Die Öko-Lebensmittelhersteller

Guidelines for quality management

Version II, 27.09.2018

Guidelines for the assessment of cases of non-compliance with the EU Regulation on Organic Production, with particular reference to contaminants.

Introduction

The instructions for handling cases of non-compliance with the organic regulation stipulate that the primary responsibility for assessing suspected cases lies with the companies concerned. The new organic law increases the responsibility of companies for such procedures and clarifies the division of responsibilities between control bodies / government authorities and companies. This relates to all possible types of non-compliance with (violation of) the organic law. If there is any indication that a product does not comply with the provisions of the regulation, companies are required to isolate the product and investigate whether there is evidence that allows the suspicion to be substantiated.

If the suspicion is substantiated or it cannot be dispelled, the situation must be reported to the control body or the competent government authority.

As there have been significant implementation problems relating to the presence of contaminants in recent years, these guidelines focus primarily on contaminants. In this context, products and substances that are subject to the regulation's authorisation proviso are particularly relevant.

These guidelines are intended to help companies act in a technically correct and legally compliant manner in accordance with the existing regulation (Art 91 EC Regulation

889/2008) and in accordance with the new organic regulation, EU Regulation 848 2018, which will come into force in January 2021.

I. Basic principles with regard to verifying information relating to non-compliance in general

Any information about possible cases of non-compliance with the provisions of the EC organic regulation and the source of such information must first be checked for reliability.

- Is the source of the information reliable? Is the technical information sound?
- Can the information be **verified** ?
- Is additional information and data about the suppliers, the goods or the processes available? (e.g. information about origin)
- Has the traceability, and thereby the identity, of the goods been ensured?
- Do competition issues play a role with regard to the informant or the goods?

If consideration of these questions results in the "suspicion of non-compliance" becoming stronger, attention should be given to the following issues:

- Is the nature of the possible case of non-compliance one which calls into question the organic integrity of the goods or the process? In other words, does the non-compliance suggest that the organic status of the goods would be withdrawn?
- Can the information be verified? If so, an investigation should be initiated. (Comparison with data from suppliers, in-house information or technical analysis, for example)

If the investigation establishes that the suspicion is substantiated and relevant, and this means that it cannot be dispelled, the company reports the suspicion to the control body or competent government authority and makes all existing information available. (Art 27 d) and e) new organic regulation)

If the suspicion can be dispelled or it is evident that the information has no relevance with regard to the organic integrity of the goods (certification status), the goods are authorised within the company and the procedure is documented. This documentation serves as evidence that a proper investigation has taken place and sets out in writing the arguments and facts that enabled the suspicion to be dispelled. (Art 27 c) new organic regulation)

II. Special recommendations in the case of contaminants

First, it should generally be clarified whether the substance that is found is subject to the authorisation proviso of the organic regulation. If this is not the case, no action is required with regard to the regulation. (Art. 28 (2) EC Regulation 848 2018)

If the substance that is found is subject to the authorisation proviso, it must be checked whether this substance, by its nature or the concentration that is measured, constitutes evidence of irregular use

and/or non-compliance with other process requirements of the regulation, such as due diligence obligations, for example.

III. The following procedural notes, questions and criteria are intended to assist with making a judgement

Analytics:

1. Is any information regarding sampling available? Does this information allow a conclusion to be drawn regarding the population concerned?
2. Is a cross-check available?
3. Has the investigating laboratory been accredited and does it have a good reputation?
4. Is the laboratory appropriate for the relevant determination – are there laboratories that are more appropriate?
5. Is the accuracy of the results, including range of variation, correctly specified?
6. Was the range of variation taken into account in the calculation of the result and the presentation?

Recommended sequence of actions for the purpose of excluding false positive results:

7. Obtain further information about the sampling and the laboratory. Critically scrutinise the results presented. This also applies if you have commissioned the analysis yourself.
8. Analyse the cross-check.
9. Or take a new sample with representative sampling - possibly with stage-by-stage control.
10. Assign the task to a second laboratory.

If the result is confirmed, further steps need to be taken to assess the contaminants that have become evident.

IV. Check list:

Criteria to observe when making a judgement with regard to substantiating or dispelling a suspicion:

1. Is it reasonable for the active substance under analysis to be used for the affected culture or foodstuff? In other words, is its use appropriate from an agronomic or technical perspective?
   - - Are there different uses/purposes for the active substance? Are all of these subject to the authorisation proviso of the organic regulation?
   - Which additional sources for the active substance are possible?
2. Are several/additional contaminants detectable that make a particular application or a conventional origin likely?
3. 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?
4. Are comparative data available concerning the specific product or process with regard to the contaminants and the affected product or process?

a) in the product chain?
b) or in-house from the same or other sources?

5. Are there guidelines in the company's internal quality assurance system and;
   a) Are external comparative figures available, e.g. from monitoring programmes?
   b) What is the MRL for the contaminants?
   c) Are appropriate organic reference values (Organic Action Level) available?
6. Has the traceability/transparency been ensured? Is the data available within the company?
7. The homogeneity of the raw product is highly relevant with regard to the assessment and analysis of faults in the process. Is this a product mix? If the answer is yes,
   a) is it one in which only one supplier or many suppliers are represented?
   b) is it one in which one region or many diverse origins are represented?
   c) If several suppliers are represented and/or b) apply, is it possible to identify the various origins? Can a possible contamination be attributed to one or several origins?
   d) In the case of large batches, e.g. several trucks/containers, individual part batches may present positive findings. Define courses of action within the company for this purpose and, if necessary, agree proportionate courses of action with the control body.
8. Clarification of the product path // contamination possibilities:
   Commingling possibilities during transport and handling, e.g. in the intermediate storage site?
   a) Contact materials involved in transport and at storage facilities or associated with conventional goods?
   b) Different possible applications of the active substance in the product chain (crop protection, storage site protection, disinfection...)?
9. Is there any evidence of manipulation/deceit or is it likely that either or both of these have occurred? Take note of market availability and the price situation.
10. Are additional data and analysis results available from the supplier?

Findings:

If the analysis of the situation establishes that the suspicion is relevant and substantiated, and this means that it cannot be dispelled, the company reports the suspicion to the control body or competent government authority and makes all existing information available. (Art 27 d) and e) new organic regulation).

If the suspicion can be dispelled or it is evident that the information has no relevance with regard to the organic integrity of the goods (certification status), the goods are authorised within the company and the procedure is documented. (Art 27 c) new organic regulation). This documentation serves as evidence that a proper investigation has taken place and sets out in writing the arguments and facts that enabled the suspicion to be dispelled.