IFOAM EU GROUP

Guideline for Pesticide Residue Contamination for International Trade in Organic

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1. Introduction/Background

Organic farming is a production system where, instead of using chemical inputs, organic operator relies on a broad range of activities which prevent problems from occurring. It is a system that limits the use of pesticides to a very small number of natural substances. However, organic products are produced in a world where pesticides and other chemical are commonly used. Hence the risk of contamination with pesticides is always there: in the field, during processing and during transport. As with any sector, the organic sector is vulnerable to fraud. So, beside the risk of contaminations, residues in organic certified crops might also be an indication of fraud.

To secure the integrity and quality of organic certified agriculture, crops, ingredients and processed food, residue analysis has become more important over the past 10 years. It is an increasing part of the quality assurance of private companies and certification and inspection bodies in organic agriculture, trade and food processing. Different monitoring programs, like the Öko monitoring from Baden Würtemberg, "BNN residuemonitoring" (Bundesverband Naturkost Naturwaren Herstellung und Handel e.V. Organic Processors and Traders Association) by BNN in Germany and BIOKAP residue monitoring by VBP (Vereniging van Biologische Productie en handelsbedrijven) in The Netherlands show the relevance of residue monitoring. Their monitoring programs of organic products show detections of prohibited substances in between 5% to 22% of samples tested. Most of these detections are below 10ppb. It must be noted that these percentage include a high proportion of results obtained through investigations of high risk products so these percentages are not representative of the level of contamination in the whole organic sector.

Also in Belgium, Italy and France more intensive residue monitoring has been started by authorities and/or the private sector. More and more private companies in EU countries set their own private standards, including very variable levels from one system to another. Two years ago an unofficial Task Force within the Standing Committee on Organic Farming, (SCOF), the advisory committee to the Commission on organic issues, was formed to discuss individual residue cases. It seems time to really discuss the residue topic on EU level with all stakeholders and work towards a common approach.

With the rising of the daily practice of residue analysis the organic sector in the EU faces new fundamental questions in regard to the residue topic. Before the issues are mentioned it is essential to keep in mind that organic legislation is structured as legislation for a process based agriculture and food processing system. In the discussion about the need for harmonization in the residue topic, we might make the mistake of transforming a more or less privately developed action level into a strict decertification level in the EU legislation. While states such as Belgium have operated this system effectively for several years much of the EU considers that this is not the ideal way to progress at present. If the action level were transformed to decertification level, residue issues could easily replace all other important aspects of organic agriculture as the arbiter of whether a product is organic, although this has not happened in Belgium.

Organic agriculture is a method, which cannot be replaced by the absence or presence of residues under or above a certain level! On the other hand, clear, harmonized guide-

lines in the EU on residue contaminations can help the organic sector to assure and develop organic quality where there is ignorance, and prevent the downfall of organic integrity where fraud is the case.

A guidance document is urgently required for further harmonized development of the organic sector in EU. The common approach proposed in this paper is based on what is actually happening in different countries like Germany, The Netherlands and France. Only the approach in Belgium and Italy is significantly different at this moment.

This document is intended to develop as experience grows in the testing and interpretation of results of residue analysis on organic foods.

For practical reasons the baby food level was taken as action level for organic products. This practice was introduced by BNN processing and trading group in 2000 and adopted later by other operators, such as VBP BIOKAP in The Netherlands.

In Belgium the national authorities also saw the need for an action level. They based it on the Limit of Quantification (LOQ) of the substances, specifically 1.5 x LOQ. More importantly, in Belgium this level acts as the decertification level. In most other EU countries the organic sector opposes a decertification level, because there is a big risk that organic will be reduced to residue free.

2. Aims of these guidelines

The aim of this paper is to give a practical set of guidelines how to act when residue contamination occurs in any operation (company).

The implementation of this guideline by operators, associations, certifiers and authorities in all EU countries will lead to the following benefits:

1. Establish a common language in case of residue contaminations and better exchange of information between operators, associations certifiers and their authorities;
2. Improvement of the communication and collaboration between private companies, certification bodies and authorities of all EU member states about residue contaminations and risk assessment;
3. Establish a common understanding about the meaning of residue contaminations;
4. Evaluation of the action level(s) based on daily practice, exchange of information, monitoring and research;
5. Structuring of both general communication about the organic approach towards residue contaminations and crisis management in case of calamities;
6. Encourage movement towards risk based approaches for residue testing and for evaluation of results of residue testing. For some operators this risk based evaluation process will enable reduction in their sampling programme;
7. It will also ensure that targeted investigations are done on the residue detections that have the highest risk of indicating serious breach of organic regulations.

