

Interpretation of Articles 27 til 29, 41 and 42 of the organic regulation (EU) No. 2018/848

(2. Version)

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Provisions on dealing with non-compliances and contaminants

The new EU regulation on organic farming No. 2018/848 (new organic basic regulation) governs dealing with deviations and non-compliance in Articles 27, 28, 29 41 and 42. It further develops and supplements the essential requirements of Article 30 of Regulation (EC) No. 834/2007 and of Articles 26, 63, 91 and 92 of Regulation (EC) No. 889/2008.

I. Procedure for companies in the event of suspicion of a non-compliance

„Article 27

Obligations and actions in the event of suspicion of non-compliance

Where an operator suspects that a product it has produced, prepared, imported or has received from another operator does not comply with this Regulation, that operator shall, subject to Article 28(2):“

Pursuant to the definition in Article 3 No. 57 of regulation (EU) No. 2018/848, the term "non-compliance"¹ covers every kind of non-compliance with the Regulation and delegated acts implemented in accordance with it. Thus the term "non-compliance" covers everything from minor labelling defects (e.g. with the display of the code number) that do

¹ "non-compliance": non-compliance with this Regulation or non-compliance with the delegated or implementing acts adopted in accordance with this Regulation;

not affect the correct production process for an organic product to deviations in the prescribed production process that could call into question the organic status of a product. In order to preserve the principle of proportionality, it is therefore necessary to bear in mind the aim of Article 41 (2) of regulation (EU) No 2018/848 as well as recitals 88 and 118² when evaluating a suspicion. These recitals and Article 41 (2) focus on possible violations (suspicious facts), that "(...) *affect the integrity of the organic products or the in-conversion products...*". Suspicious facts that call into question the integrity (Article 3 No.74 of regulation (EU) No. 2018/848³) of the organic foodstuff, are therefore the (special) focus of Article 27. By reference to integrity, the group of possible violations is thus limited to those that bring into question the production process and thus the organic status. Bearing in mind the definition under Article 3 No. 74 of regulation (EU) No. 2018/848, the integrity of an organic product is given, if there is no evidence of non-compliance that *affects* the organic or in-conversion *characteristics* of the product at any stage a) or of such non-compliance being exhibited *intentionally or repeatedly* b). In the case of point a) it is therefore a question of assessing whether the organic status has been compromised on any stage in the production process. This primarily concerns the characteristics of the production process from farm to retail, because the organic requirements relate to the production process as a whole. This becomes apparent from a number of examples in recitals in which the regulator deems the integrity to have been compromised, such as in recitals 43 and 62⁴, as well as in particular from the wording used in Art. 42 (1) of regulation (EU) No. 2018/848. In Article 42 (1) it says in part: „(...) that affect the organic integrity of the products (...) because non-authorized products or substances were used and non-authorized processes deployed or the products were mixed with non-organic products (...)“. Point b) of the definition of integrity concerns the intention of the operator's actions or repeated non-compliance.

2 (88): (...)actions in cases of suspected or established non-compliance, including the prohibition against marketing products as organic or in-conversion products where the established non-compliance affects the integrity of those products.

(118) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the content of (...)rules to ensure the application of measures in relation to cases of suspected or established non-compliance, in particular those cases that affect the integrity of imported organic or in-conversion products,

³ "integrity of ecological/organic or in-conversion products": the product does not exhibit non-compliance which:

a) in any stage of production, preparation and distribution affects the ecological/organic or in-conversion characteristics of the product; or

b) is repetitive or intentional;

4 (43) (...)in order to guarantee the integrity of organic production for consumers,(...)

(62) (...) In order to ensure the integrity of organic production and adaptation to technical developments (...)

- a) *„identify and separate the product concerned;*
- b) *check whether the suspicion can be substantiated;*
- c) *not place the product concerned on the market as an organic or in-conversion product and not use it in organic production unless the suspicion can be eliminated;“*

If a suspicion arises in a company that a process does not meet the requirements of the Regulation, the product must be identified and blocked, until it has been possible to eliminate the suspicion (Article 27 a) of regulation (EU) No. 2018/848.

The aforementioned check pursuant to Article 27 b) of regulation (EU) No. 2018/848 aims at determining whether the suspicion of a breach of the integrity of the organic product can be substantiated.

