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H.3. Organic farming

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Working document of the Commission services on official controls in the organic sector

This document has been conceived as a working document of the Commission services. It has been elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by the Commission or by a Member State within the implementation prerogatives under European Union legislation, nor any case law developed with regard to such legislation.

TABLE OF CONTENTS

INTRODUCTION

The purpose of this working document is to facilitate a common understanding between the Member States in the implementation of certain aspects of the control system for organic production which is set out by the European Union (EU) legislation, namely by Regulations (EC) No 834/2007[1], (EC) No 889/2008[2] and (EC) No 882/2004[3].

In particular, it presents the link between the specific legislation on organic production, i.e. Regulations (EC) No 834/2007 and (EC) No 889/2008, and the more general legislation on official food and feed controls, i.e. Regulation (EC) No 882/2004.

In its Special Report No 3/2005 concerning the agri-environment expenditure[4], the European Court of Auditors underlined a need for a better coordination and a clear division of responsibilities between Directorates-General Agriculture and Rural Development (DG AGRI) and Health and Consumers (DG SANCO) in respect of organic production. Furthermore, the European Court of Auditors questioned the functioning of supervision of the private control bodies and the reporting on this subject. These issues are also covered by the present document in order to strengthen the supervision and to harmonise the approach of Member States, including the reporting.

This document is targeted primarily at the Member States, in particular at the competent authorities for organic production. At a second level, it can be used by control bodies, by control authorities or by any other interested parties.

The main scope of the present document is the control system for organic production inside the European Union. Nevertheless, it also applies to controls performed by control bodies in third countries, being fully applicable for those control bodies working under compliance and serving as guidance for those control bodies working under equivalence.

Control and sanction systems set up pursuant to Regulations (EC) No 1290/2005, (EC) No 1698/2005 and (EC) No 65/2011 for rural development support measures

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1 Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91, Official Journal of the European Union L 189 of 20.7.2007, p. 1.

2 Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, Official Journal of the European L 250 of 18.9.2008, p. 1.

3 Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, Official Journal of the European Union L 191 of 28.5.2004, p.1.

4 "Special Report No 3/2005 concerning rural development: the verification of agri-environment expenditure, together with the Commission's replies"; Official Journal of the European Union C 279 of 11.11.2005, p.1.

financed from the European Agricultural Fund for Rural Development (EAFRD) or from the European Fisheries Fund - EFF (Council Regulation (EC) No 1198/2006) are excluded from the scope of this working document. However, it is important that irregularities found on organic farming are systematically communicated to the relevant authorities in charge of EU Rural Development or EU Fisheries Fund (ex. Rural Development Paying Agencies or authorities in charge of implementing EFF) by the organic farming competent authorities.

There is no connection between the present document and the control guidelines prepared to the Standing Committee for Organic Farming in the year 2001.[5] The purpose and the target group are different; the past guidelines were addressed to control bodies and aimed mainly at minimum control requirements under Council Regulation (EEC) No 2092/91[6] which has been repealed since then.

An overview table listing compulsory reporting requirements of Member States regarding organic sector deriving from the EU legislation is attached to the present document. This information has been included to provide Member States with an easily accessible overview, although the scope of the reported information is wider than the subject of this document.

This working document serves to facilitate the reading of the legislation on organic production, i.e. Regulations (EC) No 834/2007 and (EC) No 889/2008 but not to replace or modify the obligations provided for therein in any way. This document can not be considered as a binding legal interpretation of the EU legislation, as such interpretation is the exclusive competence of the Court of Justice of the European Union.

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5 "Guidelines of inspection of organic operators according to Regulation (EEC) No 2092/91", issued on 08.08.2001 by Ecocontrol.

6 Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, Official Journal of the EC L 198 of 22.7.1991, p. 1.

1. OFFICIAL FOOD AND FEED CONTROLS (OFFC)

General principles and requirements of food law are laid down by Regulation (EC) No 178/2002[7], which applies to both organic and non-organic food. This Regulation establishes the European Food Safety Authority, and lays down procedures in matters of food safety[8]. The principal aim of this Regulation is to protect human health and consumers' interests in relation to food. Article 17(2) of Regulation (EC) No 178/2002 requires that Member States maintain a system of official controls and other appropriate surveillance and monitoring activities covering all stages of production, processing and distribution of feed and food.

Official food and feed controls are dealt with by Regulation (EC) No 882/2004, which covers all types of food and feed, produced in the EU or imported, organic or non-organic. This regulation was introduced as one of the measures announced in the White Paper on Food Safety that has been adopted by the Commission in 2000 as a reaction to series of crises concerning human food and animal feed (BSE, dioxin, etc.). The White Paper sets out the plans for a proactive new food policy: modernising legislation into a coherent and transparent set of rules, reinforcing controls from the farm to the table and increasing the capability of the scientific advice system, so as to guarantee a high level of human health and consumer protection.

Regulation (EC) No 882/2004 describes in detail how the official food and feed controls shall be implemented by Member States. Official controls are defined in Article 2 of Regulation (EC) No 882/2004 as "any form of control that the competent authority or the Community performs for the verification of compliance with the feed and food law, animal health and animal welfare rules".

Official food and feed controls cover food and feed law, animal health law, animal welfare law and plant health law. Organic production falls within the scope of Regulation (EC) No 882/2004 and thus the rules on official food and feed controls apply to the controls in the organic sector. Regulation (EC) No 882/2004 refers to Regulation (EEC) No 2092/91 which has been repealed by Regulation (EC) No 834/2007[9]. From a legal point of view, this reference is now read as a reference to

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7 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, Official Journal of the EC L 31 of 1.2.2002, p. 1.