3. EU legislation on residue contaminations in both organic and non organic products

In conventional food law the legislation has set standard Maximum Residue Limits (MRL) for each substance (which vary with the crop). These levels are based on Good Agricultural Practice and assessed for safety based on the maximum daily intake of the food and toxicity data.

EU pesticide regulations confirm that foods cannot be sold if they contain pesticide residues at levels above the MRL.

Therefore processing or marketing of products is not allowed where the residue levels exceed the MRL. This includes products that exceed the MRLs for pesticides permitted in organic products, such as Azadirachtin (Neem), Copper, Sulphur, Pyrethrins, Rotenone and Spinosad.

In accordance with Article 26 2. of Regulation (EC) No 889/2008 processors have to "...establish and update appropriate procedures based on systematic identification of critical processing steps" (See Annex 4). The aim is to facilitate the organic integrity of the products. In Article 26 4, it is specified that in regard to the above mentioned procedure the processors shall "(a) take precautionary measures to avoid the risk of contamination by unauthorised substances or products".

The operators are obliged to have a strategy in place how to handle contaminants. Under obligations in article 91 1. of Regulation (EC) No 889/2008 the operator has to take actions if s/he "considers or suspects that a product is … not in compliance with organic production rules,..." (See Annex 5).

In order to fulfil this requirement a knowledge based action level for residues is an important tool. Such an action level for residues is to establish on company level or in a shared quality assurance system as required in article 26 2 4 of Regulation (EC) No 889/2008, as part of a strategy for handling contamination with pesticides. Above the action level a proved residue finding should create "suspicion" in accordance with the first line of article 91 1. of Regulation (EC) No 889/2008.

4. Action level

The basic tool of this guideline is a practical action level. This tool is an important cornerstone for every common approach in residue contaminations.

In the baby food law a different level has been set at 10 ppb for each substance as maximum level. When the 10 ppb level is exceeded the product legally cannot be sold as baby food.

In organic legislation no value is mentioned. This is the correct approach, because contaminations may occur from circumstances beyond the control of the organic operator. This means without blame to organic farmer or processor.

Legally, each contamination could be understood as a suspicion that the product is "not in compliance with organic production rules,..". This is currently the case in Belgium. When the practice of residue monitoring started operators came to a practical orientation or action level that means: when this orientation or action level is exceeded then the suspicion mentioned in Article 91 1 is present and the produce must be held while an investigation is undertaken. By this approach strong detailed investigations are made of the most serious contaminations.

Where the suspicion cannot be removed by investigation it becomes "substantiated" and the product should not be sold or processed as organic. At the latest then the control body or authority must be informed about the incident as soon as it is clear that the suspicion cannot be removed.

These guidelines recommend that processors base their action level on the baby food law. See next section for reasons.

The action level consists of the following points:

- 0.010 mg/kg (10 ppb) as action level with a correction factor for analytical variance of 50% (example: 20 ppb x 50% = 10 ppb).
- Recounting factors should be agreed and used for concentrated/dried fruit products to fresh product (example: A detection of 25ppb of a residue on dried apricots would equate to a level of 5.48ppb on the fresh fruit using a drying factor of 4.5.
- Exemptions for the following substances:
    - Inorganic bromide: This element may act as an indication of treatment of a product with Methyl Bromide, a fumigant not permitted in organic products. However we recommend no action level but levels above 5mg/kg should be investigated. Even if this value is exceeded and it can be shown that the total bromide is not above natural levels, the product should retain its organic status. This is due to the fact that inorganic bromide may be found naturally in several crops.
    - The action value doesn't count for plant protection agents that are listed in Annex II of Regulation (EC) No 889/2008, but contamination with these compounds must not exceed MRL.
    - The action value doesn't count for the synergist Piperonyl butoxide (PBO) when it is allowed by the organic inspection body.

