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Article XX/20 about obligations and actions in the event of suspicion of non-compliance

Overview about the development and relation to article 91 of regulation 889/2008

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Introduction:

Due to several reports there is a lot of uncertainty concerning article XX and 20 of the new organic regulation. Therefore we hereby offer some first technical information about the article, although the final legal text has not yet been decided on. The final legal consistency check is still missing.

The existing organic regulation (art.91 of 889/2008) states the following regulations on the handling of suspected cases of non-compliances:

> *Article 91 of EC Reg. 889/2008*
> *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.*
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> *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 fulfil 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.

3. Member States shall take whatever measures and sanctions are required to prevent fraudulent use of the indications referred to in Title IV of Regulation (EC) No 834/2007 and Title III and/or Annex XI of this Regulation.

This formulation of art. 91 are very imprecise, which has led to many different interpretations of the article. For example, there is no clear definition of what the difference is between a “consideration or suspicion” and a “substantiated suspicion” and which exact sequence of actions is necessary in relation to a market information or withdrawal.

The IFOAM EU Group and BÖLW (German organic umbrella organization) have published an interpretation to fill this gap (http://www.ifoam-eu.org/sites/default/files/page/files/ifoameu_reg_pesticide_residue_cont_guideline_201203.pdf, the updated version http://www.ifoam-eu.org/sites/default/files/ifoameu_reg_interpretation_note_art_91_20161220.pdf), which is applied on a broad basis in a number of European countries.

But there are a reasonable number of countries that have come to a complete different interpretation and have f.e. implemented decertification thresholds on basis of art. 91. Furthermore there are countries who understand from the formulation of the article, that f.e. in case of any analytical evidence of a non-authorized substance, the products need to be stopped, can provisionally not be marketed as organic and the competent authorities or control bodies need to be informed immediately. This is also the interpretation of the EU-Commission.

The basic point of IFOAM EU interpretation is that a two-step responsibility is established. Meaning, the affected operator has to evaluate on a first step, how relevant the non-compliance is and whether the suspicion can be removed. If this is not the case the suspicion becomes substantiated and the control body or authority has to be informed.

This interpretation offers an operator responsibility and decision-making in case of suspicions of non-compliances of all sorts, which is based on usual quality management procedures. Furthermore the approach supports collective Quality Management Systems working with an “action level” in relation to contaminants (as f.e. http://biokap.com/_/nl/, or http://www.n-bnn.de/qualit%C3%A4tsarbeit/bnn-orientierungswerte).

The approach describes a level of contamination, at which the mechanisms of article 91 come into force, if this level is exceeded. It establishes an area of possible findings, which are below the action level and where no measures have to be taken. This supports legal security.

1. The new regulation and it´s rules on handling suspected cases of non-compliances (Version of the 18th trialogue)

The debate about the revision has started with the proposal to deal with questions of contamination with non-compliant substances in a special way by implementing a legal action level of 0.01 mg/kg for organic products as decertification level.

In the debate of the European Council it was not possible to achieve a turning away of the special handling of contaminations, but it was possible to achieve a decision against the implementation of a decertification threshold. The parliament worked out a proposal, how to handle non-compliances in general, but it proposed a special regulation for contaminations aswell.

In general the debate has shown us, that the different european countries have very different opinions and ideas about the topic of decertification threshold, therefore focusing on this topic was not avoidable. This led to a political stalement between supporters and opponents.

The final proposal of the new regulation now states the following:

2.1 Handling of non-compliances in general:

Article XX

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

Where an operator suspects that a product he has produced, prepared, imported or that he has received from another operator is not in compliance with the requirements of this Regulation, that operator shall:

(a) separate and identify the product(s) concerned;

(ab) check whether the suspicion can be substantiated;

(b) not place the product(s) concerned on the market as organic or in-conversion product(s) and not use them in organic production, unless the suspicion can be eliminated;

(d) when substantiated or when the suspicion cannot be eliminated, immediately inform the relevant competent authority or, as appropriate, the relevant control authority or control body with, where appropriate, available elements;

(e) fully cooperate in verifying and identifying the reasons for the suspected non-compliance with the relevant competent authority or, as appropriate, with the relevant control authority or control body.