8 Council Regulation (EC) No 1224/2009 establishes a coherent traceability system complementing the provisions contained in Regulation (EC) No 178/2002 – See Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006, Official Journal of the EU L 343 of 9 22.12.2009, p. 1.

9 See article 63(2) of Regulation (EC) No 882/2004.

Regulation (EC) No 834/2007, without a need for modification of Regulation (EC) No 882/2004.

According to Regulation (EC) No 882/2004, Member States shall designate the competent authorities responsible for performing the official controls for food and feed (OFFC). The responsibility for the official controls can be shared among several competent authorities according to the sector or administrative level in one Member State. However, in this case, an appropriate coordination shall be ensured.

A competent authority responsible for the organisation of controls in the field of organic production shall also be designated by the Member States, according to Article 27(1) of Regulation (EC) No 834/2007. This competent authority for organic controls may be identical or not to the one for food safety or other food law controls.

It is very often the case that the competent authority[10] for organic production delegates controls of organic operators to private control bodies. In this case, controls performed by the private control bodies are also considered as official controls in the sense of Regulation (EC) No 882/2004.

Member States shall prepare an integrated Multi-Annual National Control Plan (MANCP) in accordance with Article 41 of Regulation (EC) No 882/2004. The MANCP shall contain general information on the structure and organisation of the systems of official controls in the Member State concerned.

One year after the implementation of the MANCP, and subsequently every year, Member States shall submit to the European Commission an Annual Report on the implementation of the MANCP in accordance with Article 44 of Regulation (EC) No 882/2004, including results of controls and audits conducted in the previous year and actions to ensure effective operation of the official controls.

The first MANCP had to be implemented by 1 January 2007 at the latest and the first Annual Report was due by 1 July 2008.

The European Commission, through the Food and Veterinary Office (FVO) of DG SANCO, performs general and specific audits in the Member States on a regular basis to verify that official controls are carried out in accordance with the national control plans and in compliance with EU law. Reports from these audits are made publicly available. In the area of aquaculture, inspections may be carried out by EU inspectors according to the provisions of Regulation (EC) No 1224/2009.

The European Commission has an obligation to submit a report to the European Parliament and the Council on the application of the Regulation (EC) No 882/2004. The report was adopted by the Commission Decision COM(2009)334 of 8.7.2009[11].

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[10] In this document, "competent authority" means the competent authority for organic farming unless it is stipulated as competent authority for food safety or other food law controls.

[11] Report from the Commission to the European Parliament and to the Council on the application of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules, COM (2009) 334 final of 8.7.2009.

The European Commission services, in particular DG SANCO, have drawn up guidelines to assist Member States with the implementation of the requirements of the official controls. The following Decisions were adopted to this end:

- Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004.[12]

- Commission Decision 2007/363/EC of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004.[13]

- Commission Decision 2008/654/EC of 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Regulation (EC) No 882/2004.[14]

[12] Official Journal of the European Union L 278 of 10.10.2006, p. 15.

[13] Official Journal of the European Union L 138 of 30.5.2007, p. 24.

[14] Official Journal of the European Union L 214 of 9.8.2008, p. 56.

2. HOW THE CONTROL SYSTEM FOR ORGANIC PRODUCTION FITS INTO THE GENERAL SYSTEM OF OFFICIAL FOOD AND FEED CONTROLS

The organic control system as outlined in Title V of Regulation (EC) No 834/2007 stipulates in its Article 27(1) that "Member States shall set up a system of controls and designate one or more competent authorities responsible for controls in respect of the obligations established by this Regulation in conformity with Regulation (EC) No 882/2004".

Regulation (EC) No 882/2004 on the official food and feed control (OFFC) is the reference legislation. As a general rule, the organic control system should be established as closely as possible to that Regulation by fulfilling its requirements and conditions but also by allowing certain discretion in the implementation of the specific provisions depending on their relevance for the organic control system. For the latter reason, the organic legislation sets out more specific provisions on organic controls in Title V of Regulation (EC) No 834/2007 and it repeats the OFFC, where full compliance in the application of the provisions is required.

Three kinds of provisions are identified in the organic production legislation for the control system:

(1) The basic rule: reference to OFFC, which shall apply in conformity, Article 27(1) of Regulation (EC) No 834/2007 provides for the designation of the competent authority, which shall be done in conformity with Regulation (EC) No 882/2004, where the relevant provisions are laid down in Article 4.

(2) Provisions in Regulation (EC) No 834/2007 repeating OFFC thus ensuring full compliance with OFFC (Article 27(5)(a),(b),(d) and (e) and Article 27(8)).

(3) Specific detailed organic control provisions in Regulations (EC) No 834/2007 and (EC) No 889/2008 to meet the unique organic situation.

The following table provides an overview of control provisions that can be found in the organic production legislation (Regulations (EC) No 834/2007 and 889/2008).