  - The action value doesn't count for 4 IPA on cumin seed, when only 4 IPA is found.
  - In case of persistent residues, like DDT, it is possible to accept exceeding of the action level, where reports of the certification body confirm that use is not suspected. However, it must be noted that for many of these compounds the MRLs are set very low or at the level of detection so it may be that products containing detectable levels of these compounds may not be sold.
  - For analytical reasons, due to the natural presence of Carbon disulphide CS_2 compounds that interfere with the analysis of dithiocarbamates, the action limit does not apply for detections of dithiocarbamates in Brassicacea and Liliacea.
- Not more than two substances above the action level may be present. In the case of multiple residue findings the correction factor for analytical variance is removed. So if two substances above 10 ppb are detected then the suspicion that the crop is not organic cannot be easily removed and must be investigated before the product can be sold as organic.
- Repeated findings (more than 3 times) of the same residue(s) in different lots of the same product from the same origin but with levels below the action level is reason for further a investigation into the cause of the repeated findings of the same residue from the same origin.
- Most importantly when any product exceeds the action level it must be held and not sold or further processed as organic until the suspicion that the product may not be from organic production is removed. The suspicion can only be removed by confirming that the farming and processing of the lot conformed to the requirements of the organic regulations. If the doubt cannot be removed the product must not be sold or processed as organic. This process of tracing and investigation must be carried out by certifiers and it is only they who can make the decision as to whether suspicion is removed or substantiated as a result of their investigations.

5. Evaluation and further development

All involved parties are invited to give feedback on this guideline when new practices and new research findings give reason to amend it, or in case new exceptions to the standard action level seem to be necessary. IFOAM EU will publish a new version of this guideline after sound analysis.

We strongly underline that the proposed common approach is based on a case by case approach. An EU or international expert group might be necessary to take decisions in difficult and/or conflicting cases, or for further development and differentiation of the action value for specific substances.

Ideally, all users of these guidelines should all have the same exceptions and action limits. However, national situations may make other requirements essential. If certification bodies wish to use different levels for the action level or to impose decertification level, for any reason they should ensure that their operators are aware of these levels.

6. Reasons for using the Baby Food regulations as the action level

As a matter of principle it is impossible to find a scientifically proven level that distinguishes between application and unintentional contamination. Pesticide residues have to be interpreted individually because the degradation of pesticides depends on various factors. So an action level alone cannot provide information about the cause of the residue detection.

The proposal to start with the 0.010 mg/kg (10 ppb) as action level, (EU Directive for Baby Food 91/321/EEG), is not based on scientific evidence. It is proposed for practical reasons, because:

1. it is adopted by most initiatives from the private organic sector,
2. it is adopted by several certification bodies and
3. it is adopted/accepted by several national authorities.

