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6.1. Assessment conducted by the operator

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

Open discussion on the concept and the content

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The Team

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The Content of the chapter

CONTENT

- **Overview of the chapter**
- **Regulatory framework Art 28 (2)**
- **Investigation in practice**
- **Tools**

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The Content/Framwork

Regulatory Framework

- *Introduction of article 28 (2) ((1)) Regulation (EU) 2018/848*
- *Introduction Art 1 Regulation (EU) 2021/279*
- *Step by Step procedure*
- *Documentation*
- *Reporting on CB CA*
- *Information to buyers*

The Content/Procedures

Procedures in Practice

- *Step 1 verification of the information*
- *Step 2 isolation of the product in case of suspicion*
- *Step 3 assessment of the case by the operator*
- *Step 4 decision and follow up*
  - *documentation in case of elimination of the suspicion (tool 4.1)*
  - *information to CB and CA in case of substantiated suspicion (tool 4.2)*
- *Step 5 cost evaluation, assumption of costs*
- *Step 6 corrective and remedial actions*

Detailed overview of actions for operators

Legend: Legal requirements | Technical reading

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Presence of non-authorised products or substances in organic products [2018/848 Art 28(2)]

Operator must confirm suspicion of non-compliance [2018/848 Art 28(2)]

- Q1: Is the substance relevant* for compliance with organic production rules?
- Q2: Is the analysis result reliable**?
- Q3: Is the sampling reliable?

If three times "Yes" ***

Suspicion of non-compliance for ORGANIC is confirmed [2018/848 Art 28(2)]

→ Identify and separate [2018/848 Art 28(2)a]

→ Provisionally block during substantiation [2018/848 Art 28(2)c]

Operator must substantiate suspicion of non-compliance by examining any possible cause for the presence [2018/848 Art 28(2)b; 2021/279 Art 1]

Focus and identify the most likely source and cause as follows:

1. Check the use of products or substances not authorised for use in organic production under own responsibility
2. Check risks, measures and records to avoid contamination and commingling under own responsibility (cross-contamination, mass balance, traceability)
3. If needed, check with the CB of the supplier and the supplier 1. & 2.

→ Suspicion has not been eliminated or has been substantiated [2018/848 Art 28(2)c]

- → Immediately inform CA/CB [2018/848 Art 28(2)d]
- → Do not place the product on the market as organic [2018/848 Art 28(2)c]

→ Suspicion has been eliminated [2018/848 Art 28(2)c]

→ Place the product on the market as organic

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Main challenge

- Appropriateness of QA measures established in the operation in accordance with 28 (1) and 28 (2) *(all kind of operators)*
- Provisionally blocking – what to block? *(when already processed mixed products, when already delivered to costumer?)*
- Decision –> can be eliminated ? –> is substantiated ?
  - Proportionated assessment procedure for the cases
  - Target of the assessment
    - Root cause? Evidenced based information?

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QA Systems Art 27/28

Organic Control Plan

- Implementation orientated at HACCP; VACCP
- Verification of the system by CB
- Risk identification:

Delivery of goods, that do not comply with the organic regulation
Mixing of goods - use of incorrect goods/loading
Errors in contract processing and transport of goods
Incorrect labeling
Contaminations of products

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QA Systems

Analytic of incoming goods

- Risk-orientated analysis plan based on a system of key figures
- Frequency per product, origin and parameter
- Parameters:

  - addressing organic integrity (art 9) and food safety - Pesticides incl. individual methods and fumigants, etc.
  - addressing food safety - mycotoxins, microbiology, heavy metals, etc.

- Goods are in quarantine status until active release

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QA Systems

Sampling strategies

- Sampling in origin by supplier according to Midsona Deutschland Standard
- Sampling by external services in origin
- Sampling at reception in warehouse
- Sampling in origin by supplier and additional internal sampling at reception

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QA Systems

In case of finding of pesticide traces

- Sampling reliability
- Analysis reliability (double check)
- Identity of the goods (organic labelling, delivery documents, organic certificate)
- Marketability (MRL)
- Questionnaire and request a statement of the supplier
- Evaluation of the trace (multiple source, occurrence, application)
- Supplier feedback (preventive measures)
- *Often, the evaluation is already started parallel, even if the check of analyses and sampling have not been completed, so that decisions can be made more quickly.*