It must be determined whether

1. The information on which the suspicion is based can be confirmed or whether this is a case of misinformation.
2. The suspicion that has arisen could represent a non-compliance with the Regulation on Organic Farming. Non-compliance with the Regulation on Organic Farming does not apply if packaging made from non organic products is used. Packaging materials are not governed by the organic regulation.
3. The suspicion that has arisen is justified and suggests a non-compliance with the regulation on Organic Farming, but it can be clarified and resolved through simple measures (e.g. document not completed correctly – new correct document is created)

Suspicious facts can be *eliminated* or *substantiated*, e.g. via a check using the systematic approach established in Appendix II Part IV 1.2, 1.3 and 1.4 of regulation (EU) No. 2018/848, via comparable requirements in Quality Assurance for food processors or via any other information and experience that could be pertinent to the matter. The companies can carry out checks to determine whether the organic status of a product is questionable based on the facts available. However, in most cases it is not possible to

assess whether a violation has been repeatedly committed. This information is only available in its entirety to control bodies or authorities.

d) „where the suspicion has been substantiated or where it cannot be eliminated, immediately inform the relevant competent authority, or, where appropriate, the relevant control authority or control body, and provide it with available information, where appropriate;“

If the company is able to substantiate the case for a suspected non-compliance, or if the suspicion of relevant non-compliance cannot be eliminated, a notification must be made "immediately" to the authority or, where appropriate, to the control authority or control body (see recital 67⁵). In its decision of 08.09.2011⁶ (C-58/10 and others) the European Court of Justice (ECJ) declared that the word "immediately" was synonymous with "as quickly as possible", and stated that the specific period of time needed to be specified more clearly, taking into consideration the urgency for an intervention and the relevant aim of the regulation concerned. In the case of the Regulation on Organic Farming the aim is therefore one of consumer protection and the protection of honest operators. This means, the notification should be made without unnecessary delay.

e) „In verifying and identifying the reasons for the suspected non-compliance, the operator cooperates fully with the authority concerned or, where appropriate, the relevant control authority or control body.“

During the review the operator works together with all the relevant bodies, first and foremost with the control body concerned and with the control authority.

⁵ (67) *In order to ensure compliance with the requirements for organic production and to ensure consumer trust in this production method, it is necessary that operators inform competent authorities, or, where appropriate, control authorities or control bodies, of cases of suspicion of non-compliance with this Regulation, which is substantiated or cannot be eliminated, concerning products they produce, prepare, import or receive from other operators. Such suspicion may, inter alia, arise due to the presence of a product or substance that is not authorised for use in the production of a product that is intended to be used or marketed as an ecological/organic or in-conversion product. Operators should inform competent authorities where they are in a position to substantiate a suspicion of non-compliance or where they cannot eliminate such a suspicion. In such cases, the products concerned should not be placed on the market as ecological/organic or in-conversion products for as long as the suspicion cannot be eliminated. Operators should cooperate with the competent authorities, and, where appropriate, with the control authorities or control bodies, in identifying and verifying the reasons for such non-compliance*

⁶ (C-58/10 and others) about Art. 54 (1) regulation (EC) 178/2002 under Rz. 72/73

II. Procedure for the authorities in cases of suspicion of a non-compliance

From a contextual perspective, Articles 41 and 42 belong to Article 27 et seq., as they describe the procedure adopted by the authorities and control bodies responsible in the event of the suspicion of non-compliance. They supplement the stipulations in Article 27 and determine the further procedure if it should transpire that the suspicion is justified at company level or it cannot be eliminated.

„Article 41

Additional rules on measures in the event of non-compliance

- (1) Subject to Article 29, where a competent authority, or, where appropriate, a control authority or control body, suspects or receives substantiated information, including information from other competent authorities, or, where appropriate, from other control authorities or control bodies, that an operator intends to use or to place on the market a product which may not be in compliance with this Regulation but which bears terms referring to the organic production, or where such competent authority, control authority or control body has been informed by an operator of a suspicion of non-compliance in accordance with Article 27“***

In Article 41 (1) of regulation (EU) No. 2018/848 it is clarified, which duties the competent authority or control body has if it receives substantiated information pursuant to Article 27 of regulation (EU) No. 2018/848 from a company, is itself fostering a substantiated suspicion of a relevant non-compliance or if it receives substantiated information that a company intends, to use a product or to bring a product to market that does not comply with the Regulation. The focus here is on substantiated or suspicious facts which can not be eliminated, that *call into question the organic integrity of the product or of the process*⁷ (Article 41(2)). This means that the suspicious facts must be examined in order to ascertain whether the nature of the possible non-compliance actually endangers the integrity of the organic product. The wording of Art. 42 (1) of regulation (EU) No. 2018/848, which must

⁷ (...) affecting the integrity of ecological/organic or in-conversion products, (...)

also be taken into consideration, highlights the fact that the focus here is primarily on the characteristics of the production process which are decisive when it comes to the question of organic integrity.