Annexes

Annex 1

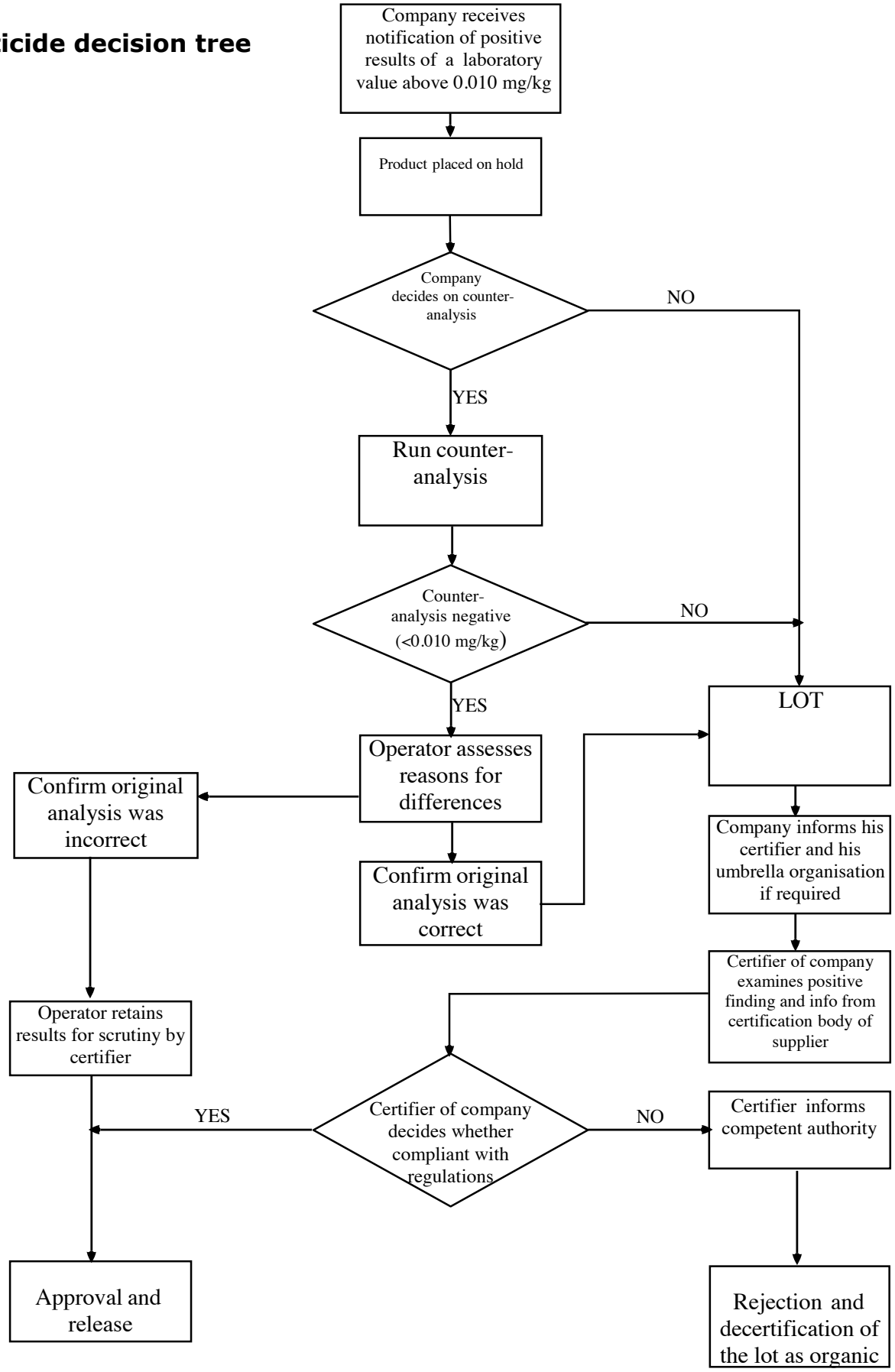
Recommendations for further work

Further investigation is needed in the following areas:

- Seeds and sowing material needs further investigation in terms of the appropriate action level. This investigation has started at the Wageningen University in The Netherlands.
- Further investigation is needed for the recounting factor for other dried products than fruits.
- Further investigation is needed about the position of different metabolites in different crops as accepted indication of the intentional use of active chemicals.
- An international or EU expert group may be required to decide on areas where there remains conflict or disagreement.
- It is important to collect case studies from Certification Bodies (CBs) and umbrella organizations and to publicise them without naming operators to enable common approaches to specific cases to be developed.

Annex 2

Pesticide decision tree



Note to decision tree: The details of the process of counter analysis are complex and have been oversimplified in this diagram.

Annex 3

Sampling organic products and soil testing

Formal sampling for pesticide analysis should be carried out according to ISO 13690. However, this is not always possible or desirable. Usually sampling will be done by operators on an informal basis. Investigations will often target higher risk areas and therefore will not be regarded as formal samples. For all sampling the relevance of all results must be considered together. In all cases sampling must be done in such a way as to prevent contamination of the sample with any material, whether from atmosphere, packaging, other products or any other sources. Samples must be handled so as to minimise deterioration of the products and prevent contamination.

Sampling Procedures

Because contamination can arise from packaging materials and from incorrect handling procedures, detailed special requirements may be required. If in doubt the sampler should check with the laboratory that will do the analysis as to the sampling method, packaging and handling. Where it is not clear from the sampling procedures outlined below, guidance may also be needed for sample size.

Sampling will normally be done into a clean plastic container or plastic bag.

Samples must be labelled and sealed so that opening them breaks the seal.
To avoid sample contamination leading to a misleading result, samplers must comply with the following procedure:

- Hands to be thoroughly washed prior to sampling, or any subsequent sub sampling. Avoid touching or handling the sample. Sampler must either use latex gloves, the sampling bag itself or a clean scoop.

- Only clean polythene bags or containers must be used (not polypropylene or PVC).

- When taking a sample it is essential that the sample should be representative of the whole lot.

- Samples must be stored in clean and dry conditions.

- It may be necessary to freeze or chill samples as soon after sampling as possible. If samples are taken frozen, or are frozen after sampling they must be kept frozen up to arrival at the laboratory.

- Sampling by official bodies or CBs must normally be done in triplicate. One sample should be left with the owner of the lot. One of the remaining two portions should be retained by the sampler/CB for recheck at a second laboratory if required.