	834/2007	**889/2008**
Set up control system	+ application of precautionary and control measures Article 27(1), 27(2)	+ minimum control requirements Title IV
Nature and frequency of controls	Article 27(3)	Title IV, frequency: Articles 65 and 90 Title V: Article 95(2)

	834/2007	889/2008
Confer control competences to control authorities	Article 27(4)(a)	
Delegate control tasks to control bodies and designate responsible authorities for their approval and supervision	Article 27(4)(b)	
Delegate tasks to control bodies	Article 27(5) whereof Article 27(5)(b), (d), (e) are in compliance with Article 5(2)(b),(e) and (f) of Regulation 882/2004	
Criteria for approval of control bodies	Article 27(6)	
No delegation for supervision and competence for granting exceptions	Article 27(7)	
Audits of control bodies	Article 27(8) is in compliance with Article 5(3) of Regulation 882/2004	
Additional criteria to supervise control bodies	Article 27(9)	
Code number, access to control bodies' facilities, report of control bodies, report on control activities	Article 27(10) – (14)	
Specific control requirements for plants and plants products, for livestock and livestock products, for preparation of products, for imports, for units using contracts to third parties and for units preparing feed		Title IV

3. CONTROL SYSTEM FOR ORGANIC PRODUCTION IN THE MEMBER STATES

Regulation (EC) No 834/2007 in its Articles 27 to 31 sets out the fundamentals of the control system that each Member State has to set up. Compared to the previous Regulation (EEC) No 2092/91, the nature of the control system has not changed substantially, except that it is now explicitly linked to the Official Food and Feed Regulation (see chapters 1 and 2). This entailed a change in the vocabulary: the terms "inspection body" and "inspection authority" have been replaced by "control body" and "control authority".

First of all each Member State has to designate one or more **competent authority/ies** (CA) responsible for organic controls.

Secondly this competent authority may[15]:
(1) delegate control tasks to one or more **control bodies**, that it has to approve and supervise – this is known as 'system A', or
(2) confer its control competence to one or more other **control authorities** – this is known as 'system B', or
(3) set up a mixture of these two systems – this is known as 'system C'.

In case the competent authority **confers** its competence to one or more control authorities, the requirements for these control authorities are only set out in general terms: objectivity, impartiality and qualified staff and resources [Article 27(4)(a)].

In case the competent authority **delegates** control tasks to control bodies, which are private entities, the Regulation sets out more detailed requirements and obligations each control body has to fulfil [Article 27(5)]:

- the tasks the control body may carry out must be described as well as the conditions,
- proof is required about expertise, equipment, infrastructure, number and qualification of staff, impartiality and freedom of conflict of interest,
- the control body must be accredited to EN 45011 or ISO Guide 65[16] and must be approved by the competent authority (see chapter 5 of the document)
- the control body must regularly communicate the results of its control to the competent authority; when a non-compliance is discovered, or the likelihood of non-compliance, the control body must inform the competent authority immediately;
- an effective co-ordination between the competent authority and the control body is required.

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[15] This implies that the Competent Authority may also choose not to confer or delegate its control tasks and thus to carry them out by itself.

[16] The current version is EN 45011:1998, which took over the text from ISO/IEC Guide 65:1996. The latter document is being revised and renamed as ISO/IRC 17065, "Conformity assessment – Requirements for bodies providing certification of product (including services) and processes".

The Regulation also indicates which other elements the competent authority has to take into account when approving (or not) a control body (Article 27(6)):

- the standard control procedure of the control body, and
- the measures the control body will apply where irregularities and/or infringements are found.

The tasks that cannot be delegated are also indicated by Regulation (EC) No 834/2007 (Article 27(7)):

- supervision and audits of other control bodies
- competence to grant exceptions

Article 5 of Regulation (EC) No 882/2004 stipulates that action in case of non-compliance, described in Article 54 of Regulation (EC) No 882/2004, cannot be delegated. However, the provisions of Article 30(1) of Regulation (EC) No 834/2007 require control authorities or control bodies to take action in case of irregularities as regards compliance with the requirements of the organic farming legislation.

The relation between Article 5 of Regulation (EC) No 882/2004 (actions in case of non-compliance cannot be delegated) and Article 30(1) of Regulation (EC) No 834/2007 (the control body (CB) has to act in case of irregularities, severe infringements and infringements with prolong effect) can be understood as follows:

the CB should decide, in accordance with the provisions of Article 30(1) of Regulation (EC) No 834/2007, to decertify a product/operator when organic law is breached and the competent authority for food safety or other food law controls shall act when food and feed law is breached (as Regulation (EC) No 882/2004 defines "non-compliance" as non-compliance with food and feed law). The relevant provisions of Regulation (EC) No 834/2007 can be regarded, as also reflected in recital 9 of Regulation (EC) No 882/2004, as a kind of *lex specialis* in relation to the provisions of Regulation (EC) No 882/2004. Products that are decertified because they are not compliant with the EU organic farming legislation could still be placed on the market, without any reference to organic farming production, if still compliant with all other EU relevant law.

How the competent authority should then supervise control bodies once it has approved them, is described in chapter 6 of this document.

Approval of control bodies already approved in another Member State

The Regulation does not specify where a control body should originate from or where it should have its offices in order to be approved by a Member State competent authority. In a number of Member States, control bodies established in another Member State have been approved.

However, some case-law exists in this regard related to the right of establishment, contained in Article 49 of the Treaty on the Functioning of the EU. When a control

body has been approved in one Member State, it cannot be refused approval in another Member State only because it has no place of business or other permanent infrastructure in that second Member State (Court cases C-393/05 and C-404/05)[17].

Nevertheless, the control body must fulfil all conditions for delegation of control tasks to control bodies as laid down by Articles 27 (5) and 27 (6) of Regulation (EC) No 834/2007. In addition, the scope of the accreditation must be extended to include the operations in the additional Member State(s).

All control bodies operating in a given Member State must be approved and supervised by the competent authority of that Member State. In cases where a control body has been established in and approved by another Member State, cooperation arrangements for supervision with the competent authority of that Member State must be made.