Article 20 XX regulates the general procedure in case of non-compliances. It basically uses the same formulations as the interpretation of IFOAM EU. Operators get the primary responsibility for a first evaluation of the non-compliance and the decision about the following procedure. The basic point is to evaluate if the first suspicion can be substantiated and the organic status of the product be questioned or not.

Proof can for example be provided by the in the processing area established OCP-concept (Annex II, Part IV, 1.2, 1.3 and 1.4; same words as in article 26 of 889/2008). Sadly this system again is only obligatory for processing companies.

2.2. Article 20a regulates the handling of contaminations and implements precautionary measures

Article 20a implements special rules concerning the handling of contaminants and substances in products which are subject to authorization in accordance with article 7 (1) b) of the organic regulation. The regulation so far does not know that. That is how this type of non-compliances gets a special importance

- ➔ (The word contaminant is used synonymically to the words products and substances as used in article 7 (1) b). Meaning, contamination of substances or products which are regulated by article 7 (1) b), but not authorized in accordance with article 19, are the main focus of this article. This is clarified in Article 7 (1) b) with the formulation „for the purposes mentioned in Article 19 and Article 19aa")

Art 20 a)

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

1. In order to avoid contamination with products and substances that are not authorised to be used in organic production in accordance with Article 7(1)(b) first subparagraph, operators shall take the following precautionary measures at all stages of production, preparation and distribution:

(a) Put in place and maintain proportionate and appropriate measures to identify risks of contamination of organic production and products with non-authorised products and substances, including systematic identification of critical procedural steps;

(b) Put in place and maintain proportionate and appropriate measures to avoid risks of contamination of organic production and products with non-authorised products and substances;

(c) Regularly review and adjust such measures; and,

(d) Comply with other relevant requirements of this Regulation that ensure the separation of organic and non-organic products.

The text focusses specifically on substances and products which are covered by the organic regulation. Meaning substances, which, to use them in organic products, need to be authorized.

In the current regulation this is not clear. In article 63 of 889 the very general wording "*to reduce the risk of contamination by unauthorised products or substances*" and in Article 26 of 889 *"avoid the risk of contamination by unauthorised substances or products"* is established. In both cases it is unclear which kind of substances and products are relevant.

Article 26, 889/2008

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.

These rules are being replaced by the following formulations in annex II part IV and the specifications in article 20a, 1)

1.2. Operators producing processed food [...] shall establish and update appropriate procedures based on a systematic identification of critical processing steps.

1.3 The application of the procedures referred to in point 1.2. shall guarantee at all times that the produced processed products comply with this Regulation.

1.4 Operators shall comply with and implement the procedures referred to in point 1.2., and in particular shall ***without prejudice to Article 20a***[1]*:*

(a) take precautionary measures;

(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 organic production.

Article 63, 889/2008

Control arrangements and undertaking by the operator

1. When the control arrangements are first implemented, the operator shall draw up and subsequently maintain:

(a) a full description of the unit and/or premises and/or activity;

(b) all the practical measures to be taken at the level of the unit and/or premises and/or activity to ensure compliance with the organic production rules;

(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.

Where appropriate, the description and measures provided for in the first subparagraph may be part of a quality system as set up by the operator.

Further on the text regulates precautionary measures. For processors the regulation updates the rules, which have already been established in article 26 of regulation 889/2008 for 9 years. Consequently annex II part IV 1.4 a) removes the reference to contaminants and replaces it with a reference to article 20 a). The described procedures for precautionary measures are well known from the hygiene law and have been long established in terms of HACCP Standards in quality management. Those measures can be taken internal in companies or set in a collective, as f.e. in associations.