No substantiated suspicion -> documentation in ERP System – release of the goods

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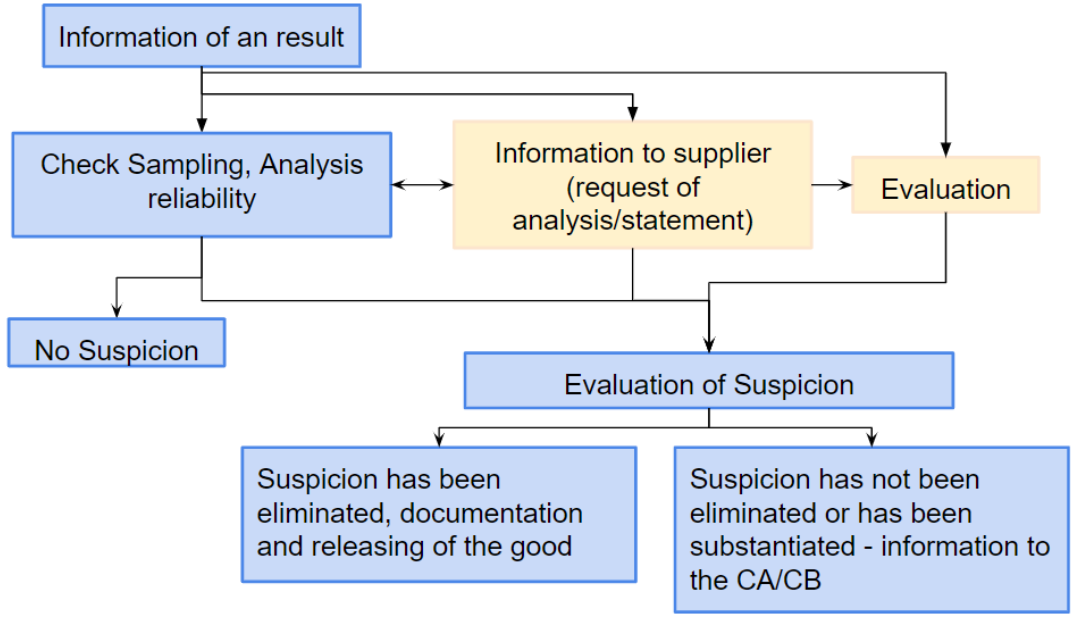
QA Systems



Trace/ Product:	
a. Identification of the goods	
b. Sampling	
c. Analytic	
d. MRL	
e. Evaluation	
i. Internal contamination possibilities	
ii. Substance specific Evaluation	
iii. Supplier feedback	
iv. Evaluation by inspection bodies	
v. Informations	
f. Evaluation	

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QA Systems

Q/A System must be adapted to kind and operations of the organization.

Focus of the System should align to activity.

- Producers *(e.g. raw materials, inputs, processes, contamination/traceability)*
- Trader *(e.g. supply chains, cooperation with producers)*
- Importers *(e.g. supply chains, import requirements)*
- Size of the organization *(e.g. small organizations step by step procedure, external expertise)*

-> The adapted system must be verified by certification body

Practical cases

Examples – contributions by

- Norbert Fuchsbauer
- Carmen Pfannkuchen
- Christine Gonzales Serrano

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Practical cases

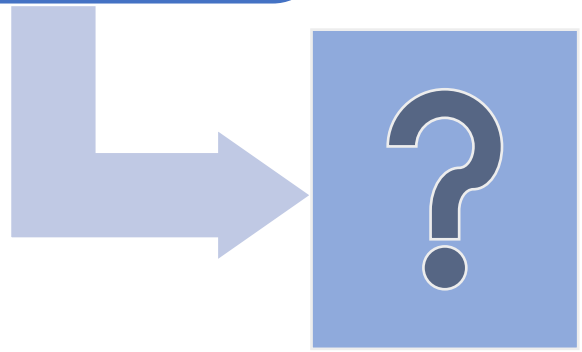
Example:

Product: organic poppy seeds

Analytic by costumer (delivered to the costumer 100 kg of 24.000 kg batch / 960 bags of 25 kg)

