On the way to a harmonized approach in the EU:

Concepts for handling residue cases in organic products

Bernhard Speiser, Regula Bickel, Ursula Kretzschmar, Alexander Beck, Bavo van den Idsert

July 17, 2020

Project carried out on behalf of OPTA

Research Institute of Organic Agriculture (FiBL) | Ackerstrasse 113 | Postfach 219
5070 Frick | Switzerland | Phone +41 62 865 72 72 | info.suisse@fibl.org | www.fibl.org

Table of contents

Tables

Figures

Summary

A previous study has shown that to date, findings of pesticide residues in organic products (thereafter called 'residue cases') are treated in very different ways across the EU. This successor study provides input on how the handling of residue cases could be improved and harmonized. The provisions of Reg. 2018/848, Art. 28 and 29 constitute the general framework. The study aims to contribute to a successful implementation of these new requirements, and also towards further improvement and harmonization when the topic which will be on agenda of the European Commission in 2024/2025.

The methodology used for this study is mainly based on a qualitative approach with questionnaires, workshops and interviews with stakeholders from the organic sector, particularly quality management experts from operators, CBs/CAs and representative organic associations on EU level.

A snapshot of the residue situation in organic processors and traders was obtained with a questionnaire. The operators stated that effects related to timely delivery (from supplier to operator and/or from operator to client) cause the greatest problems. Based on >10 000 analyses, the effects of various threshold levels were estimated. Organic operators make great efforts for avoiding residues. Many operators systematically test all incoming food lots for residues. This clearly exceeds the requirements of the food law and the organic regulation.

The following approaches are most often applied in the EU: 'de-certification level', 'zero-tolerance', 'investigation level' and 'case by case approach'. An evaluation of these approaches showed that each approach has its own strengths and weaknesses.

The following requirements were judged to be most important for an improved approach: it must be realistically workable (labour efforts; proportionate costs; realistic expectations for know-how and staff qualification; realistically enforceable requirements), it must be harmonized across the EU and possibly beyond and it must take into account background pollution.

A number of 'instruments' are proposed to mitigate specific weaknesses of individual approaches and/or to improve and harmonize the handling of residue cases. The first two instruments form the core of the system, while the remaining instruments provide additional support to it.

1. **Inclusion of Organic Control Points (OCPs), including residues, in QA system**: The identification of risks for organic aspects including residue risks and the corresponding the risk management practices specifically for organic products should be implemented in the QA system of the company and approved and audited by the CB/CA. This applies to the whole supply chain including warehouse, transport, operator, but needs specification for each type of operation.

2. **Procedure for handling residue cases**: The operator's QA system must contain procedures for handling residue cases especially for organic products. Again, these must be approved by the CB/CA.
3. **Multifactorial decision-making system**: A multifactorial decision-making system should be developed, to provide guidance to operators whether a suspicion is substantiated. This decision-making system is part of the procedure for handling residue cases.
4. **Optimizing control systems for residue handling**: Organic regulation (legal), ISO (private standard) and food safety standards (private standards as BRC, IFS) should be harmonized in handling residues for organic products. The aim is to avoid gaps between the systems, as well as duplications. Ideally, customer specific guidelines are also harmonized. As a result of the unclear legal situations, operators and private standards currently have their own guidelines**.** Where several CBs/CAs are involved along the trade chain, the organic regulation should enforce better collaboration between them (in terms of quality and of speed).
5. **Defining the limits of investigation**: There should be EU-wide guidance in which way a residue case has to be investigated and closed. It could be situation-specific, probably depending on substance, residue level and commodity. The guidance should set a clear target and defined time frame.
6. **Knowledge management**: The handling of residue cases requires highly specialized skills. Lack of knowledge leads to unnecessary investigations, delays of the investigation and to unharmonized decisions. To address this, an open-access database should be established, which documents past residue cases in an anonymized form.
7. **Knowledge on background pollution**: The new approach should take into account background pollution. Only in this way, it is possible to distinguish non-compliances from technically unavoidable contamination originating from background pollution of the environment.
8. **Specific training**: Lack of knowledge leads to unharmonized decisions and delays. In addition to the knowledge management by a data base, this could be addressed with specific trainings. These would be useful when the new concept is introduced, when new staff are employed or when new problems turn up, or new knowledge is available.
9. **Guidelines for handling standard cases**: Certain residue cases occur regularly ('standard cases', e.g. dieldrin in cucumbers; anthraquinone in tea). Their origins are well known and have nothing to do with fraud. Nevertheless, there may be known measures to reduce the occurrence of such substances. To facilitate and harmonize the handling of these cases, a series of standardized 'factsheets for standard cases' should be prepared.

10. **Backstopping by experts**: Difficult, unclear or controversial residue cases lead to different certification decisions. To address such cases, a possibility for backstopping by experts should be established.

1. Introduction

In the past two decades, pesticide residue analyses have become an increasingly important element of quality assurance in the food sector, including organic food. The analytical methods have tremendously improved in this period and are now able to detect very low levels of pesticide residues (1 part per billion or even lower). For an overview, see Rombach *et al.* (2020). At the same time, there is a growing public concern about the negative impacts of synthetic pesticides on the environment and for health.

Because organic agriculture excludes the use of synthetic pesticides, organic products contain far less pesticide residues than other foods. This fact shows up in every monitoring programme, for example those of the European Food Safety Authority (EFSA) covering the European food market. At comparison by EFSA found that 44 % of conventional foods contained pesticide residues, while only 6.5 % of organic foods contained such residues (EFSA, 2018). According to the EFSA pesticides report 2018 (EFSA, 2020), 85 % of organic foods contained no pesticide residues, 14 % contained residues at or below the MRL and 1 % contained residues above the MRL.

Maximum Residue Levels (MRLs) are set by the European Commission with regard to food safety and human health. The official statement is that food containing pesticide residues below the MRL is safe and healthy. However, a part of the consumers does not feel comfortable with this approach and request 'residue free' food. To serve these consumers, organic food is sometimes presented as the 'residue-free' alternative. As the monitoring data show, organic food can certainly be seen as a 'low residue' alternative, but it cannot fulfil the expectation of 'residue free' food. From the perspective of the organic sector, is it quite unfair to be measured by expectations which were generated in response to conventional farming practises, while general agriculture lead to unavoidable contaminations in organic agriculture and instruments. In addition, organic is not about an end-product quality, but the result of a process-based approach.

Findings of non-authorized pesticides in organic food (thereafter called 'residue cases') are handled very heterogeneously in different EU member states (Milan *et al.*, 2019). This variability is an obstacle for international trade and confronts organic operators with major problems. Therefore, the Organic Processing and Trade Association (OPTA) has mandated the Research Institute of Organic Agriculture (FiBL) with an in-depth analysis of the current approaches and proposals for improvements. The present report is the major deliverable of this project. It aims at stimulating the discussions on a harmonized approach for Europe.

The motivation for this study is to identify cornerstones for a harmonized approach for residue handling in the EU that pays right to the organic sector and does not put the complete burden of the risk of residue contaminations on the organic sector. This project first explores what needs the organic sector has with respect to residue handling, and what approaches are currently practised in the EU. Then, it evaluates to what extent the current approaches meet the requirements of the sector. Finally, it explores how the

current approaches could be amended, or whether there would be alternative approaches which better meet the requirements.

In the light of the organic regulation, residues of all kinds of substances and product groups in the scope of the organic regulation have the same legal relevance. Besides pesticides, food additives, feedstuff, seeds, fertilizers, silage agents, cleaning agents and other products are relevant. However, this report is only dealing with **residues which are presumably caused by pesticides** (see also section 1.3, last bullet point).

1.1 Technical background: origins of pesticide residues

Major origins of pesticide residues in organic products

Pesticide residues in organic products may have very different origins. Typical origins are:

- drift from a non-organic field;
- 'heritage chemicals' present in the soil as a result of historic use;
- contamination during processing, transport or storage;
- commingling of organic and conventional food or sale of conventional foods as organic;
- use of non-authorised substances in organic production;
- substances with multiple origins, where the occurrence in food may have nothing to do with plant protection.

A compilation of the European Organic Certifiers Council (EOCC) gives estimates of the relative frequency of different origins (EOCC_Task_Force_Residues, 2018) in cases where residues have been detected. The compilation is not directly comparable with the compilation above, because it does not use the same terminology for origins as we do here. The three most frequently identified origins are pollution, drift and contamination. None of these involves any intention of the organic operator.

Figure 1 illustrates the wide variety of origins of residues and contaminations, ranging from technically unavoidable (green) to avoidable or even intentional (red) (source: (Bickel and Speiser, 2019).

