.
- Possible: all possible sources should be identified, and ranked according to their degree of certainty. In any case, since the possibility of use exists, adequate investigation methods should have been used to eliminate this hypothesis with a high degree of certainty.
- Excluded: hypotheses non applicable to the type of activity or production system, or highly improbable hypotheses that can, a priori, be excluded from the scope of the investigation

V. DETERMINE THE INTENSITY OF THE INVESTIGATION: TO GO OR NOT TO GO ON-SITE?

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Vade Mecum: § 5.5

Risk Level

Product Criteria
- Reliable detection of a substance or an active substance that is **not used** in similar production systems under conventional management

Operator Criteria
- Precautionary measures under Article 28(1) of Reg. (EU) 2018/848 were implemented effectively
- No history of major or critical non-compliances

Product Criteria
- Reliable detection of a substance or an active substance that **could theoretically** be used in similar production systems under conventional management
- Analytical trace results

Operator Criteria
- Precautionary measures under Article 28(1) of Reg. (EU) 2018/848 were implemented effectively with minor deficiencies.
- No history of major or critical non-compliances

Product Criteria
- Reliable detection of a product/ active substance that is **likely** to be used in similar production systems under conventional management
- Concentration **similar to application** and/or **recurrent** contamination

Operator Criteria
- Precautionary measures (Article 28(1) Reg. (EU) 2018/848) **not** implemented effectively
- History of **major** or **critical** non-compliances

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Vade Mecum: § 5.5

The risk analysis relies on criteria concerning the type and concentration of the substance, the non-compliances identified during previous inspections. The output determines the approach to and the intensity of an official investigation.

- High-risk cases (red): situations where contamination occurs with substances typically used in the conventional production of the same crop or product; results of previous inspections show significant non compliances. In the case of high risk, the official investigation should typically include a short-term on-site visit, preferably unannounced.
- Medium-risk (yellow): traces of substances 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. The operator is required to provide additional information. If not conclusive, on-site visit must be conducted to ensure the completion of the investigation.
- Low risk (green): the evaluation is done based on a documentary review. The case is review on-site on the occasion of the next annual inspection.

VI. APPLY THE MOST EFFECTIVE INVESTIGATION TECHNIQUES.

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Vade Mecum: Chapter 4, § 5.6

Each official investigation needed to be designed for each specific case in a forensic way. CA/CB shall intelligently choose effective and efficient investigation techniques to complete the official investigation as quickly as possible and obtain factual results that clarify the suspect case, based on the systematic approach ranking the sources as “probable” and “possible”.

⇨ **Meaningful combination is crucial!**

Novak, 2023

VI. APPLY THE MOST EFFECTIVE INVESTIGATION TECHNIQUES.	Vade Mecum: Chapter 4, § 5.6

- A tool box for investigation methods and techniques
  - Documentary checks
  - Cross- and Traceability checks
  - Inspection visits
  - Sampling and analysis
  - Exchange of information
- A variety of methods and techniques can be used in off-site or on-site investigations
- The overall objective of investigation techniques: confirming the most probable hypothesis and eliminating the possible ones, in particular use and commingling.

VII. CONCLUDE WITH AN ACCEPTABLE DEGREE OF UNCERTAINTY BY FOCUSING ON USE AND COMMINGLING AND SPECIFIC FOLLOW-UP OF THE CASE.

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Basic elements to be considered

- As a general requirement, the official investigation must conclude on the source and cause.
- A key issue: what degree of certainty in determining a source and a cause must be achieved?
- The principle of proportionality should play a role in the investigation to determine the sources and causes.
- The principle of proportionality should not be used as a pretext to generalise the conclusions "source not determined", or "natural presence" without having implemented all the relevant methods of investigation.
- It is not necessary to investigate every possible source with the same intensity. The official investigation should focus on possible cases of no- compliance to verify whether the conditions of Article 29 (2) are met (use, commingling, precautionary measures).

VII. CONCLUDE WITH AN ACCEPTABLE DEGREE OF UNCERTAINTY BY FOCUSING ON USE AND SPECIFIC FOLLOW-UP OF THE CASE.	Vade Mecum: § 5.7, 6.2.8, 7.5.

The principle of proportionality may lead to a conclusion on the most probable source with an acceptable degree of uncertainty if:

- The preliminary analysis has correctly identified the most likely hypotheses and examined all other possible sources.
- The conclusion is based on factual elements, showing that the pertinent investigation methods have been implemented, confirming the most probable source and eliminating the possible ones.
- The investigation has provided solid evidence to exclude or to confirm use and commingling.
- The conclusion may be based on similar cases for which and in-depth investigation was carried out.
- The operator does not have specific history of non-compliance linked to the contamination.
- It is not a recurring case (except where recurrence is unavoidable).
- The findings regarding the contamination case are taken into account in the following inspection visit, including some specific checks.