For other areas of the value chain (farming and trading) those measures are regulated in article 63 regulation 889/2008, which is valid for all companies. Specific rules, as f.e. cleaning of harvesters or storage sites are already customary today. It might come to a new situation on the fields, as the agricultural production on the field takes places in an “open system” (with drift from the neighboring conventional fields or other entries through air). Here it is necessary to clarify, what appropriate and proportional measures are. These rules are triggering some concerns that the burden might shift to the organic farmers. From a processor´s view the existing precautionary measures (according to article 26, 889/2008) are being more specified and weakened. Contrary to the rules set in article 26, 889/2008, “only” appropriate and proportionate measures will be necessary. For farming and other stages in the value chain similar requirements are established in article 63 1 c) of 889. Even for those operators the limitation of precautions to those “appropriate and proportionate” is a clarification which can be understood as a limitation of responsibility compared to the current regulation.

2.3 Requirements for companies in case of non-compliances due to contaminations:

Article 20a

3. Where an operator suspects due to the presence of a product or substance that is not authorised in organic production pursuant to Article 7(1)(b), first subparagraph in a product that is intended to be used or marketed as an organic or in-conversion product, is not in compliance with the requirements of this Regulation, the operator shall:

(a) separate and identify the product(s) concerned;

(ab) check whether the suspicion can be substantiated

(b) not place the product(s) concerned on the market as an organic or in-conversion product(s) and not use it in organic production -unless the suspicion can be eliminated;

(d) when substantiated or when the suspicion cannot be eliminated, immediately inform the relevant competent authority or, as appropriate, the relevant control authority or control body with, where appropriate, available elements;

(e) fully cooperate in verifying and identifying the reasons for the presence of non-authorised products and substances with the relevant competent authority or, as appropriate, the relevant control authority or control body.

Here the rules as set in article XX relating to contaminants are repeated using nearly the same words. The introductory text focusses on the presence of substances and products, which require authorization in the organic regulation. If such a presence is a solid evidence for a violation of the organic law, has to, in a first step, be investigated by the operator. This investigation can take place analogue to article 20a 1).

If the first suspicion is substantiated or doubts cannot be eliminated, the control body or authority has to be informed. This means here the legal text formulates the procedure as it is long established in a reasonable number of EU member states.

4. The Commission may adopt implementing acts laying down uniform rules specifying:

- ***the procedural steps to be followed by operators as referred to in paragraph 3(a) to (e) and relevant documentation to be provided;***
- ***the proportionate and appropriate measures to be adopted and reviewed by operators to identify and avoid risks of contamination as referred to in paragraph [1] (a) to (c) ;***
- ***the details and format of the information to be transmitted by Member States to the Commission and other Member States as referred to in paragraph 6 of Article 20b].***

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

This section deals with authorization matters for updating matters of the legal regulations. The authorization for updating the rules on precautionary measures offers the possibility of practical arrangements.

2.4 Article 20 b and the actions to be taken by competent authorities in case of contaminations

20b clarifies the regulatory obligations in case of the presence of contaminants. The regulatory obligations in cases of non-compliances according to Article XX are regulated in Article 26ca) of the new regulation and will not be covered here any further, as they do more or less comply with what the valid regulation demands at the moment.

Article 20b

Measures to be taken in cases of the presence of non-authorised products and substances

4. When a competent authority, or where appropriate, a control authority or control body, receives substantiated information about the presence of products or substances that are not authorised in organic production pursuant to Article 7(1)(b) first subparagraph, or is informed by an operator in accordance with Article 20a paragraph 3 or detects such products or substances in an organic or an in-conversion product:

(a) it shall carry out immediately an official investigation in accordance with the Regulation (EU) No XXX/XXXX [Official controls Regulation to be completed as soon as possible, within a reasonable period of time, taking into account the durability of the product and the complexity of the case, with a view to determine the sources and the cause in view of verifying compliance with Article 7(1)(b) and paragraph 1 of Article 20a.

(b) it shall provisionally prohibit the placing on the market of the products concerned as organic or in conversion products and their use in organic production while expecting the results of the investigation as referred to in (a);

Point 4 clarifies, analogue to the existing regulation, that in case it gets a substantiated information, a competent authority or control body has to carry out an investigation, which is accompanied by a provisional prohibition of placing the products on the market.