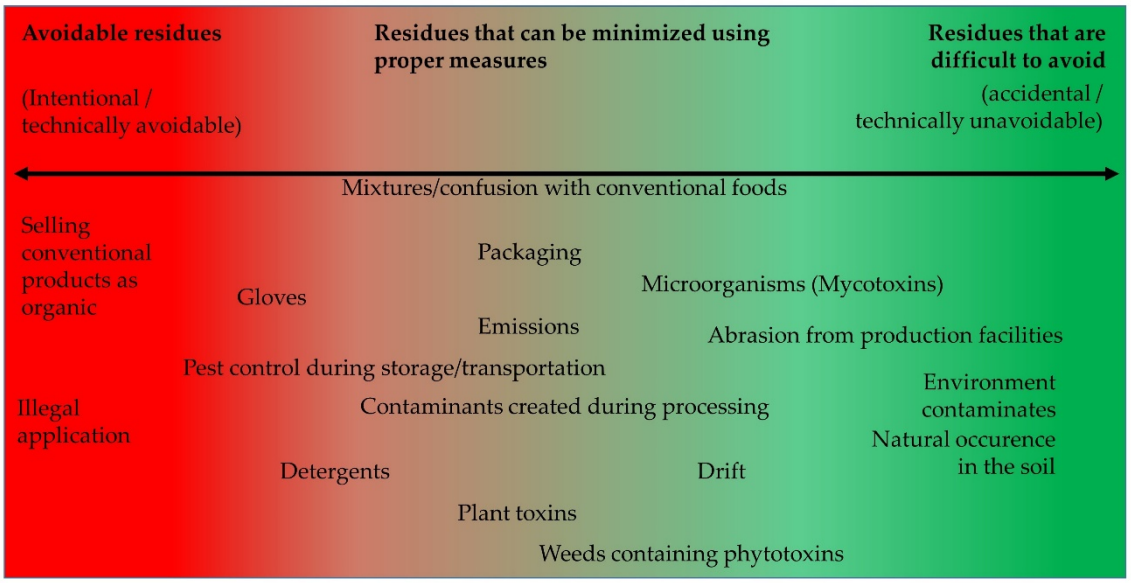

Figure 1: Origins of pesticide residues.
Figure translated from Bickel and Speiser (2019).

Necessity for determining the origins of residues

As described above, the finding of a residue causes an official investigation to determine the source/cause, and to verify whether the organic production rules were complied with (Reg. 2018/848, Article 29(1)). This is important, because

- Only when the origins are known, it is possible to avoid future residue cases reliably.
- The certification decision may vary depending of the causes for the residue. For example, fraud will lead to de-certification, while technically unavoidable residues will not lead to de-certification.

1.2 Legal framework: pesticide residues in organic products

Summary of the requirements of the EU organic legislation concerning pesticide residues

The EU organic legislation makes the following requirements concerning pesticide residues:

- *Operators* must identify the contamination risks, and they must take precautionary measures to avoid/minimise contamination.
- *CBs/CAs* must take samples (annually at least 5 % of all operators) to test for the presence of non-authorised substances in order to verify process information, and they must take measures in the case of presence of such substances.

Table 1 gives an overview which articles in the current and in the new organic legislation deal with pesticide residues. The implementing regulation regarding controls is currently under discussion. Therefore, the details of the new procedures are not yet known.

Table 1: Requirements of the EU organic legislation concerning pesticide residues.

	Current organic legislation	**New organic legislation**
Obligations for operators		
Identification of contamination risks	Reg. 889/2008, Art. 26(1) & Art. 63 (*processors only*)	Reg. 2018/848, Art. 28(1) (*all operators, including farmers*)
Avoidance of contamination (precautionary measures)	Reg. 889/2008, Art. 26(2) (*processors only*)	Reg. 2018/848, Art. 28(1) (*all operators, including farmers*)
Obligations for CBs/CAs		
Sampling to test for non-authorised substances	Reg. 889/2008, Art. 65	(not yet published)
Measures in case of presence of non-authorised substances	Reg. 889/2008, Art. 91	Reg. 2018/848, Art. 29 1.
Circumstances for decertification		Reg. 2019/848 Art. 29 2.

In conclusion, the current organic regulation leaves many aspects open. By contrast, the new organic regulation clarifies the responsibilities of operators and of CBs/CAs. It also clarifies in which cases the products may not be marketed as organic. Finally, it clarifies that all operators (including farmers) have a responsibility for avoiding residues.

Discussion of the role of residue analyses in the organic control system

Organic farming and processing of organic products is characterized by its *production methods on farms and in processing*, and not by the properties of the final products. The EU organic legislation therefore specifies the production rules that have to be fulfilled by organic operators. The organic control system must verify whether the production process complies with the organic production rules. The primary tools for verification are on-site inspections. In recent years, the control system has been complemented by

analyses as an additional tool. The target of this tool is again the verification of fulfilment of process requirements. Today, control authorities/bodies must take samples from at least 5 % of the operators under their control every year. For certain non-EU countries, analyses are prescribed for every lot imported into the EU.

At the moment, the finding of a pesticide residue has highly variable consequences in different EU member states (Milan *et al.*, 2019). Here, it is briefly summarized what the EU organic legislation states on this topic. The current organic legislation states that the finding of a residue causes a 'doubt' whether the product was produced in compliance with the organic production rules (Reg. 889/2008, Article 91). Under the new organic legislation, the finding of a residue causes an official investigation to determine the source/cause, and to verify whether the organic production rules were complied with (Reg. 2018/848, Article 29(1)). Article 29(2) specifies in which cases the product must be de-certified.

In conclusion, both the current and the new organic legislation are clear that the finding of a non-authorised substance in an organic product does not *per se* invalidate the organic status of an organic product. It causes investigations which may or may not result in the de-certification of the product.

1.3 Cornerstones for the study

The project has made the following assumptions:

- The improved system for handling residue cases in organic products shall be implemented in the context of the new EU organic legislation. The provisions of Reg. 2018/848, Art. 28 and 29 constitute the general framework.
- The implementing Regulation regarding organic controls are currently under discussion. The project aims to facilitate the transition towards an improved system with this regulation.
- The project is aware that by 2024, the provisions regarding residue cases will be reviewed and possibly improved.
- 'Residues' may potentially concern a wide array of substances. As mentioned at the beginning potentially to all substances and products in the scope of organic regulation. At the moment, however, sampling and analysis is largely focused on *pesticides* and these cause by far the greatest problems in the certification of organic products. Therefore, the scope of this report is limited to non-authorised pesticides.
- Residues may potentially affect all organic products such as food, feed, seeds, propagation material or organic animals. For simplicity, this report focuses on organic food. However, it is assumed that the general methodology will also be applicable to feed. For seeds, propagation material or organic animals, the methodology might have to be adapted. However, this is not in the focus of this report.

2. Snapshot of the residue situation in organic processors and traders

2.1 Methods for the snapshot

A questionnaire was prepared by FiBL. This was distributed by OPTA within its network and was returned mainly by European companies. To safeguard confidentiality, the companies were not asked to send original residue data, but to report aggregated data, according to the instructions in the questionnaire. The questionnaire was answered by 13 companies. 9 of these are processors, while 8 are traders (some companies are active in both roles). The responses covered more than 10 000 analyses, mostly from the year 2019. The most frequent commodities are spices, herbs and tea; grains; processed fruit. The great majority of analyses were multi-residue screening, complemented by some analyses for chlorate, glyphosate, folpet and fosetyl. In addition to analytical data, companies were also asked about their internal residue policies, the economic impact of residue cases and the efforts dedicated to risk reduction.

2.2 Results of the snapshot

2.2.1 Economic impact of residue cases

Operators were asked to rank different possible impacts according to their importance. The following effects were ranked as most important:

- Residue cases in the own company may cause blocking and thus prevent timely delivery to the clients.
- Residue cases at the suppliers may cause shortages and delays in the delivery of raw materials.

The following effects were ranked as less important:

- Investigation costs
- Loss of clients
- Additional storage costs due to temporary blocking
- Value loss due to downgrading
- Reputation damage

2.2.2 Residues exceeding different threshold levels

Operators reported analytical results from their internal quality assurance. Please note that these data may also include pre-shipment samples from lots which were never traded as organic, as well as samples from investigations of residue cases (where several analyses may relate to the same contaminated food lot). These data may therefore be biased towards more residues than in organic products on the market and are not directly comparable with monitoring data from the market. This may explain why the

operators reported 19 % of samples containing residues, while in the 2018 EU pesticides monitoring (EFSA, 2020), only 13.8 % of all organic samples contained residues. Nevertheless, the data give an impression on the workload which the organic sector might be facing in different scenarios.

- In 81 % out of the 10 000 analyses, no residues were detected.
- In 19 % of the analyses, some residues were detected (=cases above 'zero-tolerance') (as stated above, this does *not* mean that 19 % of the food lots, residues were detected).
- In 15 % of the analyses, residues above 0.01 mg/kg were detected (the level of 0.01 mg/kg is frequently used for organic food). However, only 2 %* of the analyses exceeded the 'BNN orientation value'. Although the 'BNN orientation value' is set at 0.01 mg/kg, it additionally contains provisions to account for extended measurement uncertainty and for processing factors, and differing values for a few substances, e.g. phosphonic acid. This explains the difference between the level '0.01 mg/kg' and 'BNN orientation value'.
- In 2 %* of the analyses, residues exceeding 5% of the MRL for that commodity were detected.

* The percentages for 'BNN orientation value' and '5% MRL' were estimated from a reduced data set, because not all quality assurance systems include this information.