- a) ***„it must immediately carry out an official inspection pursuant to Regulation (EU) 2017/625, in order to check compliance with the provisions of this Regulation; this inspection must be concluded as soon as possible within a reasonable period of time, taking into account the durability of the product and the complexity of the case.“***

In accordance with Art. 41 (1) (a) of Regulation (EU) no. 2018/848, the authority / control body is only obliged to carry out an immediate official investigation under the Official Controls Regulation (EU) No. 2017/625 if it has well-founded information that points to a violation of the organic integrity of the product or process. So it is not about every report but about verified findings that actually call into question the organic integrity of the product or process or compliance with the requirements for organic production (recital 69).

In the Controls Regulation 2017/625 there is no definitive definition of what is included in an "official inspection" in the area of organic control. The description simply suggests that all official control methods can be used. The legal text in conjunction with recital 69⁸ emphasises the fact that this inspection must be carried out in proportion to the nature of the suspicion and that it "*must be carried out as soon as possible within a reasonable period*". The durability of the product must be taken into account in this. In order to throw

⁸ (69) *In order to ensure a harmonised approach across the Union as regards the measures to be taken in the case of suspicion of non-compliance, especially where such suspicion arises due to the presence of non-authorised products and substances in ecological/organic or in-conversion products, and to avoid uncertainties for operators, competent authorities, or, where appropriate, control authorities or control bodies, should carry out an official investigation in accordance with Regulation (EU) 2017/625 in order to verify compliance with the requirements for ecological/organic production. In the specific case of suspicion of non-compliance due to the presence of non-authorised products or substances, the investigation should determine the source and the cause of the presence of such products or substances, in order to ensure that operators comply with the requirements for organic production and, in particular, have not used products or substances that are not authorised for use in organic production, and to ensure that those operators have taken proportionate and appropriate precautionary measures to avoid the contamination of ecological/organic production with such products and substances. Such investigations should be proportionate to the suspected non-compliance, and therefore should be completed as soon as possible within a reasonable period, taking into account the durability of the product and the complexity of the case. They could include any method and technique for official controls which is considered appropriate to efficiently eliminate or confirm, without any unnecessary delay, any suspicion of non-compliance with this Regulation, including the use of any relevant information that would permit the elimination or confirmation of any suspicion of non-compliance without an on-the spot inspection.*

as much light on the case as possible, all pertinent information and methods that can help to eliminate or confirm the suspicion can be used. The inspection can therefore also be carried out from the office desk – without an on-site inspection, if the case can be cleared up that way.

If the durability of the product and its display time in the shops are limited, as e.g. in the case of fruit and vegetables, the pertinent information and methods must be proportionate and adapted to the particular situation. For example an order for additional inspections in a country of origin in southern Europe must be carried out with express clarification of the urgency involved. If no additional information can be obtained before the end of the product's shelf life, a decision on clearance must be made before end of the product's shelf life on the basis of the information available.

b) „it shall provisionally prohibit both the placing on the market of the products concerned as organic or in-conversion products and their use in organic production pending the results of the inspection referred to in point (a). Before taking such a decision, the competent authority, or, where appropriate, the control authority or control body, shall give the operator an opportunity to comment.“

Article 41 (1) b) of regulation (EU) Np. 2018/848 requires a temporary blocking of the goods during the inspection, until the suspicion is cleared. To maintain the proportionality (recital 69) the temporary blocking of the goods by the authority or the control body, which is generally time-limited, lasts until the inspection has been carried out and the results have been presented. Whether the goods are blocked and how long they are blocked for is determined by Article 41 (1) a) and recital 69 or regulation (EU) No. 2018/848 and depends on the nature of the suspicion and the durability of the products. In the event of a blocking period, this must be kept to the absolute minimum time possible, bearing in mind the principle of proportionality.