Furthermore it states that an authority or control body can perform measurements themselves and thirdly it describes the situation that the authority or control body receives information about the presence of non-authorized products or substances.

For the last two points the regulation offers a very poor and vague formulation. Substantiated information about the presence of a product or substance triggers a notification, putting the product on an “on-hold” status, so that it will not be marketed as organic and further regulatory measures. The same applies to results of measurements taken by authorities or control bodies.

This does not make much sense and could cause extremely bureaucratic problems. Therefore linguistic improvements of the text are necessary/desirable for clarification

matters and to limit the “substantiated information” to those matters, where contaminants trigger doubts on the organic integrity of a product.

Taken from the context of the text, the legislators do not intend to have every presence of a product or substance followed by a administrative procedure, otherwise they wouldn´t have introduced the word “substantiated”. In the context of the whole section of Article XX and 20, “substantiated” should be referred to a substantiated Suspicion, which doubts the organic integrity of a product.

Further on by specifying in 4. a) the duration of the investigation carried out by a CB or CA with the words; “within a reasonable period of time, taking into account the durability of the product” the new regulation is putting more pressure to the CB/CA in order to come to an decision in time. It is a main implementation problem of the current regulation for operators. The current regulation does not have any indication for the decision period.

Conversations with all participants of the legislative procedure have shown that this “mistake” has been understood. A solution in the framework of the final legal and consistency review or by an accompanying note has been promised.

5. When the competent authority, [or where appropriate, a control authority or control body, has established that the operator concerned:

(a) has used products or substances not authorised in organic production pursuant to Article 7(1)(b) first subparagraph or:

(b) has not taken the precautionary measures referred to in paragraph 1 of Article 20a; or

(c) has not taken measures pursuant to relevant previous requests from the competent authorities, control authorities or control bodies,

the product shall not be marketed as an organic or in-conversion product or used in organic production.

This part of the article formulates the basis for decisions, under which conditions an authority can order to withdraw any reference to the organic production from the product.

6. The operator concerned shall be allowed to give his comments on the results of the investigation. The competent authority, or where appropriate, the control authority or control body, shall keep records of the investigation carried out. [Where required, the operator concerned shall take the necessary corrective measures to avoid future contamination.

Further procedures have to comply with the general regulations for the handling of non-compliances, as defined in Article 26 ca).

7. Four years after the date of application of this Regulation, the Commission shall present a report to the European Parliament and the Council on the state of play of implementation of this article, ~~and~~ on the presence of products and substances not authorised in organic production pursuant to Article 7(1)(b) first subparagraph and on the assessment of national rules referred to in subparagraph 2. This report may be accompanied, if appropriate, by a legislative proposal to provide for further harmonisation

Member States having in place rules providing for products containing non-authorised products and substances above a certain level not to be marketed as organic, may continue to apply these rules provided that these rules do not prohibit, restrict or impede the placing on the market as organic of products produced in other Member States in compliance with the requirements of this Regulation. Member States who apply this provision shall inform the Commission without delay.

This part states that until a decision has been made concerning this complex topic, no other member states are allowed to place rules, f.e. decertification thresholds , providing for products containing non-authorized products and substances above a certain level not to be marketed as organic.

8. The results of the investigations referred to in paragraph 4 shall be documented by competent authorities, together with any measures taken with a view to formulating best practices and further measures to avoid the presence of products and substances not authorised in organic production pursuant to Article 7(1)(b).

Member States shall make this information available to the other Member States and to the Commission via a computer system enhancing exchanges of documents and information made available by the Commission.

9. Member States may take appropriate measures on their territory to avoid the unintended presence of non-authorised products and substances in organic agriculture. Such measures shall not prohibit, restrict or impede the placing on the market as organic or in-conversion of products produced in other Member States in compliance with the requirement of this Regulation. Member States which apply this provision shall inform the Commission and the other Member States without delay.

These parts clarify that member states can take measures to avoid contaminations as for example reglementation of pesticide application on conventional farms. These measures would be thinkable for pesticides known to cause drift.