2.2.3 Internal policies for quality assurance

Risk assessment for incoming goods

- All companies reported having an internal risk assessment concept for incoming goods.
- 9 out of these 13 companies reported that this concept includes systematic residue testing of *every single* incoming food lot.

Costs for risk reduction

Only few companies completed this section and some of the responses were of an anecdotal nature. For example, one company stated that their quality staff had to be increased from 2 to 5 persons over the last few years. In addition, they reported that the costs for analyses increased fourfold. This could be due to increased risks and/or higher quality expectations by customers and/or growing trade volumes. The responses indicate that many companies incur *substantial costs for risk reduction / residue prevention*, in addition to the *direct costs of sampling and analysis*. From the figures given, we can tentatively conclude that

- Costs for preventive measures range between 0.3 – 1.5 % of the organic turnover, and

- Costs for analyses (internal / external) range between 0. 3 – 3.5 % of the organic turnover.

2.3 Discussion of the snapshot

In Summary, the effects related to timely delivery (from supplier to operator and/or from operator to client) cause the greatest problems. Many contracts foresee high penalties for suppliers in out-of-stock situations. These problems are ranked as more important than for example losses due to downgrading. Thus, any improvements which shorten the temporary blocking of foods will have the greatest positive impact on organic processors and traders.

Organic operators make great efforts for avoiding residues. Many operators systematically test all incoming food lots for residues. This clearly exceeds the requirements of the food law and the organic regulation.

3. Evaluation of current approaches

3.1 Methods for evaluating current approaches

An inventory of different approaches currently in use in the EU had been prepared in a precursor project (Milan *et al.*, 2019). As a first step, these approaches were categorized, and four major kinds of approaches were identified: 'de-certification value', 'zero tolerance', 'investigation value' and 'case by case approach'.

These approaches were evaluated in a workshop with invited experts in November 2019. Experts were selected in such a way that countries practicing different approaches were represented. In addition, experts also represented different steps in the trade chain (production, inspection/certification, certification authorities, as well as laboratories and research). In a group work with the 'world café' methodology, the experts were asked to identify the major strengths and weaknesses of each approach, and to draw conclusions on the approach (whether the approach was considered adequate and/or whether it could be improved). The notes of the workshop were edited for the purpose of this final report. Where additions had to be made during writing, this is marked in the text.

3.2 Results on current approaches

This chapter reports the answers given by the workshop participants. A discussion by the project team can be found in chapter 3.3.

3.2.1 Evaluation of the 'de-certification level' approach

In this project, the term 'de-certification level approach' is used for all systems where there is a *specified residue level at which the products are always de-certified*, regardless of the reasons. In different countries, the de-certification level may be specified differently. For

example, the de-certification level may be at the LOQ, at 1.5x LOQ, at 10 mg/kg or at 5 % of the MRL. In the workshop, this approach was characterized as 'quick and dirty'.

Strengths ('pros')

The major strengths of this approach are:

- It is fast.
- It is clear and simple.
- It will lead to harmonized decisions by different stakeholders (e.g. CBs/CAs in different countries)
- The system provides legal certainty to CBs/CAs.

Weaknesses ('cons')

The major weaknesses of this approach are:

- It can punish innocent operators, i.e. products may be de-certified even if the farmer has complied with all organic production rules.
- It goes against the process approach of organic production; the difference to conventional production becomes smaller.
- Once that a product has been de-certified, the actors will not invest much effort into the search for causes.
- Companies working with many food lots can mix the lots in such a way that the residue levels are below the de-certification level. In this way, they can avoid de-certification. With this approach, this means that no investigations will take place. Thus, sources of residues or even fraud cases may remain unnoticed for a prolonged time.
- This approach sets a strong focus on residues. This carries the risk that other aspects of organic quality assurance are overlooked, particularly fraud cases with residue-free conventional products.
- In situations where environmental contamination exceeds a certain level, entire categories of organic products might exceed the de-certification level, and might thus by excluded from production. Farmers would become the victims of such a situation (traders can react by changing their suppliers).

Comments and open questions of the workshop

- A multi-level approach seems more adequate than a single value applied to all substances and commodities.
- It was stated that the de-certification level should be linked to conventional practices. For example, it could be set at 10 % of the residue level expected from active use in conventional practice. However, the workshop participants agreed

that this would not be easy and would need a lot of knowledge. However, the participants doubted whether such information/data would be available.

- These approaches require precise instructions regarding the application or non-application of processing factors and the handling of (extended) measurement uncertainty.
- De-certification level approaches would be better acceptable, if there would be exceptions for drift and heritage chemicals.

3.2.2 Evaluation of the 'zero tolerance' approach

The zero tolerance approach is a special case of the de-certification level, where the de-certification level is set at 'zero'. In practise, this usually means that whenever detection of a pesticide is mentioned on the analytical report from the lab, the food is de-certified. This applies regardless of the residue levels, including traces below the limit of quantification.

Strengths ('pros')

The strengths of this approach are similar to those of the de-certification value:

- It is fast.
- It is clear and simple.
- It will lead to harmonized decisions by different stakeholders (e.g. CBs/CAs in different countries)
- The system provides legal certainty to CBs/CAs.
- In addition, this approach claims to meet the expectations of consumers.

Weaknesses ('cons')

The weaknesses of this approach are similar to those of the de-certification value:

- It can punish innocent operators, i.e. products may be de-certified even if the farmer has complied with all organic production rules.
- It goes against the process approach of organic production; the difference to conventional production becomes smaller.
- Once that a product has been de-certified, the actors will not invest much effort into the search for causes.
- Companies working with many food lots can mix the lots in such a way that the residue levels are not detected. In this way, they can avoid de-certification. With this approach, this means that no investigations will take place. Thus, sources of residues or even fraud cases may remain unnoticed for a prolonged time.

- This approach sets a strong focus on residues. This carries the risk that other aspects of organic quality assurance are overlooked, particularly fraud cases with residue-free conventional products (this aspect was not stated during the workshop, but was added here by the project team for completeness).
- In situations where environmental contamination exceeds a certain level, entire categories of organic products might exceed the de-certification level, and might thus by excluded from production (this aspect was not stated during the workshop, but was added here by the project team for completeness).

This approach also has additional disadvantages:

- There is no zero in chemistry. Whether low residue levels are detected and whether they are reported depends on the individual lab (analytical sensitivity; reporting policy). Thus, the choice of lab may determine whether a product remains organic or has to be de-certified.
- The sensitivity of analytical methods is continuously improved. At a certain point, it will be possible to detect pesticide traces in such a high proportion of organic foods that production becomes uneconomical.
- This approach can cause huge damage which is not proportionate.

Comments and open questions of the workshop

- This approach is in contrast with growing background levels of environmental pollution/contamination.
- This approach poses too high risks for production, and will therefore slow down the development of organic production.
- For these reasons, the experts agreed that the 'zero tolerance' approach should not be followed.

3.2.3 Evaluation of the 'investigation level' approach

With this approach, only cases with residue level above a specified investigation level have to be investigated. If the residue is below the investigation level, the product can be sold as organic without investigation.

Strengths ('pros')

The major strengths of this approach are:

- It is a pragmatic approach which addresses reality of widespread contamination.
- It helps to focus on the major residue cases, which are presumed to be more relevant. Less resources (money, labour) are wasted on unavoidable residues caused by environmental contamination.

- In case of residues below the investigation value, it is fast and simple.
- It is fair, meaning that it does not punish innocent operators with unjustified de-certification (however, foods might be provisionally blocked and they might be obliged to carry out investigations) (this aspect was not mentioned during the workshop, but was added by the project team for completeness).

Weaknesses ('cons')

- This approach also sets a focus on residues, risking that other aspects of organic quality assurance and the compliance of production methods are overlooked, particularly fraud cases with residue-free conventional products.
- With this approach, products may keep their organic status even if they contain traces of residues. Some stakeholders claim that this is in contradiction to consumer expectations and might undermine consumer trust.
- Investigations can be avoided by mixing food lots in such a way that the residues are below the investigation value. This opens a door for fraud.
- Depending on the outcome of the investigation, a given residue level may lead to de-certification in one case but not in another. This is often perceived as 'non-harmonized decisions' (this aspect was not mentioned during the workshop, but was added by the project team for completeness).

Comments and open questions of the workshop

- The quality of investigations would be a key issue. Related with this, the competence of staff doing the investigation is a major challenge.
- Variable outcomes of investigation are expected, with fewer cases overall.
- This approach might move away the focus from process oriented organic production to residue free production.
- A major question would be at which level the investigation level would be set. As stated above for the de-certification level approach, a multi-level approach would be preferable to a fixed level applied to all substances and commodities. Such a 'dynamic value' should be based on scientific data (e.g. environmental contamination, values expected from active use, food monitoring data). During the workshop, it was discussed whether the 95 percentile of the residue distribution might be a suitable value.

The approach might be refined by including additional aspects besides residue levels. This might result in some kind of 'action point' approach. Additionally, it could be refined with pre-defined sampling strategies and with scientific

The project team very much hope that the contributions presented in this report will be accepted as a positive contribution for the debate. To move the debate forward to a fair and harmonized approach.