In cases where a control body has been approved by more than one Member State, it must specifically report to the competent authorities of each of the Member State where it is operating concerning the activities it carries out on their territories.

[17] Case C-393/05: Judgment of the Court (First Chamber) of 29 November 2007 — Commission of the European Communities v Republic of Austria (Regulation (EEC) No 2092/91 — Organic production of agricultural products — Private inspection bodies — Requirement of an establishment or permanent infrastructure in the Member State where the services are provided — Justifications — Connection with the exercise of official authority — Article 55 EC — Consumer protection) *OJ C 22, 26.1.2008, p. 3;*

Case C-404/05: Judgment of the Court (First Chamber) of 29 November 2007 — Commission of the European Communities v Federal Republic of Germany (Regulation (EEC) No 2092/91 — Organic production of agricultural products — Private inspection bodies — Requirement of an establishment or permanent infrastructure in the Member State where the services are provided — Justifications — Connection with the exercise of official authority — Article 55 EC — Consumer protection) *OJ C 22, 26.1.2008, p. 4.*

4. REQUIREMENTS FOR THE COMPETENT AUTHORITY RESPONSIBLE FOR OFFICIAL CONTROLS IN THE ORGANIC SECTOR

Regulation (EC) No 882/2004 lists several requirements and operational criteria for competent authorities with a view to ensure their impartiality and effectiveness. Additional tasks for the competent authority for the organic production are listed in Regulation (EC) No 834/2007.

Due to the fact that Regulation (EC) No 882/2004 also applies to the regime of controls, as provided in Article 27(1) of Regulation (EC) N0 834/2007, the criteria laid down by Regulation (EC) No 882/2004 have to be also met in that sector.

According to the terminology used in Regulation (EC) No 882/2004, competent authority means the central authority of a Member State competent for the organisation of official controls or any other public authority to which that competence has been conferred (in this case the term control authority is used by the organic production legislation).

Therefore, in case the competent authority for organic production has conferred the controls of organic operators to public control authorities, the criteria for the competent authority laid down by Regulation (EC) No 882/2004 must be also met by these control authorities.

In particular, the following requirements for the competent authority (CA) derive from Regulation (EC) No 882/2004[18]:

- The competent authority shall ensure the effectiveness and appropriateness of the controls (Article 4 (2) (a));
- The competent authority shall ensure that staff carrying out the controls are free from any conflict of interest (Article 4(2)(b));
- The competent authority must have access to an adequate laboratory capacity for testing (Article 4 (2) (c));
- The competent authority must have a sufficient number of suitably qualified and experienced staff (Article 4 (2)(c));
- The competent authority must have appropriate and properly maintained facilities and equipment (Article 4 (2) (d));
- The competent authority shall have the legal powers to carry out official controls (Article 4 (2) (e));
- Efficient coordination must be ensured between all the competent authorities involved in case the competence to carry out controls is conferred to an authority or authorities other than the central competent authority or more than

[18] The list does not aim to be exhaustive.

one unit within the competent authority is competent to carry out the controls (Articles 4 (3) and 4 (5));

- The competent authority must carry out internal audits or may have external audits carried out and the CA must take appropriate measures in the light of their result (Article 4 (6))[19];

- The competent authority must ensure that all the persons performing the controls receive appropriate training, including an additional training as necessary (Article 6);

- The competent authority must ensure that it carries out its activities with a high level of transparency (Article 7 (1));

- The competent authority must take steps to ensure that its staff are required not to disclose information acquired when undertaking controls (Article 7 (2));

- The competent authority must carry out the controls in accordance with documented procedures (Article 8 (1));

- The competent authority must have procedures in place to verify the effectiveness of the controls and to ensure that corrective action is taken when needed and that the control procedures are updated as appropriate (Article 8 (3));

- The competent authority must draw up reports on the controls it has carried out (Article 9 (1));

- The competent authority shall establish adequate procedures in order to guarantee the right of operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion (Article 11 (5));

- The competent authority shall designate laboratories that may carry out the analysis of samples taken during the controls (Article12 (1));

- The competent authority shall take action in case of non-compliance of an operator (Article 54);

- The competent authority shall lay down rules on sanctions applicable to infringements of food and feed law (Article 55);

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[19] The purpose of the audit is to verify whether official controls are effectively implemented and are suitable to achieve the objectives of the relevant legislation. Commission Decision 2006/677/EC of 29 September 2006 contains guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004, Official Journal L 278, 10.10.2006, p. 15.

In case the competent authority has delegated controls to private control bodies, an adequate supervision of the delegated activities has to be carried out by the competent authority (see chapter 6).

- The operators shall be informed of rights of appeal against the decision of the competent authority (Article 54 (3) (b)).

In addition, the organic legislation requires the competent authority:

- to receive notifications from operators (Article 63 (3) of Regulation 889/2008);

- to ensure that any operator who complies with the organic rules and contributes to the control expenses is entitled to be covered by the organic control system (Article 28 (4) of Regulation 834/2007);

- to immediately exchange information in case of irregularities and infringements (Article 30(2) of Regulation 834/2007).

Remark: when the competent authority delegates specific tasks to control bodies, the competent authority must respect Article 5 of Regulation (EC) No 882/2004. (See also chapter 3 of this working document).