10. The Commission shall adopt implementing acts laying down uniform rules specifying the methodology on detection and evaluation of the presence of non-authorised products and substances to be applied by control authorities and control bodies.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

11. By 31 March of each year, Member States shall transmit by electronic way to the Commission the relevant information, including information collected at border control posts, relating to the previous year concerning the nature of contamination detected, and in particular the cause, the source, the level of contamination and the volume and nature of products contaminated. This information on findings of non-authorised products and substances shall be collected by the Commission ~~in~~ *through* the *computer* system ~~as~~ referred to in Article ~~[~~26~~]~~ and shall be used to facilitate the formulation of best practices to avoid contamination.

Annex I

Draft regulation

Article 7

General production rules

1. Operators shall comply with the following general production rules:

(a) the entire holding shall be managed in compliance with the requirements of this Regulation applicable to organic production;

(b) for the purposes mentioned in Article 19 and Article 19aa and the uses mentioned in Annex II , only products and substances authorised pursuant to these provisions may be used in organic production, provided that their use has also been authorised for conventional production in accordance with the relevant provisions of Union law and in accordance with national provisions based on Union law.

Annex II

The chapter about controls (articles 26a til 26e) regulates further rules for authorities and control bodies. Article 26ca section 1 til 3 picks up parts of article 30 in regulation 834/2007, which specify the actions of authorities. They should be read as addition to article XX, 20a and 20b:

Draft regulation

Article 26ca

Actions in case of suspicion + common catalogues (title to be finalised)

1. Where a competent authority, or where appropriate a control authority or control body suspects or receives substantiated information, including from other competent authorities or where appropriate from control authorities or control bodies, that an operator intends to use or to place on the market a product that may not be in compliance with the requirements of this Regulation but bearing terms referring to the organic production, or is informed by an operator in accordance with Article XX:

(a) it shall immediately carry out an official investigation in accordance with Regulation (EU) No XXX/XXX (Official controls Regulation) to be completed as soon as possible, within a reasonable period of time, taking into account the durability of the product and the complexity of the case with a view to verify compliance with the requirements of this Regulation;

(b) it shall provisionally prohibit the placing on the market of the products concerned as organic or in-conversion products and their use in organic production while expecting the results of the investigation referred to in paragraph 1(a). Before taking such a

decision, the competent authority, or where appropriate, the control authority, or control body shall allow the operator to comment.

2. In case the results of the investigation referred to in paragraph 1(a) 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.

3. Member States shall take whatever measures and sanctions are required to prevent fraudulent use of the indications referred to in Chapter IV of this Regulation.

4. Competent authorities shall provide a common catalogue of measures for cases of suspicion of non-compliance and established non compliance to be applied in their territory including by control authorities and control bodies.

5. The Commission may adopt implementing acts to specify uniform modalities for the cases where competent authorities are to take measures in relation to suspicion of non-compliance or to established non-compliance.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

In comparison the legal requirements of article 30 of regulation 834/2007:

ECC reg. 834/2007

Article 30

Measures in case of infringements and irregularities

1. Where an irregularity is found as regards compliance with the requirements laid down in this Regulation, the control authority or control body shall ensure that no reference to the organic production method is made in the labelling and advertising of the entire lot or production run affected by this irregularity, where this would be proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the irregular activities.

Where a severe infringement or an infringement with prolonged effect is found, the control authority or control body shall prohibit the operator concerned from marketing products which refer to the organic production method in the labelling and advertising for a period to be agreed with the competent authority of the Member State.

2. Information on cases of irregularities or infringements affecting the organic status of a product shall be immediately communicated between the control bodies, control authorities, competent authorities and Member States concerned and, where appropriate, to the Commission.

The level of communication shall depend on the severity and the extent of the irregularity or infringement found.

The Commission may, in accordance with the procedure referred to in Article 37(2), lay down specifications regarding the form and modalities of such communications.

AöL Information
The association of organic food processors (AöL) is a group of more than 100 european companies. AöL-Members generate an organic sale of more than 3 billion Euros.
They mainly work for political representation of interests on national and european level. No less important is the promotion of the dialogue and cooperation of the members.

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