3.2.4 Evaluation of the 'case by case' approach

With this approach, each case has to be considered individually and there is no specified level for investigation and no specified level for decertification.

Strengths ('pros')

- This approach is process based and thus in line with organic production principles.
- Any de-certification decisions are content-driven and based on an investigation. For this reasons, they are relatively well acceptable for operators.
- It is fair, meaning that it does not punish innocent operators with unjustified de-certification (however, foods might be provisionally blocked and they might be obliged to carry out investigations)

Weaknesses ('cons')

- Because each case has to be investigated individually, this approach causes a lot of work (for operators as well as for CBs/CAs) and is time consuming.
- Depending on the outcome of the investigation, a given residue level may lead to de-certification in one case but not in another. This is often perceived as 'non-harmonized decisions' or as an 'arbitrary system'.
- The system contains legal risks for CBs/CAs.
- This approach is more complex to explain to consumers than a simple threshold value.

Comments and open questions of the workshop

- The quality of investigations would be a key issue. Related with this, the competence of staff (CBs/CAs as well as operators) doing the investigation is a major challenge.
- To counterbalance the tendency for non-harmonization, this approach should be supported with a number of tools, such as a general framework for decision-making, possibly a decision-tree, a database with background knowledge, an expert group for backstopping (see 'instruments' below).
- Because this approach requires highly qualified personnel and is often time-consuming, the workshop participants questioned whether this approach would be workable and could be realistically handled in all countries.
- The experts also questioned whether this approach would be acceptable to the market and to authorities. At least, a communication strategy to explain the approach would be desirable.

3.3 Discussion of current approaches

Each of the approaches described above has its own strengths and weaknesses. Simplifying broadly, it could be said that approaches based on a de-certification value (including zero tolerance) generally facilitate fast, reproducible and harmonized decisions and do not require highly qualified staff. At the same time, they are not in line with organic production principles and may lead to unfair results, particularly in situations of unavoidable contamination or heritage chemicals. For the case by case approach, the opposite is true. The investigation level approach has intermediate properties: below the investigation level, the practical consequences are similar to the de-certification level, while above the investigation level, the practical consequences are similar to the case by case approach.

Table 2: Overview of the major characteristics of current approaches.
For a full description of characteristics, see the text above. The de-certification level and zero tolerance were rated identically and are therefore pooled in one column.

Properties	**de-certification level & zero tolerance**	**investigation level**	**case by case**
clear and simple	yes	no	no
Fast	yes	partly	no
workable, realistic, pragmatic	yes	partly; with improvements	with improvements
Requires specialized knowledge, highly qualified personnel	no	yes	yes
harmonized decision possible	yes	partly; with improvements	with improvements
legal certainty	yes	partly; with improvements	with improvements
punishing innocent operators, unfair	yes	no	no
in line with organic principles (process approach)	no	partly	yes
fraud prevention: may also detect residue-free conventional food	no	partly	yes

Properties	de-certification level & zero tolerance	investigation level	case by case
Fraud prevention: inhibit mixing of lots to decrease residue levels	no	no	yes
takes into account environ-mental contamination/ pollution	no	yes	yes
(strong) focus on residues	yes	partly	no
influenced by sensitivity of analytical methods, reporting policy of the labs	yes	partly	no
focussing on major residue cases possible	no	yes	no
incentive to carry out investiga-tions (and thus finding of causes)	no	yes	yes
meets consumer expectation (residue free products)	yes	no	no

Improvements

Having said that each approach has its weaknesses, we can identify possibilities for improvement which would mitigate these weaknesses. Here, we provide a brief overview. For more details, see chapter 5 unterhalb.

- For all approaches based on a value, a single value applied to all substances and commodities seems too simple and a *multi-level approach* seems more adequate.
- Residue levels could be combined with other indicators into an 'action point' approach. If chosen adequately, such action points might be more reliable indicators of possible non-compliance than residues alone (seeSupporting instrument no 3: multifactorial decision-making system).

Approaches with investigation need the following improvements:

- *better training*, more *background information* and possibly *backstopping by an expert group* would improve the quality and speed of investigations, and thus make it better acceptable for operators.

- more precise *instructions* / *guidance* seem desirable. They would lead to more harmonized outcomes and would make the approach better acceptable for operators.
- *special provisions for handling technically unavoidable contaminations* (e.g. caused by drift or heritage chemicals) would make the approach better acceptable for operators.

4. Requirements for an improved approach

4.1 Methods for an improved approach

Based on the outcomes of the company questionnaire (chapter 2) and the evaluation of the current approaches (chapter 3), the requirements for a new approach were put into words. They were presented at a public workshop in February 2020, which was organized by OPTA and comprised mainly participants from organic processing and trade. However, some participants represented also other stakeholders. The experts had the opportunity to comment on the requirements during the workshop, and to rank them according to their priority. One company also took the opportunity to comment after the workshop. Based on this feedback, the project team revised the proposals.

4.2 Results for an improved approach

A new approach to the handling of residue cases should fulfil a number of requirements. The following requirements were ranked as most important in the workshop:

- It must be realistically workable (labour efforts, know-how, staff qualification, costs, realistically enforceable etc.).
- It must be harmonized across the EU (and possibly beyond).
- It must take into account background pollution (including, but not limited to, conventional farming).

The following requirements were also considered to be important:

- It must be fair (no punishing of innocent operators).
- It must be in line with organic principles (process based).
- It must be as fast as possible.
- It must be consistent and transparent. This would make it clearly understandable for operators, CBs/CAs and authorities, and easy to communicate.

4.3 Discussion of the requirements for an improved approach

The three main requirements for a new approach named by the experts are:

- It must be *realistically workable*. It is vital that the new approach must be realistically fulfillable. Key words are: proportionate labour efforts; proportionate costs; realistic expectations for know-how and staff qualification; realistically enforceable requirements.
- It must be *harmonized* across the EU and possibly beyond. This means that if an organic food has been accepted as organic after residue testing, it should also be accepted as organic in all countries to which it is sold.
- It must take into account *background pollution*. Background pollution is important to distinguish technically unavoidable from other residues, and technically unavoidable residues should be treated differently from avoidable residues.

From the snapshot of the company situation, another main requirement can be derived. The companies indicated that effects related to timely delivery (from supplier to operator and/or from operator to client) cause the greatest problems. Thus, we can conclude that *speeding up the process* (shortening the temporary blocking of foods) is another main requirement. In addition, the new approach should be fair, in line with organic principles, consistent, transparent and easy to understand / communicate.

5. Instruments for an improved approach

5.1 Methods for new instruments

During the evaluation of the current approaches, a number of weaknesses were identified and in some cases, possibilities for improvement were outlined. Based on this, we prepared eight 'instruments for a new approach'. Two instruments were classified as 'core instruments', while the rest were classified as 'supporting tools'. These were presented at the public workshop in February 2020 and the participants were asked for feedback. One company also took the opportunity to comment after the workshop. Based on this feedback, the project team revised the proposals.

During the preparation of this final report, we came across a number of issues which had only been briefly mentioned in one of the workshops. Based on these ideas, we developed additional instruments (no Supporting instrument no 3: multifactorial decision-making system and Supporting instrument no 7: knowledge on background pollution). Although these instruments are based on input from the workshop participants, they were never presented to them as explicit proposals and therefore not approved by them.

5.2 Results I: Core instruments

5.2.1 Core instrument no 1: Inclusion of OCPs including residues in QA system

For the prevention of organic quality risks, in particular residues as well as for the handling of residue cases, a clear allocation of roles between operators and CBs/CAs is needed.

The *operator* is responsible for the product, including the avoidance and/or minimization of organic risks including residues.

- The operator has to include aspects of residue avoidance as well as initial handling of residue cases in his QA system (e.g. GMP, HACCP).
- He has to handle initial suspicions (preliminary assessment).
- In case of substantiated suspicions, he is responsible for notifying his certifier.
- He should have an important role in handling residue cases, including investigations.

The CB/CA supervises the operator and takes the certification decision.

- The CB/CA has to approve the operator's QA system, including residue handling. If he considers the QA system insufficient, he may request additional precautionary measures for residue avoidance.
- During the annual inspections, the CB/CA has to check how the operator has handled the cases of non-substantiated suspicion. If he is not satisfied with the way in which the operator has handled these cases, he may request modifications of the QA system.
- In cases of substantiated suspicion, the CB/CA takes the lead over the investigations.
- When the investigations are terminated, the CB/CA takes the certification decision.