(2) „In the event that the results of the investigation referred to in point (a) of paragraph 1 do not show any non-compliance affecting the integrity of organic

or in-conversion products, the operator shall be allowed to use the products concerned or to place them on the market as organic or in-conversion products.”

Article 41 (2) of regulation (EU) No. 2018/848 determines, that a product can be used or marketed as organic, if the results of the inspection *in the blocking period to be routinely determined (see Art 41 (1) a) reasonable period)* do not result in disqualification of the goods, since there is no relevant breach of the integrity of the goods as organic goods. ‚In dubio pro reo‘ should apply.

„Article 42

Additional rules on measures in the event of non-compliance

- (1) In the event of non-compliance affecting the integrity of organic or in-conversion products throughout any of the stages of production, preparation and distribution, for example as result of the use of non-authorized products, substances or techniques, or commingling with non-organic products, competent authorities, and, where appropriate, control authorities and control bodies, shall ensure, in addition to the measures to be taken in accordance with Article 138 of Regulation (EU) 2017/625, that no reference is made to organic production in the labelling and advertising of the entire lot or production run concerned.***
- (2) In the event of serious, or repetitive or continued non-compliance, competent authorities, and, where appropriate, control authorities and control bodies, shall ensure that the operators or the group of operators concerned, in addition to the measures laid down in paragraph 1 and any appropriate measures taken in particular in accordance with Article 138 of Regulation (EU) 2017/625, are prohibited from marketing products which refer to organic production for a given period, and that their certificate referred to in Article 35 be suspended or withdrawn, as appropriate.”***

Article 42 clarifies that in the case of an *identified non-compliance* affecting the integrity of an organic product or of the corresponding process, the competent authorities or, where appropriate, the control authorities and/or the control bodies, can prohibit the marketing of the product as an organic product (Article 41 (1)). It is also quite clear from the examples given in article 42 (1) that this not only refers to defects ascertainable in the product, but also violations during the process that cannot be quantified in the product: for example, the use of non-authorized products and not just the analytical evidence of non-authorized products. In the case of major or repeated non-compliance, the organic certificate can be withdrawn from the company temporarily or permanently and a marketing ban be imposed (Article 42 (2) of regulation (EU) No. 2018/848).

III. Requirements for companies in the event of the suspicion of non-compliance, triggered by contamination

Article 28 of the new Regulation on Organic Farming deals with precautionary measures to avoid the risk of contamination through the use of products and substances that are not authorized pursuant to the Regulation.

„Article 28

Precautionary measures to avoid the presence of non-authorized products and substances

(1) In order to avoid contamination with products or substances that are not authorised in accordance with the first sub-paragraph of Article 9(3) for use in organic production, operators shall take the following precautionary measures at every stage of production, preparation and distribution:“

Firstly, in Article 28 (1) of regulation (EU) No. 2018/848 it is definitively clarified that it only refers to the products and materials that are subject to the authorisation proviso

of the Regulation on Organic Farming pursuant to Article 9 (3)⁹ of regulation (EU) No. 2018/848.

In accordance with the provisions of Article 9 (3) 1) and the reference there to Articles 24 and 25 of Regulation (EU) No. 2018/848, this relates to the products and substances governed in Article 24 (1) a) to g) and (2) a) to c), such as fertilisers, soil conditioners, feed, feed additives, pesticides, cleaning and disinfection agents as well as additives and technical adjuvants for processing, and to conventional ingredients permitted in accordance with Art. 25.

The global term "*presence*" with regard to the operational implementation of the stipulation and the maintenance of proportionality requires the specification of the suspicious facts that, pursuant to Article 29 (2) a) of regulation (EU) No. 2018/848, suggest the "*use*" of a non-authorized product or substance in the organic production process or pursuant to Article 29 (2) b) of regulation (EU) No. 2018/848 indicate *that precautionary measures* have not been taken. Processes that call into question the organic integrity of the product or the production process are relevant here.

Furthermore, it is clarified that all companies on every stage along the value chain must implement measures in those areas that are under *their control* (recital 68¹⁰).