5. ACCREDITATION OF CONTROL BODIES

According to Article 5 (2) (c) of Regulation (EC) No 882/2004, control bodies to which control tasks have been delegated by the competent authority have to be accredited to the European Standard EN 45004[20] **and/or another standard if more relevant to the delegated tasks in question**. For the controls in the organic sector, the European Standard EN 45011 appears more relevant than the European Standard EN 45004. Therefore, Article 27(5)(c) of Council Regulation (EC) No 834/2007 stipulates that organic production control bodies have to be accredited to the European Standard EN 45011. As a consequence, control bodies certifying exclusively organic production are not obliged to be accredited to Standard EN 45004 but are under the legal obligation to be accredited to Standard EN 45011.

Accreditation is an impartial means of assessing and conveying an authoritative statement of the technical competence, impartiality and professional integrity of conformity assessment bodies (CABs). Accreditation is a quality infrastructure tool which supports the credibility and value of the work carried out by CABs and thus of the corresponding attestations issued by them (test and inspection reports, calibration certificates, certifications of management systems, products and personnel and other attestations). It provides confidence as it assures direct and indirect users of conformity attestations such as industry, regulators and consumers that they can rely upon these attestations. A product or service accompanied by a conformity attestation delivered by an accredited conformity assessment body inspires trust as to the compliance with applicable specified requirements. It favours the elimination of technical barriers to trade.

A new legal framework for accreditation was established by Regulation (EC) No 765/2008[21] (one of the legal texts forming the "Goods Package") setting out requirements for accreditation and market surveillance. This Regulation embodies the European policy for accreditation. The Regulation establishes for the first time a common legal basis for accreditation, providing for a comprehensive horizontal legal framework regulating the operation and organisation of accreditation in the European Economic Area applicable as from 1 January 2010. This framework covers accreditation linked to conformity assessment independently whether the conformity assessment is performed in the mandatory or voluntary area and independently of the sector in which they carry out their activity. In the organic sector it is in all cases mandatory.

Accreditation is recognized as the ultimate level of control of the adequacy of the conformity assessment services in both the voluntary and mandatory area. The obligations and requirements set out in the Regulation have been designed so as to achieve this objective. Accreditation is protected from becoming a commercial activity, which could undermine the value and credibility of accreditation. Regarding accreditation the main requirements of Regulation (EC) No 765/2008 are:

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[20] Replaced by EN ISO/IEC 17020.

[21] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance), Official Journal L 218, 13.8.2008, p. 30.

- To have only one accreditation body per Member State, designated as such by the Member State;

- No competition between accreditation bodies and between accreditation bodies and conformity assessment bodies;

- The accreditation body to be fully independent of conformity assessment activities;

- The strict limitations to operation of cross frontier accreditation;

- Accreditation is a public authority activity ;

- The accreditation bodies are non-profit, impartial and objective;

- Accountability towards interested parties.

Pursuant to Regulation (EC) No 765/2008, the European Cooperation for accreditation (EA) is recognised as official European Infrastructure for Accreditation. EA is the Association of the national European accreditation bodies providing accreditation of all conformity assessment activities in both voluntary and mandatory spheres. EA was operationally formed in 1997, following the progressive merges of pre-existing European co-operations dating back to 1976 and was established as a legal entity in 2000 as a non-for-profit association. At present EA has 33 full members, these being accreditation bodies of countries member of EU and EFTA or officially candidate to join them.[22] The Commission signed a Memorandum of understanding with EA in 1999 and a Framework Partnership Agreement in June 2010.

EA will be responsible for the management and ruling of a sound, robust and reliable peer evaluation whereby the proper control of the competence and functioning of the national accreditation bodies is exerted and the conformity to the new legal requirements is verified. More importantly EA, through the peer evaluation mechanisms, contributes to the equivalence of the quality of the national accreditation bodies' services and therefore to the mutual acceptance of conformity certificates throughout the Union and in the rest of the world.

The Commission services, in particular DG Enterprise and Industry, have drawn up two guideline documents in relation to accreditation.

– General guidelines for the cooperation between the European Co-operation for Accreditation and the European Commission, the European Free Trade Association and the competent national authorities.[23]

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[22] List of members of the EA, including contact details, can be found at http://www.european-accreditation.org/content/ea/members.htm

[23] Official Journal C 116, 21.5.2009, p. 6.

– Document concerning the interpretation of the cross border accreditation policy as enshrined in Article 7 of Regulation (EC) No 765/2008 in relation to multinational conformity assessment bodies.[24]

[24] The final version of the cross-border accreditation document is available to download from: http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/accreditation/index_en.htm

6. SUPERVISION OF CONTROL BODIES

In case Member States approve one or more control bodies, the only way to find out whether they adhere to all the criteria and perform the tasks delegated to them in a satisfactory matter, is to supervise their activities.

Moreover these bodies nowadays operate in a highly competitive business environment, involving certain risks. Supervision is meant also to limit those risks, by verifying whether all control bodies fulfil the requirements.

Article 27(8) of Regulation (EC) No 834/2007 obliges competent authorities to organise audits or inspections of control bodies as necessary. The scope of this supervision should be:

- to verify that the control bodies properly carry out the tasks designated to them,
- to verify the controls are objective, independent, effective,
- to verify that the basic criteria for their approval are still fulfilled (see chapter 3 of this document).

The supervisory activities of the competent authority[25] shall focus on evaluation of the operational performance of the control body; it should therefore include:

(1) a document review of the relevant general documents describing the structure, functioning and quality management of the control body;

(2) an office audit of the control body, including:

  (a) checking of operator files and verification of handling of non-conformities and complaints, including the minimum control frequency, the use of risk based approach, unannounced and follow-up visits, the sampling policy and the exchange of information with other control bodies and control authorities;

  (b) an evaluation of the knowledge, qualification, training and experience of the staff with respect to organic agriculture in general and with the relevant EU regulations in particular;

  (c) the conclusions from interviews with control and certification staff.