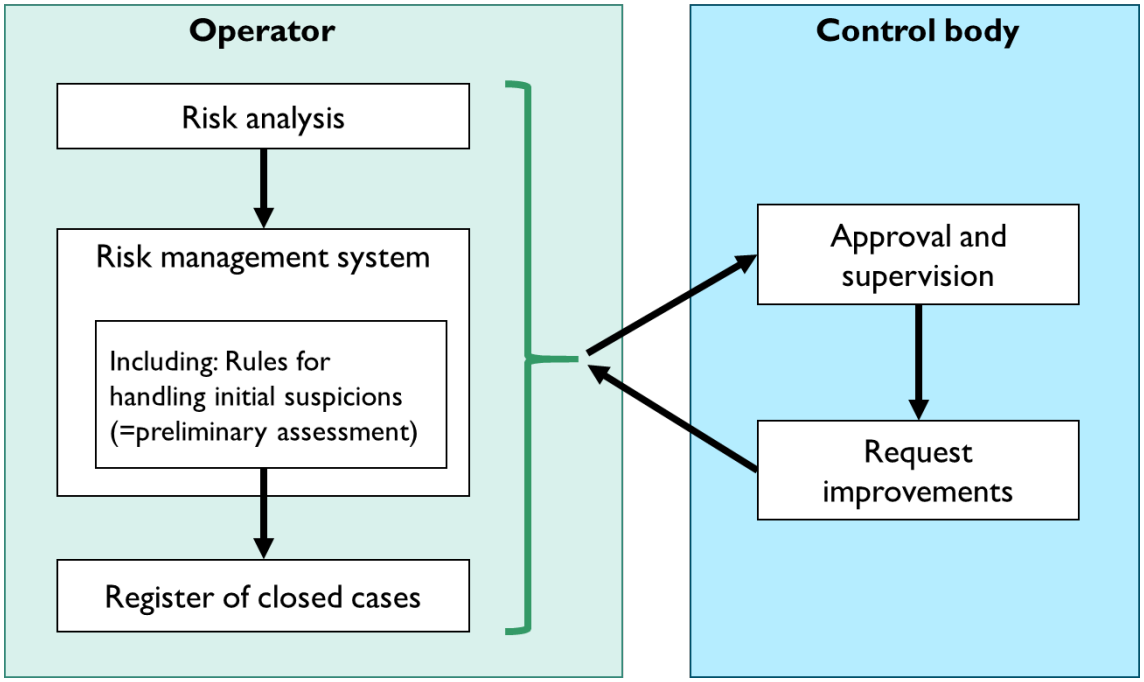

Figure 2: Inclusion of residues in the QA system (original figure as presented in the second workshop).

Comments during the workshop

The participants of the workshop agreed with this proposal. However, they emphasized that the requirements for the management system would need to be defined more precisely and that the management system as well as the precautionary measures should be realistic and proportionate.

Many companies have already a QA system for the food safety standards like IFS or BRC. These standards are audited by another CB than the organic regulation, and so the involvement of *two certifiers* might lead to unnecessary complications. For other operators, on the other hand, the system has probably not been installed before and support is needed.

5.2.2 Core instrument no 2: Procedure for handling residue cases

The operator's QA system must contain procedures for handling residue cases. These should cover the following aspects:

- whether to provisionally block any food lots, and which;
- whether to take additional samples for analysis, and how;
- whether to inform his furnishers and/or his clients;
- how to search for causes;
- in which cases to inform the certifier immediately (= when is a case substantiated?)

- in which cases and how to conclude that a suspicion is not confirmed (note by the project team: after the workshop, the 'multifactorial decision-making system'; instrument no 3 has been elaborated as a solution for this aspect);
- how to document all measures and conclusions taken.

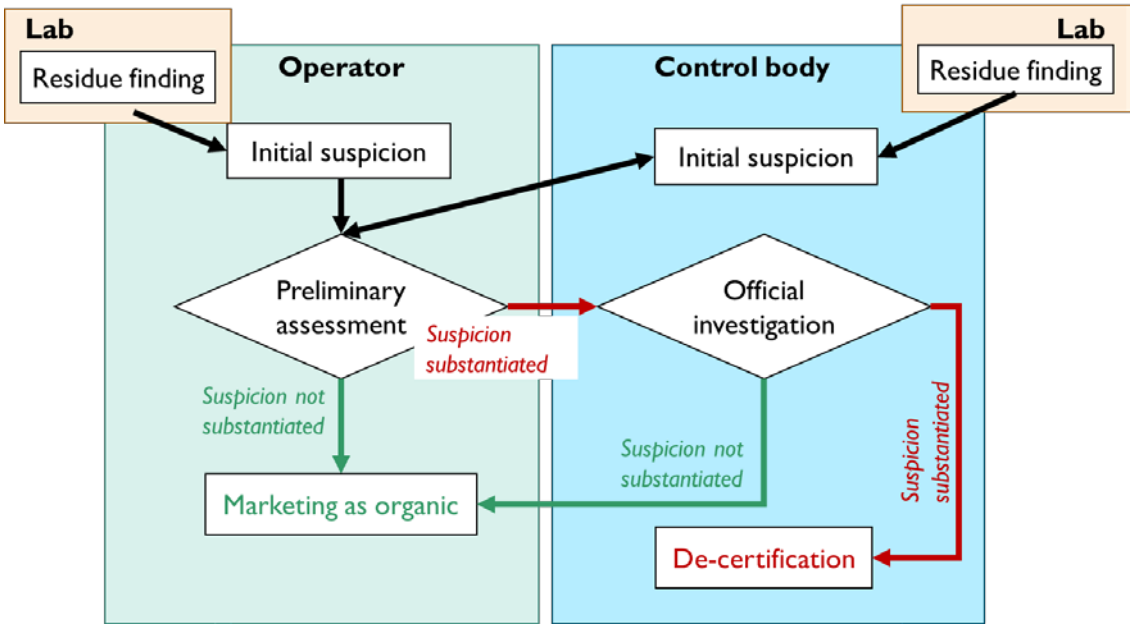

Figure 3: Procedure for handling residue cases (original figure as presented in the second workshop).

Comments during the workshop

The participants of the workshop agreed with the general idea of this proposal. Their main remark was that this instrument would need guidelines how the operator should conduct the assessment, including definitions of 'suspicion' and 'substantiated suspicion'. Some participants noted that the BNN orientation level is widely used in a similar way. Other participants stated that a 'best practise' approach would be preferable to a hard limit. The question was raised whether residues could be handled in a similar way as cross-contamination with allergens.

5.3 Discussion of the core instruments

Both proposed core instruments are accepted by the participants of the workshop. They agreed to include the residue topic in the QA system. As mentioned in chapter 2 (snapshot), operators are aware of the residue topic and they have already included it in their QA system in the same way as some of the operators are dealing with allergens and know about handling contamination spots all over the supply chain.

The risk management system is individually adapted to the situation of each operator. Within this system, the operator handles individual residue cases as specified by the system. Each operator has to decide case by case about the risks and if a case occurs to

do the preliminary assessment. The approaches with investigation or action levels as the BNN approach is a combination between the case by case and a level approach. Therefore, the remarks from participants that the BNN orientation level is widely used in a similar way and that a 'best practise' approach would be preferable to a hard limit should be considered. But even if we would propose an investigation level system the risk management and the preliminary assessment have to be part of the new system.

The project team recognizes that operators would need additional guidance. Blueprints of such QA systems could be made available by the industry and/or CBs/CAs and/or authorities (or a combination). The following aspects should also be considered:

- The system must be proportionate and realistic.
- The auditing system has to be organized to avoid a gap between organic audit and food safety audit (see Supporting instrument no 4: optimizing control systems for residue handling)
- The specific organic requirements should be integrated in the established QA systems.
- A simple solution has to be found for small operators
- Suspicion and substantiated suspicion have to be defined (see supporting instruments)

5.4 Results II: Supporting instruments

5.4.1 Supporting instrument no 3: multifactorial decision-making system

The experts stated that for core instrument no 2 (procedure for handling residue cases), the companies would need more guidance for deciding whether a suspicion is substantiated. Whenever a residue is found, the operator would determine the 'action points' to decide whether the suspicion is substantiated (and thus has to be handed over to the CB/CA) or not (ECC reg 848/2018 Art 82). The multifactorial decision-making system can provide such guidance.

The company questionnaire has revealed that many operators implement a system for quality control, where residue testing is one element that is combined with other risk indicators. The potentially relevant indicators for taking the decision whether a suspicion is substantiated must be part of the risk management system and of the decision-making process. The resulting multifactorial decision-making system as part of the organic risk assessment is established by the operator and has to be discussed with and approved by the CB/CA (see Core instrument no 1: Inclusion of OCPs including residues in QA system).

Today, comparable systems are applied in the private sector. For example, the 'Guidelines for quality management' (AÖL, 2018) and the Biotrust organic risk assessment system of Bionext.

The presence of a residues would always be one indicator in this system. The multi-factor approach for taking a decision, whether the suspicion is substantiate or not, could be set up for example on following indicators:

Residue level

- Is the substance detected covered by substance categories in the scope of organic regulation?
- Is the substance detected a typical environmental contaminant?
- Is MRL exceeded?
- Is the application of the substance found in the product senseful from agronomic or other technical perspective?
- Is an "action level" available which could be applied?
- Are comparative data and result of investigation available concerning the specific product or process with regard to the contaminants and the affected product or process?
- Does the level of the contaminants found give an indication of a possible application or of unfulfilled due diligence obligations in production, transport or processing, or does it constitute evidence of spreading or drift?