- a) „They shall put in place and maintain measures that are proportionate and appropriate to identify the risks of contamination of organic production and products with non-authorized products or substances, including systematic identification of critical procedural steps;“**

⁹ 9(3) *For the purposes and uses referred to in Articles 24 and 25 and in Annex II, only products and substances that have been authorised pursuant to those provisions may be used in ecological/organic production, provided that their use in non-ecological/non-organic production has also been authorised in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law.*

¹⁰ 68 *In order to avoid the contamination of ecological/organic production with products or substances that have not been authorised by the Commission for use in ecological/organic production for certain purposes, operators should take proportionate and appropriate measures which are under their control to identify and avoid risks of such contamination. Such measures should be regularly reviewed and adjusted if necessary.*

What is new is that the measures must be *proportionate and appropriate* and apply to products and substances that are subject to the authorisation proviso of the Regulation and are limited to fields of activity that are within the *control* (recital 68) of the company.

- b) They shall put in place and maintain measures that are proportionate and appropriate to avoid risks of contamination of organic production and products with non-authorised products or substances;***
- c) They shall regularly review and adjust such measures; and***
- d) They shall comply with other relevant requirements of this Regulation that ensure the separation of organic, in-conversion and non-organic products.***

This requirement for precautionary measures represents a further development of Article 63¹¹ of the existing EU Regulation 889/2008.

For **processing companies and feed businesses**, this rule updates what is already established in Article 26 of the existing EU Regulation 889/2008¹². From the perspective of food processors and feed manufacturers, the precautionary measures to date (pursuant to Article 26 of the existing EU Regulation 889/2008) are specified. In a clarification of the text of Article 26, in the future "only" more appropriate and proportionate measures shall be necessary. The systematic procedure is known from hygiene legislation and has been operationally established for many years within the meaning of an HACCP concept within the framework of quality assurance. These quality assurance measures can be individual to a company or can be implemented as a collective measure, e.g. in associations.

These proportionate and reasonable measures refer to the *avoidance of contamination risks*. In analogy to the HACCP concept in hygiene legislation, the legislator requires the systematic managing of risks in order to avoid non-authorised products and substances. These risks at critical control points (OCCP - Organic Critical Control Points) must be

¹¹Art. 63 Description of measures that the operator shall subsequently keep up to date:

c) the precautionary measures to be taken in order to reduce the risk of contamination by unauthorised products or substances and the cleaning measures to be taken in storage places and throughout the operator's production chain;

¹²Article 26 (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;

identified, the measures to contain them must be determined and regularly reviewed. It is therefore a question of a *risk minimisation concept* and not a procedure for the complete exclusion of non-authorised materials and products.

As with all the other requirements of the Regulation on Organic Farming, the implementation of the precautionary measures to avoid contamination are also monitored and confirmed by organic inspection. This means that the risk minimisation concept and the precautionary measures taken are part of the organic certification process and that organic businesses and companies receive confirmation via this certification that they have implemented said measures appropriately. Companies can rely on this confirmation from the organic certification, when buying products from their suppliers.

Raw material traders and **importers** must establish systematic concepts to keep control of the risk of contamination under this new requirement.

For **agricultural farms**, the provisions regarding precautionary measures are more detailed than those set out in the provisions of Art. 63 of Regulation (EU) no. 889/2008. The aim is to systematically review possible entry routes for non-authorised products and substances in accordance with Article 9 (3) (1) and to take measures to avoid risks of contamination with these substances and products. Such contamination risks arise in particular for mixed farms with both organic and conventional operations, which are the exception in Germany but continue to be the norm in the EU, as well as at the 'interfaces' with conventional farms and the technology used on them.

Precautionary measures in the case of parallel organic and conventional production or in businesses with operational units in conversion, for example, are such as guarantee the safe segregation of operating materials, machines, storage and operating facilities. Similarly, precautionary measures with regard to the commissioning of service providers, who are also engaged by conventional farmers (such as machinery pools, transport companies) are necessary, which are aimed at ensuring the necessary cleaning measures between batches, for example, are conceivable. This also applies to cooperation companies.

The limitation to proportionate and appropriate measures, which are under the direct control of the operator leads to measures, which therefore concern its own conduct or conduct that it can control by issuing instructions (*vis-à-vis* employees, service providers or subcontractors).

Conduct in the neighbourhood is not included for example. And it cannot be assumed that the Organic Regulation that applies throughout the EU can demand or even force far-reaching intervention into the farming practices of conventional neighbouring businesses and thus into the ownership rights of third parties.