CBs should normally obtain a consent form. However, CBs may take samples where an operator refuses to sign the form.

Sampling Methods

Depending on the nature of the sample being taken, there are two sampling methods, informal and formal. Informal sampling is defined as not following statistically appropriate methods described below. For example, taking a sub sample of a licensee's retained routine sample would be classed as informal, as would taking a product off a production line, or just taking some product from a bulk bag or on floor store.

Formal Sampling should be done in the following situations:
- Where contamination has previously been identified following informal sampling, and this sample is to confirm the result,
- Where a Certification Body is taking samples.

However, it is not possible to take a formal sample in all cases due to unavailability of the batch concerned or access problems (such as silos). In this case an informal sample may be taken and used as the basis of a decision on the organic certification of a batch of product or entire operation.

Samples must be taken from clearly defined lots. A "lot" is an identifiable quantity of goods having common properties or uniform characteristics. In the field, a lot would comprise a crop of a single variety in a clearly defined area which has been treated as a single crop. In post harvest situations, whether in bulk, or packaged goods, the lot should reflect the field lot as near as possible. In processing operations the lot may be a 'batched' delivery of raw materials or a clearly defined production run of goods awaiting dispatch.

In order to arrive at a "laboratory sample" for analysis, a number of primary samples are taken from the lot, which are combined to form the bulk sample. Where possible the bulk sample should be sent for analysis as the laboratory sample. Depending on guidance from the laboratory the bulk sample may need to be reduced in size.

Soil sampling is included here because processors, importers, CBs etc may need to carry out investigations of sources of contaminations including investigations on farm, in co operation with the farmer concerned.

Soil Sampling

Visually split the field/block up into 4 ha (10 acre) blocks. Walk the field in a W shape avoiding headlands and any unrepresentative areas e.g. gateways and water troughs. Take samples along the arms of the W.

The number of samples to be taken will depend on the size of the block but as a guide the following criteria should be used:

Area of Lot in hectares	Minimum number of primary samples to be taken
Less than 0.5 ha	4
0.5 ha to less than 2.5 ha	4 to 8
2.5 ha to less than 25 ha	8 to 20
25 ha to less than 250 ha	20 to 70
Greater than 250 ha	70 +

Take a sample of the top 6” or 150mm using a trowel or auger and put into a clean bucket or polythene bag. The actual quantity is not important but about 0.5kg per sample should be enough. Combine all samples from each 4 ha (or less) block. Remove stones, bulky plant material and soil fauna from the samples as they are taken.

Mix the samples together on a clean plastic sheet by rolling the soil about. Divide the soil into four and discard the two opposite quadrants. Repeat for each bulked sample until about 1 kg of soil is left.

Crop/Tissue Analysis

Every sampling situation must be evaluated before starting to avoid those parts of the lot which are likely to be highly variable, but to ensure that the remainder of the lot is represented in the sample. Specifically diseased or infested product should be avoided unless this is typical of the lot.

Establish area of field/plot in hectares and determine the number of primary samples to be taken (according to the guidelines outlined for soil sampling).

Avoiding 2m area at edge of field/plot (1 tree for top fruit) the lot should be divided into sections according to the number of primary samples required. (These should approximate to square sections rather than strip sections.)

One primary sample is taken per lot section. One whole plant, or the product of one plant is taken. For fruiting crops samples are taken from both sides of the plant as well as upper and lower fruits.
For fruit and vegetable packers samples may be taken before or after packing or both. To investigate the supply, take samples before packing if possible. To evaluate risks of contamination at the packer, samples both before and after packing are required.

Grain Sampling

When sampling grain stores, a sampling spear should be used wherever possible. It will consist of either a hollow ‘bullet’ screwed onto the end of a draining rod or a tubular spear in one or more pieces. It must be clean before use. Samples are taken from a number of positions and depths and mixed in a clean bucket. If no spear is available, samples should be taken from as far from the surface as can be reached. Additional access may be possible from access hatches in storage bins. Clean boots must be used for walking on grain. Note safety concerns.

About 1kg of grain should be sampled per 50 tonnes or part thereof. From this, a sample is drawn from the bucket and packed into a labelled plastic bag. For larger quantities, use a separate bucket for each 100 tonnes.

