

Potential impact of reglementation 882/2004 (Official Food and Feed Controls) on legislation of organic 834/2007 and the referring implementation rules

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Summary:

In the following proposal, EOCC presents an overview where the 834/2007 and the referring new implementation rules (draft dated 10.01.2008) give no or less requirements than 882/2004 on a topic. In those cases 882/2004 requirements would be directly valid for organic controls even though not explicitly mentioned in the 834/2007 and the implementation rules.

Aim of this proposal is:

- defining the interferences of the regulation 882/2004 and the 834/2007 where the case described above occurs,
- evaluating the potential impact of those interfering topics on organic inspection and certification,
- suggesting corrective actions in case that the impact of 882/2004 is considered as disadvantageous for the organic control system and
- giving an outlook for the following implementation process.

Four fields of interference have been identified. With regard to the potential impacts that have been disclosed for those interferences, EOCC suggests to consider the following aspects in the final draft of the new implementation rules:

- control methods given in 882/2004 may be applied for organic controls (with exception for audits) provided that the scope of inspection covers the 834/2007 and the related implementation rules
- to define in Article 60 precautionary and control measures / activities that are applicable during organic controls
- to include in Article 60(1) the statement that "...the CB is free to decide whether its inspections are announced or not"
- to add in Article 60(2) that CBs may additionally choose an accredited laboratory
- to amend Article 60 by requirements for inspectors' training (e.g. the obligation to define and set up a training program by the CB or to cover during training all requirements given in the 834/2007 and the implementation rules)
- to include in Article 60(3) a general statement that "...controls in the organic sector are restricted to a verification of requirements regarding the organic status of products /processes"
- the discrepancy between measures that cannot be delegated according to 882/2004 and measures that can be delegated according to 834/2007 and the implementation rules should be verified. Based on this evaluation, the established list of measures that *can be* delegated should be amended by measures that *cannot be* delegated.
- to clarify frequency and content of communications of inspection results
- to identify the need for control authorities (CAs) to be accredited acc. to ISO 65 or EN 45011
- risk assessment parameters given in Article 60(3) should be amended by a fourth parameter concerning "product related risks"
- responsibilities for new tasks (e.g. for granting exemptions, set up and supervision of CB lists for import etc.) have to be defined
- to include financing of CBs in Title IV stating that "CBs fix their fees appropriate to the expenses that are calculated under defined aspects"

Within an ongoing discussion and implementation process EOCC sees a strong need to clarify the relationship between controls realised by CBs regarding the respect of the 834/2007 and those realised by CAs implementing the 882/2004. Additionally, the procedures of sample taking and evaluation of analysis results given in Article 11 of 882/2004 should be verified for transferability in the organic sector.

Potential impact of reglementation 882/2004 on legislation of organic 834/2007 and the referring implementation rules

Description of the legal situation:

In the following proposal, EOCC gives an overview where the 834/2007 and the referring new implementation rules (draft dated 10.01.2008) give no or less requirements than 882/2004 on a topic. Consequence: according to the legal principle of dominance (lex specialis), in those cases 882/2004 requirements would be directly valid for organic controls even though not explicitly mentioned in the 834/2007 and the implementation rules.

The aim of this proposal is to

- define interferences of the regulation 882/2004 and the 834/2007 where the case described above occurs. These topics are considered as the ones with the highest expectable impact of 882/2004 on organic certification.
- evaluate the potential impact of those interfering topics on organic inspection and certification
- suggest corrective actions in case that the impact of 882/2004 is considered to have an adverse impact on harmonisation and/or inspectability regarding organic controls and certification
- give an outlook on topics that should be considered during the following discussion and implementation process.

Four fields of interference have been identified:

- **control activities,**
- **certification activities,**
- **risk classification and**
- **two further points (Competent Authorities and financing of CBs)**

1. Control activities, method and nature of inspections

Potential impact:

With regard to the following topics, 834/2007 provides less detailed or no information on the control system itself, e.g. on

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|---|--------------------------------------|
| 1.1 activities, methods and techniques for verification of compliance | (Art 10) |
| 1.2 performance and frequency of physical on-site inspections | (Art 3.1) ok, NIROF
Article 60(1) |
| 1.3 announcement of inspections | (Art 3.2) |
| 1.4 methods of sampling and analysis | (Art 11 and 12) |
| 1.5 inspection reports | (Art 9) |
| 1.6 management of non-compliances on site (e.g information of CAs) | (Art 3.7) |
| 1.7 inspection personnel | (Art 4(2) and 6) |

it can be assumed that the different aspects of the 882/2004 might apply for these topics of official organic controls.