VIII. ADDRESS RECURRING CONTAMINATION CASES.

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Recurrence of contamination cases is a vital signal that must be considered, taking into account two distinctive categories of cases

1) <u>The "avoidable" recurrent cases</u>

- A recurrence can happen in an individual context (originating from the same operator).
  - Suspicion of intentional use or commingling
  - Structural deficiency concerning insufficient precautionary measures
- A recurrence can happen in regional context (recurrence of similar cases at difference operators of the same region).
  - Lack of available labour force for weed control (use of herbicides)
  - Unhealthy sanitary conditions (use of plant protection products)
  - Harvesting and transportation costs (use of flowering induction)
  - Low yield combined with contractual obligations (commingling to fulfill contracts)
- These factors need to be considered during an official investigation of a recurrent case. Recurrent cases serve as an input to the risk analysis, leading to increased unannounced inspections, more frequent calculation of mass balances or traceability checks, more frequent and targeted sampling.

VIII. ADDRESS RECURRING CONTAMINATION CASES. | Vade Mecum: § 5.8

2) The "unavoidable" recurrent cases (where contamination is inevitable, and the operator cannot take the proportionate and appropriate measures to avoid risks of contamination). 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),
- 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 of a subsequent "recurrent case" 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.

IX. COOPERATE EFFECTIVELY, REPORT PROPERLY, CONCLUDE AND FOLLOW-UP TIMELY, WITH A SPECIAL ATTENTION TO OFIS.

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The decisions to be made during an official investigation.

- 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 operator's certification status at the end of the official investigation (including the option of certificate suspension or withdrawal)
- 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 follow-up to the investigation, including documentation (preferably through a database) and revision of the risk classification of the operator.

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A crucial element: the timing and the duration.

- The investigation period is an essential component for the control system to function effectively.
- Excessive delays in concluding official investigations have an economic impact on operators when an organic product is provisionally blocked.
- Excessive delays have also an overall impact on the robustness of the control system. It is the responsibility of the CA/CB to identify all operators concerned and block further sales of all lots potentially affected and act at subsequent steps of the supply chain.
- The systematic approach for official investigation aims to reduce the duration of the investigation while maintaining or strengthening its effectiveness:
  - well defined scope of investigation based on the most probable hypotheses,
  - implementation of appropriate investigation methods,
  - conclusion with a reasonable level of certainty, provided that the possibility of use or commingling has been conclusively eliminated.

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A higher priority should be given at all levels to cooperation and exchange of information on contamination cases.

- Official investigations often involve multiple companies and different CA/CBs. Instead of working together towards a common goal of clarifying an initial suspicion, the parties involved sometimes try to avoid responsibility and accountability.
- Poor quality of questions and answers contributes to delays, such as when hypotheses on possible sources of contamination or investigation techniques are not included, 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, resulting in a never-ending cycle of questions and answers back and forth.
- Transparency and good collaboration are essential. All relevant factual information to support an official investigation should be shared without delay with other involved CA/CBs. CA/CB must specify the investigation's scope, the methods used, and the conclusions drawn from factual evidence. Slow communication, asking additional questions that are not directly linked to the case should be avoided.

IX. COOPERATE EFFECTIVELY, REPORT PROPERLY, CONCLUDE AND FOLLOW-UP TIMELY, WITH A SPECIAL ATTENTION TO OFIS	Vade Mecum: § 5.9, 5.10, 5.11, Chapter 6.4, § 7.1.

All parties involved should consider the OFIS notification as a priority task. Closing an OFIS case should be a matter of months if not weeks, not years!

Challenges for notifying EU member states

- Verify the validity of the analysis report, provide detailed information needed to understand the nature non-compliance and its potential impact.
- Attach the traceability documents to clearly identify of the product and trace back the operators and CA/CB involved.

Challenges for the notified part

- Collect the evidence and prepare a clear and complete response within the appropriate time frame.
- Describe the investigation methods implemented to determine the source and cause of the contamination.
- List the actions taken concerning the product and the operator and the measures implemented to avoid recurrences of the cases that originated the notification.
- Provide evidence to support the decisions taken, avoiding uploading those that do not complete or add anything to what already was explained.

X. SUPERVISE OPERATOR'S PRACTICES AND EXPERTISE FOR ELIMINATING SUSPICION AT HIS LEVEL.

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The provisions of Article 28 provide the opportunity to assess at operator level a suspicion of non-compliance. If the suspicion is eliminated, the product may be placed on the market without having to initiate an official investigation.

- These provisions give operators a responsibility which must be assumed 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.

X. SUPERVISES OPERATOR'S PRACTICES AND EXPERTISE FOR ELIMINATING SUSPICION AT HIS LEVEL.	Vade Mecum: Chapter 6.1.

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.
- The operator should have the competence and capacities to efficiently manage the self-control system established in the company.
- Competent 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, 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 should 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.