In this respect, nor does the new Organic Regulation require that organic farmers must proactively draw the attention of their neighbours to their right to injunctive relief, such as with regard to plant health measures not permitted in organic farming, in order to meet their precautionary requirements under Regulation (EU) no. 2018/848. In addition, a claim for injunctive relief by a landowner/estate manager under German civil law (§ 1004 (1) (2) of the German Civil Code) can generally not be made in advance, but only when a disturbance has already occurred and there is a risk of recurrence in the future. In addition, the cause of the damage must also be proven to be attributable by the injured party to a perpetrator.

It is therefore also not to be assumed that by restricting measures to those that are proportionate and appropriate the new Organic Regulation requires organic farmers to take new measures such as hedge planting or buffer strips, which, even under the present law without this restriction, are not seen as necessary.

Overall for farmers it is a question of precautionary measures in areas where there are relevant carryover risks that can jeopardise the integrity of the organic products.

Based on the provisions of the new regulation it will however be necessary for agricultural businesses to analyse the processes in their operations systematically, in order to identify where there is an increased risk of infiltration of non-authorized materials. Based on this adequate precautionary measures and procedures for implementation and self-monitoring have to be determined and introduced in agricultural operations. This is especially relevant for agricultural operators, who have parallel organic and conventional operations or cooperate closely with conventional structures. This specification of the precautionary measures must be regularly updated. The precautionary measures can be restricted to those proportionate and appropriate measures that lie within the company's scope of influence. They must be regularly documented, because it is the task of the control authorities and control bodies to check the appropriateness of the content of these precautionary measures and to ensure that they are in place (Art. 38 (1) a) of

regulation (EU) No. 2018/848¹³) and they will consult the company's documentation for this.

If, for example, there is a case of spray drift for which neither the organic operator nor his personnel is responsible, i.e. due to the involvement of external third parties, this has to be viewed as not having been caused by the organic operator and thus as unavoidable.

(2) ***„Where an operator suspects, due to the presence of a product or substance that is not authorised pursuant to the first sub-paragraph of Article 9(3) for use in organic production in a product that is intended to be used or marketed as an organic or in-conversion product, that the latter product does not comply with this Regulation, the operator shall:“***

Article 28 (2) of regulation (EU) No. 2018/848 clarifies that only contamination by products and substances that are subject to the authorisation proviso of the Regulation and that call into question the organic integrity of the goods is the object of this Article. The global term "*presence*" with regard to the operational implementation of the stipulation and the maintenance of proportionality, requires the specification of the suspicious facts that, pursuant to Article 29 (2) a) of regulation (EU) No. 2018/848 suggest the "*use*" of a non-authorized product or substance in the organic production or that pursuant to point b) indicate *that precautionary measures* have not been taken. It has to be assumed that in all other cases the any contamination is an unavoidable one. The mere presence of a contamination with a non-authorized product or substance does not say anything about the question, whether really a relevant violation of the regulation exists.

As with all the other requirements of the Regulation on Organic Farming, compliance and appropriateness of the precautionary measures to avoid contamination as well as non-application of non-authorized substances is also monitored and confirmed by organic inspection.

¹³ Article 38 (1) Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall include, in particular:

(a) the verification of the application by operators of preventive and precautionary measures, as referred to in Article 9(6) and in Article 28 of this Regulation, at every stage of production, preparation and distribution;

Non-compliance with already enacted regulatory requirements pursuant to Article 29 (2) (c) of regulation (EU) No. 2018/848 can only be checked by a company if it knows about them, which usually is not the case.

- a) ***„identify and separate the product concerned;***
- b) ***check whether the suspicion can be substantiated;***
- c) ***not place the product concerned on the market as an organic or in-conversion product and not use it in organic production unless the suspicion can be eliminated;“***

Further requirements of article 28 (2) of regulation (EU) No. 2018/848 concerning the obligations of companies in the event of suspicion of non-compliance due to contamination are a repeat of the requirements from Art. 27 of the same regulation for the special case of the presence of non-authorized materials and products. Thus the same requirements apply.