(3) The report and conclusions on a representative number of visits to representative[26] operators to carry out review audits[27] and/or witness audits[28]. These visits shall be geographically scattered within the Member State concerned.

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[25] According to the provisions of Article 4(6) of Regulation (EC) No 882/2004, the competent authority for organic farming is itself subject to audit.

[26] Representative as regards type of production, range of inspection, size of operations and location of operators under the control of the control body. Representative is to be understood also as sufficiently diversified.

[27] Review audit: inspection of an operator by the competent authority to verify compliance with the operating procedures of the control body and to verify its effectiveness.

[28] Witness audit: observation by the competent authority of an inspection by an inspector of the control body.

The Commission services consider it very important that the competent authority has a sound knowledge of the activities and performance of all CBs which it has approved to operate on its territory. Experience has shown that the following elements contribute to an efficient supervision of the CB:

- Verify sampling policy of the CB and its results in particular for residue analysis;
- Verify decision making process (link between inspection and certification, measures in case of infringements and irregularities);
- Monitor organisational elements such as budget, tariffs, number of sanctions applied, working hours, etc.;
- Monitor correct co-operation with other control bodies in MS, EU and non-EU;
- Verify whether the control body has a contact point for complaints from operators and from the public and verify how complaints have been dealt with;
- Document the supervision activities;
- Verify whether the control body is accredited according to EN 45011. Verify that, after the initial accreditation, surveillance by the accreditation body is in place;
- Communicate and co-operate with the national accreditation body; agree on a work plan with it in order not to repeat certain audit tasks.

The competent authority shall ensure that their staff involved in supervising the control bodies has sufficient knowledge, qualification, training and experience with respect to organic production and with the EU legislation concerned.

Supervisory activities carried out by the competent authority have to be documented.

Competent Authorities must ensure that all criteria enumerated for control bodies enumerated in Regulation (EC) No 834/2007 are met all the time and remedy any failure.

7. MINIMUM CONTROL REQUIREMENTS

For the adherence of the organic control system minimum control requirements are set out in Title IV of Regulation (EC) No 889/2008 based on Article 28 of Regulation (EC) No 834/2007 and completed in Chapter 6 of Title II of Regulation (EC) No 889/2008 on exceptional production rules. The control requirements are crystallized in general and specific commitments explicitly laid down for operators, for control bodies/authorities and for the competent authority of the Member States. Along these commitments the (physical) inspection of operators is conducted by control bodies/authorities, which verify the validity, accuracy and completeness of the control arrangements put in place by the operator.

The minimum control frequency is fixed with at least one physical inspection every year (Article 27(3) of Regulation (EC) No 834/2007 and Article 65 of Regulation (EC) No 889/2008). In addition, the control body is obliged to carry out random control visits.

For feed preparing units one full physical inspection of all premises per year is obligatory (Article 90 of Regulation (EC) No 889/2008) and in addition, targeted visits have to be carried out.

Random visits shall be primarily conducted unannounced and like the targeted visits of feed preparing units, they shall be based on an evaluation of risk (see chapter 8 of this document).

Sampling and analysing of products can be used as a supplementary tool to the physical inspection and to the verification of documentary evidence with the aim to detect the use of non-authorised products or production techniques. In case the use of non-authorised products is suspected, sampling becomes obligatory (Article 65 of Regulation (EC) No 889/2008).

Exemptions from the control system

Member States may decide to exempt from the control system operators who sell products directly to the final consumer or user, provided that they do not produce, prepare, store other than in connection with the point of sale or import such products or have not contracted out such activities to a third party (Article 28(2) of Regulation (EC) No 834/2007). Recital 32 of Council Regulation (EC) No 834/2007 recognises that it may be disproportionate to apply notification and control requirements to certain types of retail operators such as those who sell products directly to the final consumer or user. However, it stipulates that in order to avoid fraud it is necessary to exclude from the exemption those retail operators who produce, prepare or store products other than in connection with the point of sale, or who import organic products or who have contracted out the aforesaid activities to a third party. In this context, the Commission services consider that storage in connection with the point of sales should be understood as a physical/material link. In case of sales by Internet to the final consumer or user (e.g. internet web shop), the place where the products are physically kept by the operator should be examined.

Hence, in accordance with provisions of Article 28(2) of Regulation (EC) 834/2007, in practice:

- If the Member State decides to exempt these operators, they don't have to notify their activity to the competent authority and they don't have to submit their undertakings to the control system.

- If the Member State decides not to exempt these operators, they are obliged to notify their activity to the competent authority and they have to submit their undertakings to the control system. However, these operators can be inspected at a lesser than once per year frequency, (Article 27(3) of Regulation (EC) No 834/2007), for example every two years.

Furthermore, wholesalers dealing only with pre-packaged products must be subject to the control system but they could be inspected at a lesser than once per year frequency (Article 27(3) of Regulation (EC) No 834/2007).

A) Commitments addressing the operator can be classified in (source Regulation (EC) No 889/2008):

- general obligations for all operators at the initial control (Article 63) and for follow-up controls (Articles 64, 66, 67)

- specific obligations for operators involved in specific areas including the use of exceptional provisions (Chapter 6 of Title II):

    - plant production: Articles 70, 71, 72;
    - animal production: Articles 74, 75, 76,77,78;
    - preparation of plant and livestock products: Article 80;
    - imports: Articles 82, 83, 84;
    - in case of contracts with third parties: Article 86;
    - preparing feed: Articles 88, 89.