Suggestion:

EOCC strongly suggests to revise or amend Article 60 of the new implementation rules considering the following aspects:

- 1.1 activities, methods and techniques for verification of compliance:
 - a) control methods: monitoring, surveillance, verification, inspections, sampling and analysis given in Art 10.1 of 882/2004 are applicable for organic controls provided that the scope of inspection is restricted on the 834/2007 and the related implementation rules. However, audits as defined in 882/2004 are not considered as suitable method for verification of organic operators.
 - b) systems verified during organic controls: implementation rules should restrict verification of compliance to requirements related to the organic status of products /processes exclusively

(and not related to any other control system). This statement should be urgently included in Article 60(3).

c) control activities: besides the precautionary and control measures to be set in accordance with Article 27.2 and 37.2 of the 834/2007, only the control activities given in Art 10.2 of the 882/2004 parts (a); (b); (e); (f) and (g) seem to be feasible and appropriate for the organic verification of compliance when the scope is restricted to the organic regulation. Therefore EOCC strongly suggests to define in Article 60 the precautionary and control measures / activities applicable during organic controls.

- 1.3 announcement of inspections: in the new implementation rules only supplementary controls given in Article 60(3) are intended to be announced or not. There is no detailed information provided for announcement of regular annual controls (Article 60(1)). Therefore the statement that “The CB is free to decide whether its inspections are announced or not.” should be included in Article 60(1).

- 1.4 sample taking: in general, it should be clarified that sampling and analysis represent just one tool to control the conformity of organic products.

Concerning the selection of competent laboratories, 882/2004 Article 12(1) restricts the choice of laboratories to those designated by CAs. This requirement seems to be far too limited for analysis of organic products since expertise and parameters of analysis required for organic products may differ from those required for analysis of food and feed safety. Therefore, Article 60(2) of the new implementation rules should be amended by the statement that CBs may additionally choose (in own responsibility) an accredited laboratory.

- 1.7 inspection personnel: the competences of and requirements for personnel performing inspections given in 882/2004 (Art 4(2) and 6) are not adequate for inspectors acting in the organic sector since in some points too detailed and in some not detailed enough. To ensure adequate competence of personnel for organic inspections, Article 60 of the implementation rules should be amended with the aspects of inspectors training that has to

a) be based on a training program that is defined and set by the CB in advance

b) cover the requirements given in the 834/2007 and the Commission regulation

2. Certification activities: delegation of measures and sanctions

Potential impact:

Since the 834/2007 does not provide detailed information on the following aspects:

- corrective measures and sanctions (Art 5.1; 54 and 55)
- action and documentary follow up in case of establishment of non-compliance (Art 54.3)
- procedures for withdrawal or replacement of a certificate (Art 30.1.a-g)
- models of certificate (OK NIROF Annex XII, EOCC commented)
- information on certificate (other official controls, consignment) (Art 30.2.a) (OK NIROF Annex XII, EOCC commented)

while the 882/2004 does, it is in all probability that the 882/2004 requirements reign over those from 834/2007. According to the 882/2004, competent authorities (CAs) handle the measures referring to non-compliances, sanctions and the entire appeals process. Moreover, it is mentioned explicitly in Art 5(1) that the activities given in Article 54 can not be delegated.

In general, the action of CAs in case of non-conformities may contribute to a more harmonized handling of non-compliances and imposing of measures in future. In this case, a grid of sanctions and eventually a grid of non-compliances including referring measures can be established on a national level (cfr. Belgian “common grid of corrective measures or sanctions”).