The aforementioned review under Art. 28 (2) (b) seeks to establish whether the suspicion that there has been a violation of the integrity of the organic products, by the use of non-permitted substances or products and/or lack of precautionary measures, appears to be justified. It must therefore be checked whether the information available is correct; and if the suspicion is confirmed, whether it substantiates a possible infringement of the Organic Regulation depending on its nature and focus and/or if the suspected defect can be eliminated.

If a suspicion arises in a company that a process does not meet the requirements of the regulation, the product must be blocked, until it has been possible to eliminate the suspicion. A suspicion is substantiated, if the occurring contamination suggests the active use of a non-authorized substance or lack of precaution against contamination risks.

Suspicious facts can be *eliminated*, or *substantiated* by applying the systematic concept established pursuant to Article 28 1) of regulation (EU) No. 2018/848, comparable requirements in Quality Assurance or based on comparable data and cases.

- d) *„where the suspicion has been substantiated or where it cannot be eliminated, immediately inform the relevant competent authority, or, where appropriate, the relevant control authority or control body, and provide it with available information, where appropriate;“*

If an inspection of the company proves the suspicion of non-compliance to be justified, the authority must be informed immediately.

- e) *„fully cooperate with the relevant competent authority, or, where appropriate, with the relevant control authority or control body, in identifying and verifying the reasons for the presence of non-authorized products or substances.“*

The operator is obliged to assist with clarification of the suspicious facts.

IV. Procedure by the authorities in the event of the suspicion of non-compliance,, triggered by contamination

„Article 29

Measures to be taken in the event of the presence of non-authorized products or substances

- (1) Where the competent authority, or, where appropriate, the control authority or control body, receives substantiated information about the presence of products or substances that are not authorised pursuant to the first sub-paragraph of Article 9(3) for use in organic production, or has been informed by an operator in accordance with point (d) of Article 28(2), or detects such products or substances in an organic or an in-conversion product:“*

Article 29 (1) of regulation (EU) No. 2018/848 clarifies the duties of a competent authority or, where appropriate, control authority/control body if this should receive *substantiated information* about the presence of a substance that *calls into question the organic integrity of the product or the process* (Article 29 (2) of regulation (EU) No. 2018/848) . Such information

can come from a company or from the results of their own investigations (see explanations relating to Art. 41 of regulation (EU) No. 2018/848).

The global term "*presence*" with regard to the functional implementation of the stipulation and the maintenance of proportionality, requires the specification of the suspicious facts that, pursuant to Article 29 (2) a) of regulation (EU) No. 2018/848 suggest the "*use*" of a non-authorised product or substance in the organic production or that pursuant to point b) indicate *that precautionary measures* have not been taken. During the organic inspection it is checked whether adequate precautionary measures have been taken. For this it is necessary to focus on the processes that call into question the organic integrity of the product (Article 29 (2) of regulation (EU) No. 2018/848).

It concerns well-founded or unresolved suspected cases caused by the presence of unauthorised substances and products that are subject to the conditional approval of the Regulation and/or precautionary measures that have not been taken. When assessing precautionary measures that have not been taken and measures to be derived from this, it must be taken into account that Art. 28 and Art. 29 (3) provide that a review of the precautionary measures can also result in rectification. It is thus clear that at least previously unknown risks cannot constitute grounds for disqualification.

Based on the reference to Art. 28 (2) and the connection with Art. 27 and recital 69, it has been clarified that in the event of an official determination of contamination, a check must be carried out to determine whether the presence of contamination points to a relevant violation that calls into question the organic integrity of the product and the information therefore represents *a reasonable indication of the use of non-authorised substances or products or of precautionary measures that have not been taken.*

- a) *„it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 with a view to determining the source and the cause in order to verify compliance with the first sub-paragraph of Article 9(3) and with Article 28(1); such investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case;“***

Art. 29 (1) (a) requires that, in these suspected cases that are justified or cannot be resolved, an official investigation be carried out without delay – although only when there

is well-founded information regarding the presence of a substance or product that calls into question the organic integrity of the product or process.

In the Official Controls Regulation (EU) no. 2017/625 there is no definitive definition of what is included in an "official inspection" in the area of organic control. The description simply suggests that all official control methods can be used.

Well-founded information in this case refers to checked information that actually justifies a relevant suspicion and is not just a positive finding that, for example, is due to omnipresent pollution or unavoidable contamination and does not indicate a violation.