Supplier

- Is it the first occurrence of such a residue, or does it occur regularly?
- Is there a long-term relationship with the supplier?
- Is the supplier experienced in organic?
- Has the supplier an internal control system via QA established?

Traceability/origin

- Is country of origin known as safe source?
- Is the technical background properly checked (mode of transportation, mode of packaging, site of cargo handling and so on)?

These requirements for an instrument was developed by the project team as a reaction to various input during both workshops. The formal proposal for a separate instrument combining these inspirations was developed by the project team after that workshop and could therefore not be formally approved or modified by the experts.

5.4.2 Supporting instrument no 4: optimizing control systems for residue handling

Organic processors are audited not only for organic compliance, but also for ISO 9001 and/or food safety issues. Some of these concepts include very efficient, advanced system checks which have much potential to improve organic control measures. The participants of the workshop stated that the control concepts should be further developed, better harmonized and may be integrated. The aim would be to avoid gaps between the two, as well as duplications.

One possibility is that the audit persons should work together and the systems should refer to each other. The main problem is that the ISO and food safety systems are private and the organic regulation is not private. In addition, there are customer specific guidelines which have to be taken into account, too.

Competition between CBs gives incentive to minimalize investigations and co-operation of CBs in residue cases is sometimes a bottleneck. As a result, causes for residues are sometimes not found out, and/or unnecessary time is lost waiting during the investigation (while the food is blocked). In addition, each CB/CA has a different approach to deal with residues, sometimes the instructions are coming from the government, sometimes it is their own policy. As a proposed solution, the organic regulation should enforce better guidance and collaboration between CBs/CAs (in terms of quality and of speed).

The participants of the workshop agreed with this proposal. They raised the question how CBs operating worldwide should be included in this ingredient.

5.4.3 Supporting instrument no 5: defining the limits of investigation

It exists the possibility that the cause of the residues cannot be exactly found.

In that case the limits of investigation in this situation must be clear. We propose the following solution:

- There should be some EU-wide guidance in which way a residue case has to be investigated and closed. The guidance should set a clear target. CB has to make a decision based on the information within a defined time frame.
- It could be situation-specific, probably depending on substance, residue level commodity and other circumstances. Ideally, this guidance would be officially recognized by CBs, CAs and the EU Commission.
- If there is no evidence of 'use' or 'insufficient precautionary measures, and no other critical information is found, the investigation must be closed.

The participants of the workshop agreed with this proposal. They stated that *time limits* for the investigation should also be part of this instrument.

5.4.4 Supporting instrument no 6: Knowledge management

The handling of residue cases requires highly specialized skills. Lack of knowledge leads to unnecessary investigations, delays of the investigation and to unharmonized decisions.

To address this, an open-access database should be established, which documents past residue cases. It should contain a short description of

- the analytical findings and the used methodology,
- the outcomes of the investigation and
- the measures taken by the operator and by the certifier.

All of these information must be presented in anonymous form. In order to be up to date, the database should be 'self-learning'. This means that users would need to enter their own cases into the database. The data would need some maintenance by qualified staff.

The participants of the workshop agreed with this proposal. However, they pointed out that databases are complex and that it is questionable whether such a system could be managed seriously.

5.4.5 Supporting instrument no 7: knowledge on background pollution

As stated in section 4.2, the new approach should take into account background pollution. Only in this way it is possible to distinguish non-compliances from technically unavoidable contamination originating from background pollution of the environment. Background pollution and the resulting residues may vary from one substance to another, from one region to another and from one commodity to another. It could be addressed in the proposed 'residue database' (see Supporting instrument no 5: defining the limits of investigation) or in the 'standard cases' (see Supporting instrument no 9: Guidelines for handling standard cases).

This instrument was inspired by the participants of the February 2020 workshop. Indeed, inclusion of background pollution was ranked as a top priority (see section 4.2). The formal proposal for a separate instrument was developed by the project team after that workshop and could therefore not be formally approved or modified by the experts.

5.4.6 Supporting instrument no 8: specific training

As stated in the previous chapter, lack of knowledge leads to unharmonized decisions and delays. In addition to the knowledge management (see previous chapter), this could be addressed with specific trainings. These would be useful when the new concept is introduced, when new staff are employed or when new problems turn up, or new knowledge is available.

- Trainings may be conventional courses or webinars.
- For CBs/CAs, the training might be incorporated into the BTSF programme.

- Trainings should be accompanied by official training materials, which are public and can be shared.

The participants of the workshop agreed with this proposal.

5.4.7 Supporting instrument no 9: Guidelines for handling standard cases

Certain residue cases occur regularly ('standard cases', e.g. dieldrin in cucumbers; anthraquinone in tea). Their origins are well known and have nothing to do with fraud. Nevertheless, there may be known measures to reduce the occurrence of such substances.

A series of standardized 'factsheets for standard cases' should be prepared. These factsheets would

- summarize the current state of knowledge and
- advise operators on preventive measures, and
- advise CBs/CAs on necessary investigations, possibly also on certification decisions.

The participants of the workshop welcomed this proposal and pointed out that this would lead to more harmonized decisions.

5.4.8 Supporting instrument no 10: backstopping by experts

Difficult, unclear or controversial residue cases lead to different certification decisions. To address such cases, a possibility for backstopping by experts should be established. Proposed solution:

- There could be a group of highly knowledgeable, independent experts, which can be consulted in such cases. This group could be consulted for arbitration in cases where operators do not agree with the decisions of their CBs/CAs.
- The group's opinions are published in anonymized form (so that the concerned operators cannot be identified), available for all stakeholders. These opinions would provide guidance for future evaluations of similar cases.
- Ideally, this guidance would be officially recognized by CBs/CAs, control authorities and the EU Commission.

The participants of the workshop agreed with this proposal. In particular, they appreciated the possibility for consulting *independent* experts. They suggested that the group could operate as a private-public agency.

The project team would like to add that it needs to be clarified who may consult this group under what conditions, and how this is funded.

5.5 Relationship of the supplementary with the core instruments

Figure 4 and 5 illustrate how the proposed supplementary instruments (no 3 – no 10) might be integrated with the two core instruments (no 1 & 2).

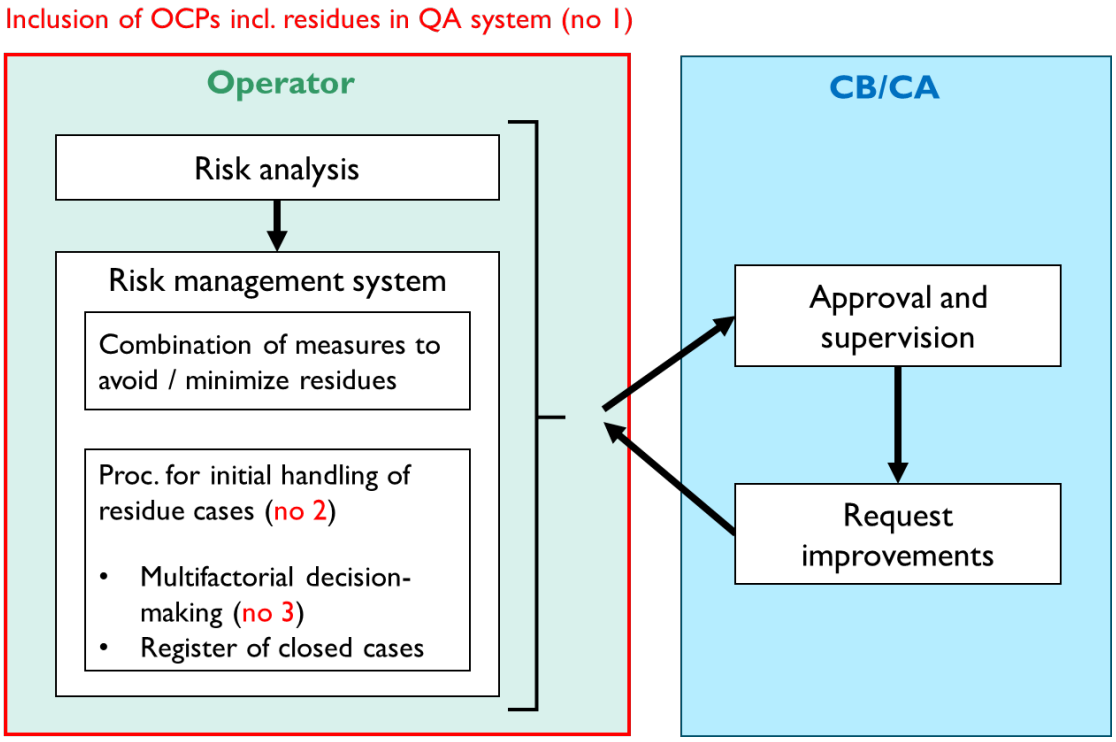

Figure 4: Inclusion of OCPs including residues in QA system, with proposed improvements. Proposed instruments are shown in red, with the same number as in the text.