Analytic in the supply chain	sampling	result of 2,4-D
Costumer	1 bag 250 g	0,03 mg/kg
Operators own check	root n+1 -> 21 bags	<0,01 mg/kg
Supplier check	sampling of 100 bags	<0,01 mg/kg

Relevant
Analysis reliable
Sampling reliable



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Practical cases

Example:

Product: organic oat

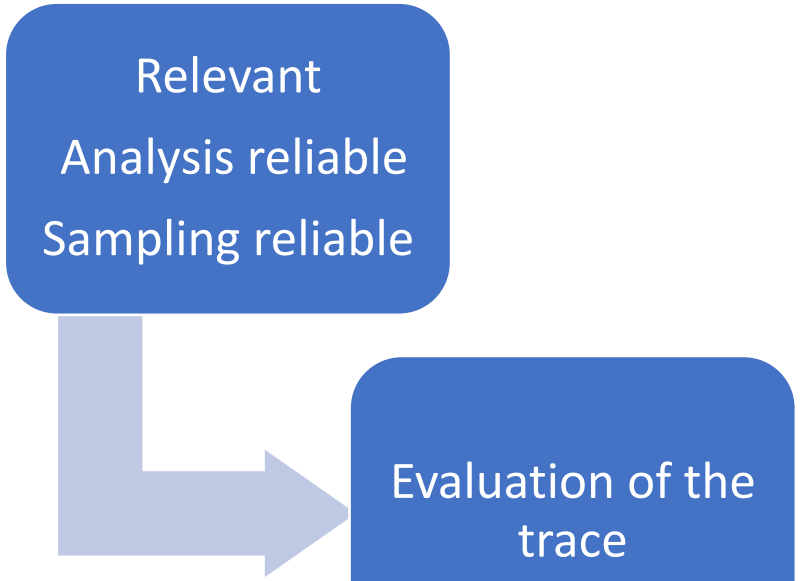
Finding: 0,11 +/- 0,055 mg/kg

Chlormequat

(Product in the market and raw material warehouse)

Sampling: single consumer package

MRL: 15 mg/kg



- Supplier has an organic certification
- Supplier does not have conventional products/oat
- nearest conventional field with wheat at a distance of 70 m
- bushes for prevention of drift
- If applied, the results of chlormequat would be higher

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Practical cases

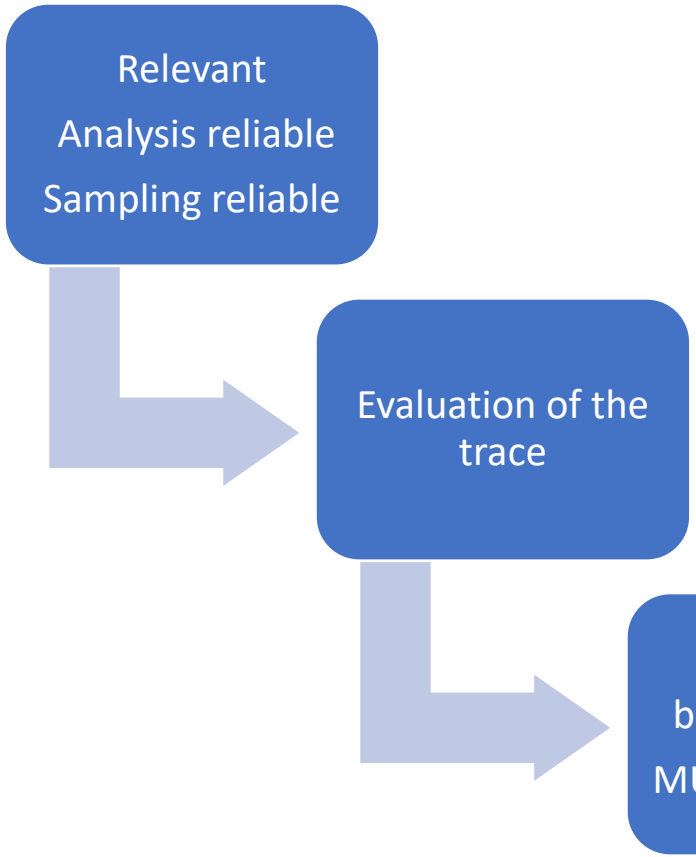
Example:

Product: organic liquorice

Finding: **Matrine/Oxymatrine**

Level: 0,014 +/- 0,07 mg/kg

MRL: 0,01 mg/kg



"Analysis and occurrence of matrine in liquorice raw materials - Exclusion of its application as pesticide"
https://doi.org/10.1080/19440049.2021.2005261

- Botanical contamination by Sophora
- Sophora, high contentrations of Oxymatrine/Matrine
- Use of Oxymatrine/Matrine for liquorice needless

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Practical cases

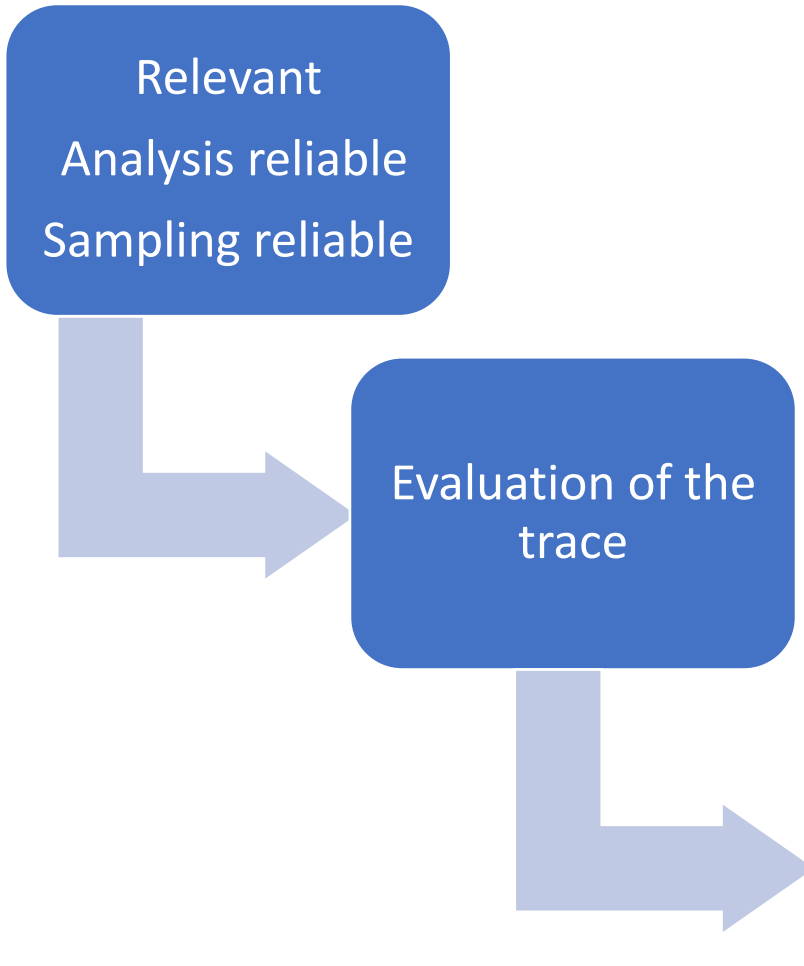
Example:

Product: organic rose hip (dried)

Finding: 0,025 +/- 0,013 mg/kg

Glyphosate

MRL: 0,1 mg/kg



- Wild collection
- Applying of glyphosate does not make sense
- Certified collection area
- Processing factor
- Product certified and controlled according to several standards

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Practical cases

Example:

Product: Organic mango puree

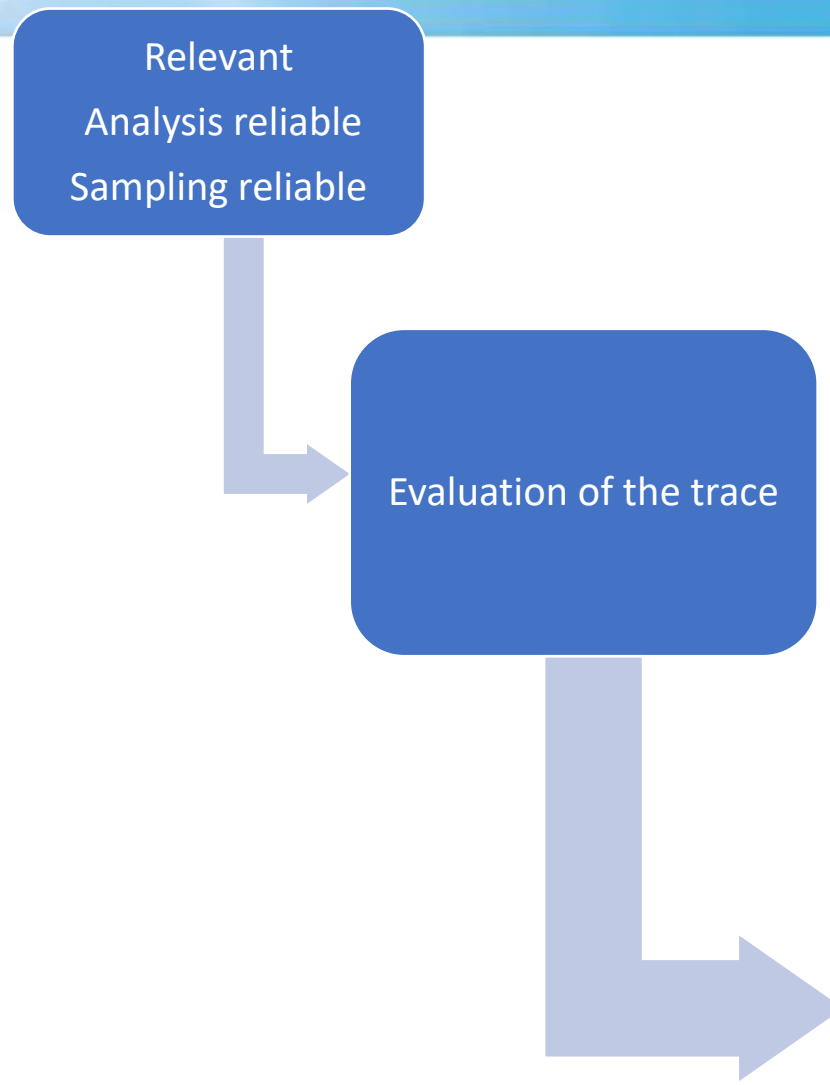
Prior shipment: < 0,01 mg/kg

After shipment:

0,04 +/- 0,02 mg/kg **Carbendazim**

In two barrel

MRL: 0,5 mg/kg (mangoes)



- No sealing of the goods after initial sampling and pre-shipment analysis
- Carbendazim is recommended for mango
- Expected residue value after treatment is in the range of the finding