In accordance with the requirements of Article 29 (1) a) explanations in recital 69 of regulation (EU) No. 2018/848 the sources of and reasons for the presence of non-authorised materials must be investigated in order to guarantee that the company has complied with the requirements of the organic Regulation.

According to recital 69¹⁴ this investigation must be carried out in a manner proportionate to the nature of the suspicion and as quickly as possible in an appropriate period of time. The durability of the product must be taken into account and can limit the duration of the inspection. The intention is to speed up the investigation, as the goods are blocked during that time (see Article 29 (1) b)). In order to throw as much light on the case as possible, all the pertinent information and methods that can help to eliminate or confirm the suspicion can be used. The investigation can therefore also take place from the office desk without an on-site inspection, if the case is clearable that way (compare explanations relating to Article 41 (1) a) of regulation (EU) No. 2018/848).

b) „it shall provisionally prohibit both the placing on the market of the products concerned as organic or in-conversion products and their use in

¹⁴ (69) In the specific case of suspicion of non-compliance due to the presence of non-authorised products or substances, the investigation should determine the source and the cause of the presence of such products or substances, in order to ensure that operators comply with the requirements for organic production and, in particular, have not used products or substances that are not authorised for use in organic production, and to ensure that those operators have taken proportionate and appropriate precautionary measures to avoid the contamination of organic production with such products and substances. Such investigations should be proportionate to the suspected non-compliance, and therefore should be completed as soon as possible within a reasonable period, taking into account the durability of the product and the complexity of the case. They could include any method and technique for official controls which is considered appropriate to efficiently eliminate or confirm, without any unnecessary delay, any suspicion of non-compliance with this Regulation, including the use of any relevant information that would permit the elimination or confirmation of any suspicion of non-compliance without an on-the spot inspection.

organic production pending the results of the inspection referred to in point (a)."

Art. 29 (1) (b) of Regulation (EU) no. 2018/848 requires a temporary blocking of the product during the official examination, until the suspicion is clarified. In order to ensure proportionality (recital (69) (...) *as quickly as possible within a reasonable period of time*), the temporary blocking of the goods by the authority or control body is limited to the time it takes for the investigation to be completed and the investigation results made available (see in this respect the statements regarding Art. 41(1) b) of Regulation (EU) No. 2018/848).

- (2) ***„The product concerned shall not be marketed as an organic or in-conversion product or used in organic production where the competent authority, or, where appropriate, the control authority or control body, has established that the operator concerned***
- a) has used products or substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production;***
 - b) has not taken the precautionary measures referred to in Article 28(1); or***
 - c) has not taken measures in response to relevant previous requests from the competent authorities, control authorities or control bodies“***

Article 29 (2) of regulation (EU) No. 2018/848 defines the decision criteria regarding which conditions enable the disqualification of a batch as an organic product to be declared, meaning the goods can no longer be used or marketed as organic. Crucially, Article 29 (2) a) includes use of the term "*used*". "Used" emphasises the procedural approach of the Regulation. This means that contamination is to be judged according to whether the non-authorized materials were used by the company. Article 29 (2) b) aims to identify, whether the company has taken the proportionate and reasonable precautionary measures to avoid contamination risks and in point c) if measures already issued to the company by the authorities have been implemented.

If the results of the investigation *in the blocking period to be routinely determined (Art 29 (1) a) of regulation (EU) No. 2018/848 „reasonable period“*) do not result in disqualification of

the product or process due to proof of a non-compliance, the products may continue to be marketed as organic products. ‚In dubio pro reo‘ should apply.

(3) „The operator concerned shall be given an opportunity to comment on the results of the investigation referred to in point (a) of paragraph 1. The competent authority, or, where appropriate, the control authority or control body, shall keep records of the investigation it has carried out.

Where required, the operator concerned shall take such corrective measures as necessary to avoid future contamination.“

The operator has the opportunity to comment on the authority's decision. The operator is obliged to implement any corrective measures required. The authority is obliged to document the conducted investigations.

AÖL Information

The association of organic food processors is an association of over 100 European companies of the organic food industry. Members generate an organic turnover of over four billion Euros.

Contact:

Alexander Beck

Assoziation ökologischer Lebensmittelhersteller e.V.

Untere Badersgasse 8 | DE-97769 Bad Brückenau | Tel: 0049 9741- 938 733 - 0

alexander.beck@aoel.org | www.aoel.org