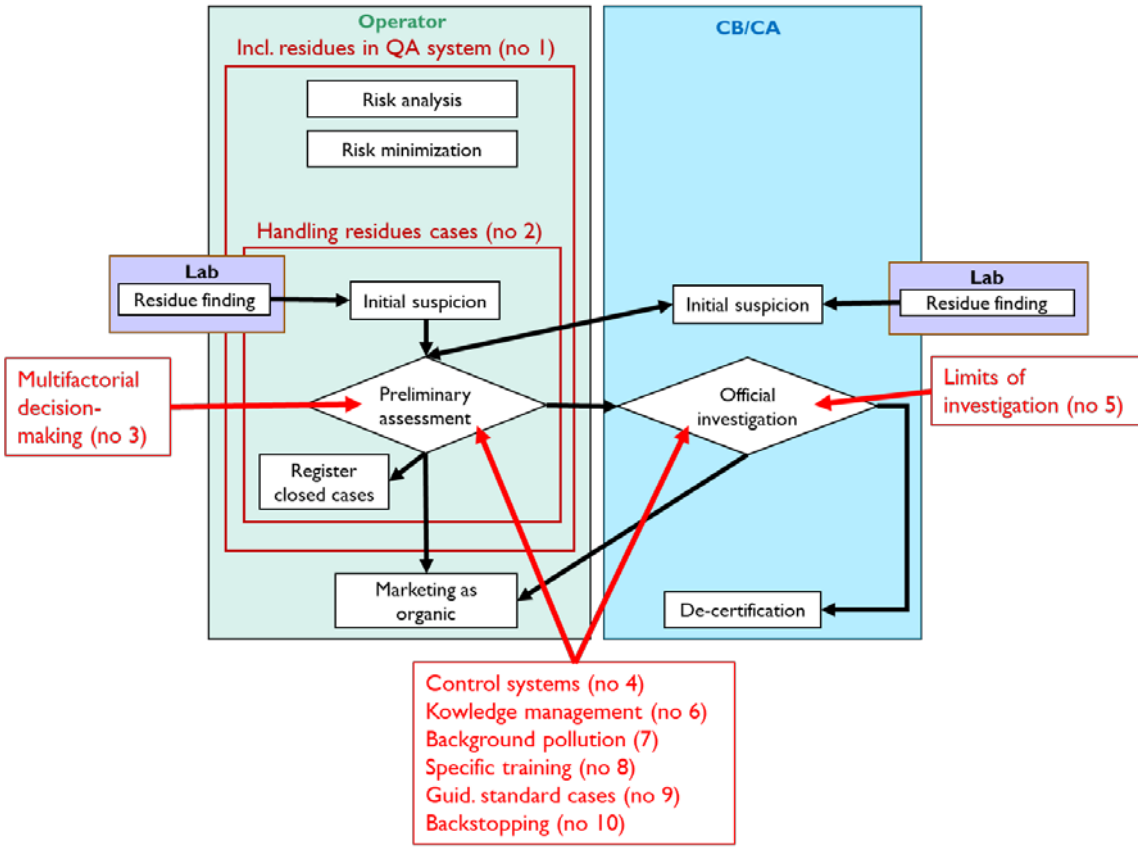

Figure 5: Procedure for handling residue cases, with proposed improvements. Proposed instruments are shown in red, with the same number as in the text.

5.6 Discussion of the supporting instruments

All of the supporting instruments were widely accepted by the participants of the workshop. The supporting instruments address various challenges. Because some instruments address more than one challenge, they can be mentioned several times below.

Instruments improving the operators QA system and its interaction with organic controls

Core instrument no 1: Inclusion of OCPs including residues in QA system clarifies the roles of operators and CBs/CAs. Core instrument no 2: Procedure for handling residue cases clarifies the decision-making process by the operator, while Supporting instrument no 3: multifactorial decision-making system provides the technical guidance for decision-making. Supporting instrument no 4: optimizing control systems for residue handling addresses the interaction of the operator's QA system including food safety audits with the organic control system. Expected achievements:

- The process can benefit from the operator's knowledge;

- better (more targeted) investigations;
- faster investigations (shorter blockage of foods).
- More harmonized decision (indicators, action points)

Instruments improving the organic control system

Supporting instrument no 4: optimizing control systems for residue handling addresses the interaction and communication between different CBs/CAs involved in a residue case. Supporting instrument no 5: defining the limits of investigation addresses the intensity and duration of investigations. Supporting instrument no 6: Knowledge management – Supporting instrument no 10: backstopping by experts address different aspects of knowledge management (see separate section below). Expected achievements:

- better / faster investigations;
- more harmonized decisions.

Instruments addressing the need for highly specialized know-how

Supporting instrument no 6: Knowledge management – Supporting instrument no 10: backstopping by experts address different aspects of knowledge management. Supporting instrument no 6: Knowledge management aims to make knowledge widely available in a database allowing targeted searches. Supporting instrument no 7: knowledge on background pollution provides knowledge needed to determine whether the presence of a substance is technically unavoidable. This knowledge could finally be made available in the same database. However, much of this information is not yet available and would need to be established by research. Therefore, this topic is presented as a separate instrument here. Supporting instrument no 8: specific training addresses the aspect of staff qualification. Supporting instrument no 9: Guidelines for handling standard cases aims to provide detailed guidance for frequently occurring cases, while Supporting instrument no 10: backstopping by experts specifically addresses demanding cases. Expected achievements:

- Knowledge generated by one operator or CB/CA is made available to all, resulting in maximum benefit for the entire organic sector.
- better (more targeted) investigations;
- better (more harmonized) decisions.

6. General reflections

This chapter provides some general reflections of the project team, which were not discussed in any workshop.

6.1 Achievement of major goals

This section discusses to what extent the major requirements can be met by the proposed instruments.

6.1.1 Fraud prevention

Fraud cases have the potential to undermine consumer trust and are therefore a major threat to organic production. Fraud prevention must be a major goal of the organic control system.

Residue analysis is one tool to make organic fraud difficult, but it cannot prevent it. Some of the big fraud cases have involved residue-free conventional food, which cannot be detected with residue analyses. If too much emphasis is put on residue analysis, there is a high risk that other signals which point towards fraud are overlooked.

- From the fraud prevention point of view, it might be argued that every investigation has the potential to detect a fraud case. From this point of view, those approaches which cause most investigations are preferable.
- Residue cases due to drift or heritage chemicals are usually not connected with fraud. From this point of view, approaches which allow treating these cases differently from other residue cases are preferable.

6.1.2 Minimizing negative side-effects

In the company questionnaire (see section 3.1), processors and traders indicated that they suffer the most severe economic impact from *interruptions / delays of the trade chain* and running out of stock (blocking of their own goods; blocking or delayed delivery of raw materials from their suppliers), while the *value loss due to downgrading* was ranked as a lower priority.

It is inevitable that residue cases impact trade chains negatively. When non-compliances are discovered, lots have to be de-certified. Any even those lots which can ultimately be marketed as organic may be blocked temporarily. The new approach should be designed in such a way that the duration of temporary blocking is minimized.

From this point of view, all approaches with investigation are less desirable than the other approaches, because blocking of goods lead to delays of delivery.

6.1.3 Compliance with organic production principles

As explained in section 1.2, organic production is characterized by the production processes. This corresponds to the case by case approach, and to a lesser extent also with the investigation level approach. However, it is difficult to reconcile with a de-certification level approach.

From the organic production principles point of view, the case by case approach, and to a lesser extent also the investigation level approach is preferable.

6.1.4 Practicability and fairness

The handling of residue cases is complex and requires highly specialized knowledge. Unfortunately, such expertise is not always available to a satisfying extent. Lack of expertise is often observed with operators as well as CBs/CAs, and is one of the key factors responsible for prolonged and/or unnecessary investigations and/or non-harmonized decisions. Another aspect is that investigations may cause enormous amounts of work, which cannot be planned in advance.

When the requirements for a new approach were discussed in the second workshop, one of the major requirements was therefore that the new approach 'must be realistically workable' (see section 3.3). Approaches which need less knowledge like the de-certification or zero tolerance approach are practicable but not fair, because they punish innocent operators and do not prevent fraud.

Easy approaches are practicable but not fair. From this point of view, the case by case approach should be accompanied by a number of instruments that makes it practicable to handle in a harmonized manner.

6.1.5 Harmonization

One on the main requirements was that the new approach must lead to harmonized decisions within the EU, and possibly beyond. Approaches with a de-certification level achieve this goal most easily, but they are not in line with organic principles. For approaches without a de-certification level, harmonization is more difficult to achieve. However, all instruments address knowledge management (no Supporting instrument no 6: Knowledge management – Supporting instrument no 10: backstopping by experts) will lead to improvements and make a case by case system workable and harmonised.

International harmonization is a key requirement for the new approach. However, harmonization which violates organic principles is not desirable. Thus, harmonization should be achieved with additional guidance and decision-making steps to a case by case approach.

6.1.6 'Polluter pays' principle

Pesticide residues are ultimately caused by pesticide application. They affect organic and conventional farmers who are not themselves the users of these pesticides. It seems thus fair that the operators using pesticides share the burden of residue handling with other, negatively affected operators, for example in the organic sector.