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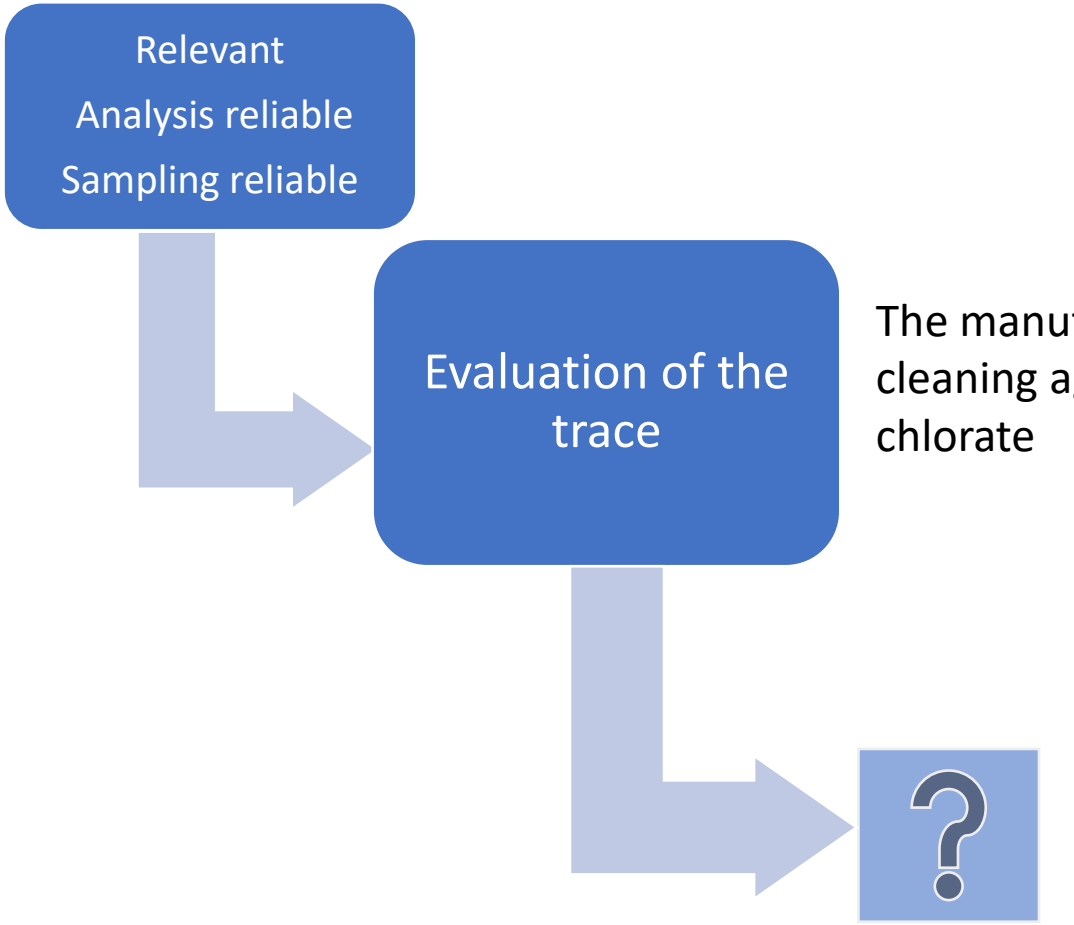
Practical cases

Example:

Product: Organic minced pork, frozen

Finding: 0,025 mg/kg **Chlorate**



The manufacturer uses cleaning agents containing chlorate

End

Documentation

CHECKLIST - Procedure in the event of a suspected infringement under Articles 27 and 28 (2)

Datum:	
Information on a suspicion:	
Documents of information:	
Responsible person:	

Done	Step	Relevant	Measures / Questions	Additional info	Answer if necessary	Document(s)	No
☐	**1.**	**Checking whether the information is valid.**		**If necessary, consult OPTA, national association, BLQ GmbH, inspection body.**			
☐	**a)**		**Check whether the product or substance found is subject to authorisation according to Art. 9 (3) 1) of the Organic Regulation. If this is not the case, there is no need for action with regard to Article 28 (2) of Regulation (EU) 2018/848.**	e.g. as active substances to be used in plant protection products, fertilisers, food additives and processing aids			
☐	**b)**		**Check the validity of the finding/information by means of the following questions:**				
	The following question pool is available as an example:						
		☐	Can the laboratory result be traced back to the allegedly affected batch?				
		☐	Does the sampling information technically meet the requirements?	What are the technical requirements? Comparison of target/actual + documentation + photo			
		☐	Is a counter sample available?				
		☐	Is the laboratory suitable for the relevant determination?				
		☐	Is the reporting limit appropriate?	(Values below the reporting limit are not meaningful).			
		☐	Accuracy of results including range of variation correctly stated?				
		☐	Has an appropriate method been used?				
		☐	For findings with complex residue definitions: Was the result stated correctly?	(Sum marked as such, all individual components listed, calculation of the sum correct?)			
		☐	In the case of findings of substances that have different sources of input, is this circumstance taken into account in the assessment?	(e.g. phthalimide, anthraquinone, phosphonic acid, dithiocarbamates, bromide, chlorate, etc.)			
☐	**c)**	**Exclusion of false positive results. The following measures can help to achieve this:**					
		☐					

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Sensitive & complex issues and challenges

Sensitive & complex issues

- Appropriate QA measures established in the operation in accordance with 28 (1) and 28 (2) (all kind of operators)
- Proportionated investigation for the cases
- Target of the investigation –> root cause? Evidence based information?
- Definition of harmonised actions for situations that are often dealt with on a case-by-case basis
- Multiple specificities of substances *=> "infocards"*

Challenges

- Addressed topic # 1
- Addressed topic # 2
- Addressed topic # 3