The general control arrangements commit the operator:

- to notify his undertaking to the competent authority including information on the entrusted control body;

- to sign a declaration that he performs according to the organic rules, including the acceptance of enforcement of measures in case of infringements and irregularities, and furthermore his undertaking on information in case of removal of the organic indication;

- to record and to keep descriptions and documentary accounts of his operation and any relevant action set in the course of the organic production;

- to verify the documentary evidence of his suppliers (Article 29(2) of Regulation (EC) No 834/2007) and the vendor declaration (Article 9(3) of Regulation (EC) No 834/2007);

- to notify any relevant change and modification of the organic production to the control body/authority;

- to allow access to all concerned premises, including non-organic production units in case of parallel production and provide any relevant information to the control body/authority;

- to countersign the control report.

The specific control arrangements commit the operator regarding the control body/authority:

- to declare and to describe their specific operations (Articles 70, 72, 74, 75, 76, 77, 78, 80, 82, 83, 84, 86, 88, 89);

- to notify annually the schedule of crop production (Article 71);

- to notify the harvest at least 48 hours in advance and upon the completion and quantities of the harvest in case of exception for parallel production of perennial crops (Article 40(1)(a)(iii) and (iv));

- to notify in advance of appropriate separation, delivery and quantities of livestock products in case of exception for parallel production of livestock (Article 40(2)(a) to (c));

- to ask for agreement on a plan to spread the manure (Article 74(2)(a));

- to declare the use of veterinary medicinal products before livestock and livestock products (including honey, propolis, etc.) are marketed (Articles 77 and 78(3));

- to notify the movements of apiaries (Article 78(4));

- to inform in due time of each consignments to be imported (Article 84).

B) Control commitments addressing the control body/authority:

- obligations for the control body/authority regarding the operator, who has entrusted the control body/authority:

    - to carry out a physical inspection of the operator at least once a year;

    - to carry out random visits;

    - to verify the operators declaration;

    - to verify the operators documentary accounts as regards the general and specific control arrangements with the operator;

- to take samples and to carry out analysis in case of suspicion of non-authorised products;
- to draw up a control report;
- to provide the documentary evidence (certificate) to the operator in case he meets the organic requirements (Article 29 of Regulation (EC) No 834/2007), or
- to prohibit the operator from marketing products with reference to organic in case of infringements (depending on the nature and circumstances of the irregular activities).

– specific control commitments of the control body/authority regarding the operator, who has entrusted the control body/authority:
  - to check the specific documentary accounts for import;
  - to carry out annually a full physical inspection of all premises of any feed preparing unit;
  - to make targeted visits based on potential risks in case of feed preparing units.

– obligations for the control body/authority regarding interested parties:
  - to keep and to make available an updated list containing names and addresses of operators under their control (Article 28(5) of Regulation (EC) No 834/2007).

– obligations for the control body/authority vis-a-vis the competent authority and other control bodies/authorities:
  - to immediately exchange information in case of irregularities and infringements (Article 30(2) of Regulation (EC) No 834/2007);
  - to exchange, upon duly justified request or on own initiative, relevant information on control results (Article 31 of Regulation (EC) No 834/2007).

    Remark: Article 31 of Regulation (EC) No 834/2007 can be used as the legal base for “cross-checking”; that is exchanging, on a random basis, information about traded consignments between control bodies/authorities. Such cross-checking has proven to be a highly effective tool in the organic production control system.

The scope of controls carried out by the control bodies/authorities at the organic operators should be thus primarily aimed at the respect of requirements laid down by the EU legislation on organic production. However, in case the control body/authority has doubts concerning the respect of horizontal legislation by an operator (i.e. animal welfare, nitrate directive, EU Rural Development, European Fisheries Fund etc.), it is important that it informs the competent authority for the

organic production about its suspicion. The competent authority for the organic production should communicate the case to the authority competent in the field concerned.

8. RISK BASED APPROACH

The general rule, as laid down by Regulation (EC) No 882/2004, is that the official food and feed controls shall be carried out regularly, on a risk basis and with appropriate frequency.

More specific rules on the nature and frequency of controls of organic operators are given in the organic production legislation. All operators shall be subject to a physical inspection at least once per year. Moreover, additional control visits shall be carried out based on the assessment of the risk of non-compliance with the organic production rules.

The Commission services consider that the control body or the control authority should determine the risk of non-compliance with the organic production rules for each operator based on an objective method. Operators with higher risk will receive additional controls.

In practice each operator should be assessed against pre-defined risk criteria. The result of the assessment needs to be quantified, e.g. translated into points. The scoring per each criterion can be for example as follows: 0 – no risk, 1 – low risk, 2 – medium risk, 3 – high risk. In the end, the total amount of points per operator is calculated. The operators with a total amount of points exceeding a certain amount are to receive an additional control visit. The control body or the control authority needs to define from which level of points they consider an operator to represent a higher risk. The Commission services consider 10% as a minimum of operators to receive an additional visit to be respected each year in each Member State.

Nature of the additional control visit shall depend on the result of the risk analysis. The additional control visit should be primarily targeted at the verification of compliance in the areas where a high risk of non-compliance has been identified during the risk assessment.

The results of the risk assessment should also be reflected in sampling policy, resulting in a minimum number of samples taken by the control body or control authority. It is to be noted that in cases where the use of non-authorised product is suspected sampling and analysis must be carried out in addition to such a risk based sampling (Article 65(2) of Regulation (EC) No 889/2008).