However, there remains a strong need to clarify the following topics:

- **tasks and measures** that may and/or can not be delegated to a CB
- **measure (Art 54) / sanction (Art 55):** definition for organic certification
- **communication of inspection results from CBs to CAs:** frequency and content
- **expertise and capacity of CAs:** accreditation according to ISO 65 or EN 45011

Suggestion:

EOCC proposes regarding

- **delegation of tasks, measures and sanctions:** according to 834/2007 CAs have to describe tasks *to be* delegated to CBs (Art 27 5a). This list should be accomplished by measures or sanctions that may *not* be delegated to CBs (according to Art 5.1 of 882/2004). For the establishment of that list, special concern should be given to discrepancy / contradiction issuing from the preference of measures that cannot be delegated according to Article 5 (1) and 54 2 (b) of 882/2004 and the statements given in Article 30 of 834/2007 and Article 85 of the new implementation rules that measures can be delegated.
- **communication of inspection results:** frequency and content of communications should be clarified
- **expertise of CAs:** in case that it is the CAs who impose sanctions in future, there would be a need that those authorities are accredited according to ISO 65 or EN 45011.

3. Risk classification

Potential impact:

Risk assessment has an important influence on the management of inspections. The general text of 834/2007 and the implementation rules do limit risk assessment of operators on three risk parameters (results of former inspections, quantity of referring products and risk of commingling). However risk assessment as it is mentioned in Article 3.1 of the 882/2004 is the tool to organize controls. Risk parameters given in 882/2004 include product-related risks, the internal quality management system of the operator and any further information on suspects connected to non-compliances (e.g. by the inspector). Together with the expertise of Food Feeds Security sector, 882/2004 may therefore have a positive impact towards harmonized risk assessment of operations.

Due to the role of risk assessment in the 882/2004 compared to its role in the 834/2007 and the implementation rules, 834/2007 provides not sufficient information on:

- parameters taken into account in this risk assessment should be based on (Art 3.1a-d)
- the output / impact of risk assessment (risk based inspections, risk based samplings)
- how this output of risk assessment of CBs could be related to existing activities like the OFFC controls in MS and the national control plans (Art 42.2b)

Suggestion:

with reference to the presentation of the EOCC given at the AG meeting in February and the outcome of the meeting on Friday, 08.02.2008, EOCC asks the EC to

- clarify that risk assessment should be applicable for all controls additional to the annual inspections
- enlarge the risk assessment to samplings. Therefore, "sample taking" has to be added in Article 60.3 of the implementation rules (eventually as from 1/1/2011 on to give enough time to implement this new requirement)
- amend the given parameters for risk assessment by a product-related risk parameter (e.g. type or origin of the product, gmo-relevance, etc...)
- to oblige CBs to an annual update of the risk assessment system
- re-consider to provide a minimum number of additional controls (and samplings) e.g. in guidelines for risk assessment

4. Others

4.1 Competent Authorities (CAs)

Potential impact: will depend strongly on

- who is designed as CA (Food authorities or other services) (Art 4)
- what is the CA's expertise and capacity

Suggestion:

Clarification is needed especially on the points if

- CAs will be the authorities responsible for food and feed security
- there will be a new CA for new tasks (e.g. for granting exemptions, set up and supervision of CB lists for import etc.)
- organic controls are considered as being parallel to official controls. In that case, supervision of the quality of controls (procedures, activities, methods, instruments) may be performed by the same CA as those for food security matters, while another service might supervise the implementation of the organic regulations.

4.2 Financing of CBs (Article 26; 27 and 28 of 882/2004)

Potential impact:

Since there is no information given in 834/2007, 882/2004 may have a high impact on that topic. E.g. member states will be authorized to define minimum and maximum fees (Article 27). However CBs as private entities should have the possibility to achieve appropriate earnings.

Suggestion:

- amend Title IV by the statement that "CBs fix their fees apt to the expenses including the aspects of
 - a) ensuring appropriate earning
 - b) considering the structure of the operator
 - c) including the efforts for controls that have been performed according to best inspection practise
- the definition of minimum fees on a Member State level may be considered as one tool to ensure a minimum quality of the certification and to achieve harmonized prices for inspections within the EU.

Outlook:

Within an ongoing discussion and implementation process EOCC sees a strong need to clarify the relationship between controls realised by CBs regarding the respect of the 834/2007 and those realised by CAs implementing the 882/2004.

- The EOCC is in favour of a parallel relationship regarding the scope of the controls (e.g. CBs realise controls regarding the 834/07 and CA realise controls regarding the 882/07 and related fields) but the control methods and activities as mentioned in the 882/2004 should be applied as much as possible by both CB and CA in order to have more coherent controls in the food and feed sector.
- the procedures of sample taking and the evaluation of analysis results given in Article 11 of 882/2004 should be verified for transferability in the organic sector.