If there is a risk of contamination from dust, spray or fumigant, residues are most likely to occur near the exposed surface of the grain. Where the structure has been treated with a chemical, the greatest risk will be near the walls and floors. In such cases, a second sample biased towards these high risk areas may be worth taking.

Bulk Goods

For bulk goods the number of primary samples to be taken varies with the weight of the product.

Weight of lot in tonnes	Minimum number of primary samples to be taken
Less than 10	4
10 to less than 50	4 to 8
50 to less than 500	8 to 20
500 to less than 5000	20 to 70
Greater than 5000	70 +

Divide the bulk lot into sections according to manner most appropriate for the situation. Avoid all goods within 0.5m of external surfaces and the upper surface of bulk bins. Take one primary sample per lot section.

Commodity	Minimum laboratory sample required.
Light weight Products (Up to 25g)	1 Kg
Medium weight Products (between 25g and 250g)	1 Kg (at least 10 items)
Higher Weight Products (over 250g)	2 Kg (at least 5 items)

Packaged Goods

The number of primary samples depends on the number of packs in the lot.

Number of Outers in the lot	Minimum number of primary samples to be taken
Less than 100	4
100 to less than 500	4 to 8
500 to less than 5000	8 to 20
5000 to less than 50,000	20 to 70
Greater than 50,000	70 +

The packaged lot should be divided into sections according to the number of primary samples. Take one primary sample per lot section. Ensure that samples are taken from upper, middle and lower packages to make up the primary sample. Do not sample top surface packages

Annex 4

Article 26 of Regulation (EC) No 889/2008

Rules for the production of processed feed and food

1. Additives, processing aids and other substances and ingredients used for processing food or feed and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice.

2. Operators producing processed feed or food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.

3. The application of the procedures referred to in paragraph 2 shall guarantee at all times that the produced processed products comply with the organic production rules.

4. Operators shall comply with and implement the procedures referred to in paragraph 2. In particular, operators shall:

(a) take precautionary measures to avoid the risk of contamination by unauthorised substances or products;
(b) implement suitable cleaning measures, monitor their effectiveness and record these operations;
(c) guarantee that non organic products are not placed on the market with an indication referring to the organic production method.

5. Further to the provisions laid down in paragraphs 2 and 4, when non organic products are also prepared or stored in the preparation unit concerned, the operator shall:

(a) carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non organic products;
(b) store organic products, before and after the operations, separate by place or time from non organic products;
(c) inform the control authority or control body thereof and keep available an updated register of all operations and quantities processed;
(d) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non organic products;
(e) carry out operations on organic products only after suitable cleaning of the production equipment.

Annex 5

Article 91 of Regulation (EC) No 889/2008:

Measures in case of suspicion of infringements and irregularities

1. Where an operator considers or suspects that a product which he has produced, prepared, imported or that he has received from another operator, is not in compliance with organic production rules, he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. He may only put it into processing or packaging or on the market after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method. In case of such doubt, the operator shall immediately inform the control body or authority. The control authority or control body may require that the product cannot be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated.

2. Where a control authority or control body has a substantiated suspicion that an operator intends to place on the market a product not in compliance with the organic production rules but bearing a reference to the organic production method, this control authority or control body can require that the operator may provisionally not market the product with this reference for a time period to be set by that control authority or control body. Before taking such a decision, the control authority or control body shall allow the operator to comment. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the control authority or control body is sure that the product does not fulfill the requirements of organic production.

However, if the suspicion is not confirmed within the said time period, the decision referred to in the first subparagraph shall be cancelled not later than the expiry of that time period. The operator shall cooperate fully with the control body or authority in resolving the suspicion.

Annex 6

Comment to Annex III No. 9 (Minimum Control Re-quirements) of Regulation (EEC) 2092/91

The present document has been edited in 2003 as part of the project "Development of quality assurance system for the ecological food sector with special consideration of communicational and organisational structures" and therefore makes reference to the former regulation (EEC) 2092/91. Nevertheless the main conclusions of this document are still valid.

The present document is a recommendation of the BÖLW committee.

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Legal Arguments with acknowledgements to BÖLW

Annex III No. 9 to Regulation (EEC) 2092/91[1] on organic production and indications referring here to agricultural products and foodstuffs

I. Legal Text

9. Products suspected not to satisfy the requirements of the Regulation

1. Where an operator considers or suspects that a product which he has produced, prepared, imported or been delivered from another operator, is not in compliance with this Regulation, he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product.