On the *income* side, a pesticide tax might be a useful tool. For countries which do not have a pesticide tax, an alternative solution would need to be specified. A solution might also be found in the context of the farmer's liability for applying pesticides.

On the *expenses* side, it would need to be clarified how the money is used. One possibility would be to use this money in the context of unfair de-certifications (particularly in situations of unavoidable contamination or heritage chemicals). If operators would

receive financial compensation for the value loss in such situations, a major criticism of the de-certification level approach could be mitigated, and thus that approach would be much better accepted by operators. Such a fund might want to limit payment to cases where the operator is innocent. There would need to be a clear catalogue for defining in which cases operators may use money from this fund.

It seems fair that the operators using pesticides share the burden of residue handling with other, negatively affected operators, for example in the organic sector. The details need to be elaborated.

6.2 Strategic reflections

This section discusses a number of aspects which are relevant for the process of developing a new approach for residue handling.

6.2.1 What to regulate at which level

In this report, we mainly discuss *what* might be done to improve the situation. In addition, it should also be considered *how* this is done. At which level an improvement is implemented influences in particular flexibility and harmonization. In the EU, the rules for handling residue cases are specified at different levels.

- The main principles are set in the 'framework regulation' no 2018/848, Articles 28 and 29.
- The implementing rules will be set in an 'implementation act' which is currently still under discussion.
- There will be a report in 2024 on the topic accompanied by a legislative proposal for a harmonised residue handling.
- There is complementary legislation in some EU member states.
- There could be guidance documents from the European Commission and from national authorities.
- CBs/CAs have internal procedures and policies.
- Guidance documents set up by associations and/or experts for operator.
- Operators have internal procedures and policies.

Harmonization is one of the key requirements for a new approach and of the upcoming debate in the next years preparing the final decision on the task. It can only be achieved through rules issued by the European Commission, either laws or guidance documents. Guidance can be set up on different levels. At the level of authorities, at association level or at company level. Those documents offer less legal certainty, but address the operators' needs in a more targeted way and may be adapted more rapidly to new situations. Taking into account the complexity of residue handling, it might be best to regulate certain aspects at legal level, and others at guidance document level at private or authority level.

Residue handling must be regulated at EU level. Taking into account the complexity of residue handling, certain aspects might be regulated at legal level, and others at guidance document level.

6.2.2 Official procedures versus trade policies

This report deals mainly with official procedures how CBs/CAs handle residue cases. In addition, however, many traders have their internal policies how to deal with residues (Speiser *et al.*, 2013; Neumann *et al.*, 2016). These internal policies are neither harmonized among companies, nor between companies and CBs/CAs. The new organic regulation will provide more harmonisation at this level. This means that after finding a residue and completing the investigation, a product might keep its organic certification but might not be marketed as organic, due to trade policies.

Operators need to implement their own internal policies. However, the more certainty the official procedure used by CBs/CAs offers and the more CBs/CAs take responsibility for checking the internal QA systems of operators, the more operators systems can be harmonised and operators can rely on the official procedure.

The project has decided to focus on official procedures how CBs/CAs handle residue cases and the internal QA systems established by operators. If a good solution is found at this level, some harmonization with operators' internal policies is expected.

6.2.3 Need for compromises

When we started this project, we liked to contribute substantially to the ongoing debate for an harmonised residue approach. Unfortunately, we could not identify a single approach (old, new, or old with amendments) which can fully meet all requirements of the sector. Nevertheless, it is important to find a harmonized solution for the handling of residue cases, and so it will be necessary to make compromises. The improved approach proposed in this study aims to embed the residue topic into existing QA systems of operators and CBs/CAs. The supporting instruments mitigate shortcomings of individual approaches. This makes the resulting system better acceptable for stakeholders and should therefore prepare the path for a compromise.

The topic of residue handling has been discussed for a number of years, often with strong emotions. It is obvious that it will not be possible to fulfil all wishes of all stakeholders. We hope that the European organic sector manages to come to a *pragmatic compromise* which safeguards the critical needs of all stakeholders. All members of the organic production chain are sitting in the same boat!

It is important to find a harmonized solution for the handling of residue cases. To achieve this, it will be necessary to make compromises.

6.2.4 How to proceed

First, a decision must be taken on the general approach to be followed (de-certification level, zero-tolerance, investigation level or case by case approach). As stated previously, *the project team recommends the case by case approach*.

Next, it should be considered which instruments to implement, in order to improve the general approach and make it more practical, fairer, faster or more acceptable to the stakeholders. However, the different instruments fall into different stakeholders' spheres of responsibility. Thus, different routes must be taken for their implementation. Table 3 gives a very broad overview which stakeholders would in general be most competent for addressing the different instruments.

Table 3: Competence of the main stakeholders regarding the different instruments.
Com = EU Commission; experts = independent experts, e.g. from research. *participation of Com in the case of BTSF programmes.

	operators	CBs/CAs	Com	experts
1: Inclusion of OCPs in particular residues in QA system	x	x		
2: Procedure for handling residue cases	x	x		x
3: Multifactorial decision-making system	x	x		x
4: Optimizing control systems		x	x	x
5: Limits of investigation		x	x	x
6: Knowledge management		x		x
7: Background pollution				x
8: Specific training		x	(x)*	x
9: Guidelines for standard cases		x		x
10: Backstopping				x

7. Epilogue

This study has evaluated different approaches for residue handling and has derived proposals for improvement and harmonization. The overall aim is to contribute to the political debate aiming for a harmonised approach in residue handling after 2024/2025.

However, a part of the instruments could also be implemented in the new organic regulation as part of Implementing/Delegating Acts and/or in the Organic Action Plan.

The following instruments were worked out to improve the system for handling residue cases in organic products in the context of the new EU organic legislation:

- inclusion of OCPs and in particular residues in the operators' QA systems;
- procedure for handling residue cases in the operators' QA systems;
- multifactorial decision-making system;
- optimizing control systems for residue handling;
- defining the limits of investigation;
- knowledge management;
- knowledge on background pollution;
- specific training;
- guidelines for handling standard cases;
- backstopping by experts.

The results of this research are based on intensive communication with and involvement of organic stakeholders.

After many years of debate, it is very clear that there is no easy solution. And it is very clear that the different stakeholders involved in this debate need to go forward open minded, based on scientific input and inspired by new thoughts. To provide reasonable input to this debate is the main target of the project.

In this sense the project is not presenting a final solution for the challenge. The project team has extracted from communication, workshops and questionnaires carried out in the project the most promising and inspiring cornerstones as recommendations and impulses for the ongoing debate. The main elements provided are the ten 'instruments' for an improved and harmonized handling of residue findings in organic products and processes as described in the report. The project team very much hopes that this report will contribute to move the debate forward to a fair and harmonized approach.

8. Acknowledgements

We warmly thank all companies for providing residue data, all colleagues and experts for fruitful discussions. This study has been made possible by the financial support of OPTA and a number of individual sponsors. The individual sponsors can be found on the OPTA website, see http://opta.bio.

9. Literature

AÖL, 2018. Guidelines for quality management, Version II, 27.09.2018.

Bickel, R., Speiser, B., 2019. Rückstände - benennen, verstehen, vermeiden. FiBL Merkblatt Nr 5005, Ausgabe Schweiz. FiBL Frick.

EFSA, 2018. Monitoring data on pesticide residues in food: results on organic versus conventionally produced food. doi:10.2903/sp.efsa.2018.EN-1397.

EFSA, 2020. The 2018 European Union report on pesticide residues in food. doi: 10.2903/j.efsa.2020.6057.

EOCC_Task_Force_Residues, 2018. Pesticide monitoring in organic products: Facts and figures from control bodies from various EU member states. Presentation held at BioFach 2018. https://eocc.nu/news/eocc-presentation-pesticide-monitoring-biofach-2018/.

Milan, M., Bickel, R., Speiser, B., 2019. Improving the handling of residue cases in organic production – part 1 "Quick Scan". FiBL, Frick. http://orgprints.org/35522.

Neumann, N., Speiser, B., Rüegg, E., Liebl, B., 2016. Survey 2016 of the Residue Situation in Turkish Organic Products. German-Turkish Cooperation Organic Agriculture, http://orgprints.org/32168/.

Rombach, M., Lach, G., Friedle, A., Eckert, G., Schigulski, S., 2020. MANUAL laboratory analysis and pesticide residues in the control procedure for organic farming. Prüfgesellschaft ökologischer Landbau mbH, Karlsruhe.

Speiser, B., Ertem, S., Rüegg, E., Huber, B., 2013. Survey of the Residue Situation in Turkish Organic Products. German-Turkish Cooperation Organic Agriculture, http://orgprints.org/25032/.

10. Terms and definitions used in this report

In this report, the following terms and definitions are used:

residue	=pesticide residue. Unless specified otherwise: residue of a pesticide which is not authorized for organic production.
MRL	maximum residue level
CA	control authority
CB	control body
operator	organic farmer, processor or trader
de-certification	withdrawal of the organic certificate for a food lot by the certifier
GMP	Good manufacturing practise
HACCP	Hazard analysis critical control points
BRC Food	British Retail Consortium – Food
IFS Food	International Featured Standards – Food