2. He only may put it into processing or packaging or onto the market after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method.

3. In case of such doubt, the operator shall immediately inform the inspection body or authority.

4. The inspection body or authority may require that the product not be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated.

5. Where an inspection body or authority has a substantiated suspicion that an operator intends to place on the market a product which is not in compliance with this Regulation but bearing a reference to the organic production method, this inspection body or authority can require that the operator may provisionally not market the product with this reference.
6. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the inspection body or authority is sure that the product does not fulfil the requirements of this Regulation.

7. However if the suspicion is not confirmed, the above decision shall be cancelled not later than a time period after having been taken.

8. The operator shall cooperate fully with the inspection body or authority in resolving the suspicion.

II. Comments

9. Products suspected not to satisfy the requirements of the Regulation[1] where an operator considers

"Considers" denotes "has reliable knowledge".

or suspects

A "suspicion" exists where, following the dutiful discretion of the operator, concrete and significant indications point to non-compliance. Should any suspicious factors arise during the internal inspections or based on evidence from third parties, these should first be rapidly followed up as part of an intensive, in-house investigation.
A few examples of concrete reference points are:

- inspection of incoming goods, appearance, remnants of labelling, packaging, contaminations,
- product undercuts normal market prices,
- doubts regarding the authenticity of certificates or
- the detection of residue values that point to the use of substances not permitted under the EU Org. REG.

that a product which he has produced, prepared, imported or been delivered from another operator, is not in compliance with this Regulation,

The provisions at issue serve the purpose of establishing the origin of a product and of ensuring that the regulations for organic farming were observed during all phases of production and processing. Regulation (EEC) 2092/91 uses, as evidenced by its arguments for consideration, a process-based approach.
he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product.

The operator decides which procedural steps are to be initiated based on its dutiful discretion. The aim of the procedural steps should be to stop further marketing until the questions have been resolved (so-called self-inhibited).

Insofar as the operator possesses reliable knowledge that the product is not up to the standards for production and/or processing according to Regulation (EEC) 2092/91, these measures are final in nature; otherwise they serve as a temporary safeguard.

[2] He only may put it into processing or packaging or on the market after elimination of that doubt, unless it is placed on the market without an indication which refers to the organic production method.

The aim of the provision of Annexe III No.9 EU Org. REG. is to protect consumers and market participants alike from deception vis-á-vis the product's organic status according to EU Org. REG. Divergent views held by consumers and market participants as to the quality of organic products are not of legal significance[2].

This provision does not serve the purposes of the protection of public health or food safety. This definitely must be taken into consideration when the inspection bodies or authorities decide what steps are required to be undertaken by the operator.

The operator is bound by the principle of proportionality to take measures that are:

- suitable,
- absolutely necessary,
- appropriate and
- reasonable.

This means:

- The objective defined above must always be attainable using those measures (suitability).
- In principal, the operator is only required to take the measures from the list of suitable ones that result in the least burden for the operator (necessity).
- The burden created by the required measures should be proportionate to the resulting advantages to the public; it is necessary to ensure that the limits of reasonability be preserved when generally considering the severity of the infringement versus the gravity and urgency of the arguments used to vindicate such actions (suitability/ reasonability)[3].

The operator is to establish from in-house investigations and/or the cooperation of third parties the important facts and to carry out an analysis. Concrete measures can generally be derived from the analysis itself. The exact list of the measures is made on a case-by-case basis. The demands placed on the operator should be weighed up against the Principle of Proportionality or the Ban on Excessive Punishment[4] as recognised by the supreme courts; the resultant limitations should be observed, particularly by inspection bodies or authorities.

If only traces of residue are present, the operator's investigative options are severely limited. It is often not possible to produce an unequivocal categorisation of relevant and irrelevant facts in the above sense of the word. In the spirit of the provisions laid out here, the strain on operators created by shouldering them with the unlimited bur-

den of proof is disproportionate. The reservations that often continue to linger despite intense efforts especially in the area of trace residues are acceptable according to the principle of proportionality.

[3] In case of such doubt, the operator shall immediately inform the inspection body or authority.

The general aim of this rule is to provide an explanation of the facts in question as quickly as possible based on expert information and comprehensive practical experience.

Notification is absolutely required where sufficient knowledge is available of either confirmed findings or significant, clear indications of non-compliance. Together with the notification, the operator transfers any information which could be used to support the suspicions or likewise counter them.

The operator is obligated to "immediately" notify the bodies or authorities as one of the stipulations described in Paragraph 1, Annex III No. 9. "Inmediate" is legally defined in § 121 of the german Civil Code (BGB, Bürgerliches Gesetzbuch) as follows: "without culpable delay". "Without culpable delay"[5] is not to be interpreted as immediately! In the rulings derived from the area of private law, the notified operator is legally entitled to a just period of consideration that is limited to two (2) weeks maximum[6].

In countries where private inspection bodies are commissioned with such inspection activities, notification is made exclusively to the competent private inspection body.

[4] The inspection body or authority may require that the product cannot be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated.

The corresponding provision is part of the dutiful discretion of the competent inspection body or authority. Based on the list of circumstancess presented to it and considering all the facts already established, the body is obligated to assess whether further investigations are necessary. The inspection body or authority is urged to maximally utilise its expertise and extensive practical experience towards the end of producing a rapid explanation for the facts in question and to participate in additional investigations to the best of its abilities.

[5] Where an inspection body or authority has a substantiated suspicion that an operator intends to place on the market a product not in compliance with this Regulation but bearing a reference to the organic production method, this inspection body or authority can require that the operator may provisionally not market the product with this reference.

The corresponding stipulation is contained in the dutiful discretion of the competent inspection body or authority.

- The possible sanctions available to the supervising authority or inspection body presume that it has indications that the operator would like to market the product in question **and**
- based on the facts gathered, it comes to the conclusion that clear, significant evidence **overwhelmingly** points to non-compliance.

The inspection body or authority is obligated to disclose detailed information of the considerations involved in the decision to the company. This is to be done in writing.

[6] This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the inspection body or authority is sure that the product does not fulfil the requirements of this Regulation.

Based on the facts gathered, the inspection body or authority must come to the con clusion that absolute certainty of non-compliance exists. The inspection body or authority is obligated to disclose detailed information on decisions on this matter to the company. This is to be done in writing.

[7] However if the suspicion is not confirmed, the above decision shall be cancelled not later than a time period after having been taken.

The inspection body or authority is obligated to rescind the aforementioned conditions if the suspicious factors pointing to the fact that the operator could possibly market dubious products cannot be substantiated within the given time limit. According to the intention of the legislation, such uncertain and unexplainable facts should not result in decertification.

The time limit as laid out by the inspection body or authority is to be determined following dutiful discretion and upon consideration of the principle of proportionality. The time limit is determined upon issuance of the sanction. At this legislation's time of writing, the periods discussed were between two and three weeks; this time period should act as a general frame of reference.

[8] The operator shall cooperate fully with the inspection body or authority in resolving the suspicion.

A very comprehensive investigation of the facts and the fastest possible resolution of any suspicions should all be the objective of the operator, and the inspection bodies and authorities. This demands wide-ranging co-operation, required of each party according to his abilities based on the principle of proportionality.

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NOTE THAT THIS DOCUMENT IS ALSO AVAILABLE IN GERMAN AND FRENCH.

Notes to annex 6:

1. Subsequently referred to as EU Org. REG.

2. Zipfel/Rathke, Lebensmittelrecht (Food Legislation), Bd. C 130, Vorb. Rn. 3; Rathke/Weitbrecht/Kopp, Ökologischer Landbau und Bioprodukte (organic production and eco product), Teil 1. M. III. Irreführung und ÖkoV, Rn. 161.

3. Jarass/Pieroth, Grundgesetz (basic law), Art. 20 Rn. 86 with information pertaining to the ruling of the Federal Constitutional Court (Bundesverfassungsgericht).

4.Bundesverfassungsgerichtsentscheidungen (federal constitutional court decision): Amtl. Sammlung 35, 400; 84, 72; Deutsches Verwaltungsblatt DVBl 1992, 145; Neue juristische Wochenschrift – NJW 1878, 2442; 1985, 2019; Bundesverwaltungsgerichtsentscheidungen(Federal Administrative Court decision): Amtl. Sammlung 1, 163; 30, 313; 44, 159; 51, 115; 54, 62; 56, 123; 59, 108; 62; 219; 70, 56; 70, 141; 75, 61.

5. According to opinion in general, this legal definition is equally applicable within the entire sphere of private and public law, cf Palandt/Heinrichs, Bürgerliches Gesetzbuch, § 121, Rn. 3.

6. Palandt/Heinrichs, e.s.

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