There are three risk criteria laid down by Article 65 (4) of Regulation (EC) No 889/2008 that shall be taken into account in the risk assessment in all cases. These compulsory criteria are as follows:

- the results of previous controls;

- the quantity of products concerned;

- the risk for exchange of products.

Furthermore, the characteristics of the organic market in a given country or region makes it necessary for additional risk criteria to be taken in the account, examples include:

- type of operator (producer, processor, importer, distributor);

- structure of operator (stages of production, type of staff, number of premises);

- new operators;

- operators with mixed production / processing;

- type and value of products;

- rapid increase of production;

- complaints / denunciations received;

- suspicion of fraud;

- other criteria.

The procedure for risk analysis and its annual implementation should be documented by the control bodies and authorities.

The competent authority should review the procedure for risk analysis upon approval of a control body with a view to verify its compliance with the regulatory requirements and to ensure harmonisation among all control bodies operating in the Member State. Furthermore, annual implementation and results of the risk analysis should be monitored by the competent authority during its supervisory activities over the control bodies.

9. DOCUMENTARY EVIDENCE

The appearance of the documentary evidence[29] in particular as regards the minimum information given is harmonized:

Annex XII of Regulation (EC) No 889/2008 provides for a model containing the necessary information to demonstrate in writing that the operator has submitted his activities under control and meets the requirements of the organic legislation.

Both, the verifying control body/authority and the operator have to identify themselves by identifying their names, addresses, and in case of control bodies, their code numbers. The document has to be signed by the control body/authority.

Supplementary information such as decorative elements, logos of the signing control body or other control relevant information may be added, provided it does not hamper the reading of the document and the visibility of the requested information.

However, adding of supplementary information on the documentary evidence shall not in any case constitute a barrier to the free movement of organic products as stipulated in Article 34(1) of Regulation (EC) No 834/2007.

Re-issue of documentary evidence when new products are added and validity:

Article 29 of Regulation (EC) No 834/2007 stipulates that the control body/authority shall provide documentary evidence to any such operator who is subject to control. Such documentary evidence shall list all activities (and product groups) for which the operator has made a notification to the competent authority. It is logical to issue one single document for a given period. However, there is no obligation to issue the documentary evidence of all products on one single document. By considering their supervision obligation it is up to the competent authority to decide the appropriate procedure.

Electronic certification:

Electronic certification is mentioned as a possibility in Article 29 of Regulation (EC) No 834/2007. This technique uses IT tools and will help rationalising procedures. For the time being, such systems are offered by some control bodies, but no harmonized e-certification systems are in place, neither on Member State level nor on EU-level. In any case it must contain all information required by Annex XII of Regulation (EC) No 889/2008.

[29] "Documentary evidence" is a term used by Regulation (EC) No 834/2007. It should be regarded as a synonym for a term "certificate" which is commonly used by control bodies.

10. SANCTION SYSTEM

This chapter consists of an overview of existing provisions on sanctions.

I. Provisions in the EU legislation

Regulation (EC) No 834/2007

Article 27(6)

When the competent authority is approving a control body, it shall take into account the measures that the control body intends to apply where irregularities and/or infringements are found.

Article 27(9)(c)

When the competent authority is supervising a control body, it shall take cognisance of any irregularities or infringements found and corrective measures applied.

Article 30(1)

Where an irregularity is found as regards compliance with 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 of 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 from marketing organic products for a period to be agreed with the competent authority.

Article 30(2)

Information on cases of irregularities or infringements 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 severity and the extent of the irregularity or infringement found.

Regulation (EC) No 889/2008

Article 91(1)

When operator suspects products not to be in compliance with organic production rules, he has to eliminate doubt before processing or packaging the product. In case of doubts the operator shall immediately inform the control body or the control authority.

Article 91(2)

When control body or authority has a substantiated suspicion that an operator intends to sell product not in compliance with the organic production rules, it can stop the operator from doing that.

Regulation (EC) No 882/2004

Article 2(10)

Non-compliance means non-compliance with feed or food law.

Article 5

Activities referred to in Article 54 shall not be delegated to control bodies.

Article 54

Action in case of non-compliance. In case of non-compliance, the competent authority shall take action to ensure that the operator remedies the situation. The competent authority has a wide choice, it can take any measure it deems appropriate. Need to notify the measure to the operator and inform on rights of appeal.

Article 55(1)

Member States shall lay down rules on sanctions applicable to infringements of feed and food law. Sanctions must be effective, proportionate and dissuasive.

Article 55(2)

Member States shall notify the provisions applicable to infringements to the Commission.

II. Other provisions

ISO 17000 series

IAF[30] guidance to EN 45011:

Nonconformity = deviation of product from specific requirements, or the absence of, or failure to implement and maintain, one or more required management system elements, or a situation which would, on the basis of available objective evidence raise significant doubts as to the conformity of what the supplier is supplying.

The word or concept "sanction" does not seem to be used. The actions of a certification body vis-à-vis an operator are only suspension or withdrawal of the "attestation", which is also known unofficially as "decertification".

[30] International Accreditation Forum

IOAS[31] accreditation system

non-conformity: an instance where a particular standard is not being met.

Sanctions: measures taken against operators who have failed to comply with the standards or other requirements of the certification body.

The certification body shall have a documented range of sanctions including measures to deal with minor-conformities with the standards. Where a non-conformity that affects organic integrity is found, the certification body shall require that the certification mark or any other indication is removed from the entire production run or product affected by the non-conformity concerned. Where a serious non-conformity is made by the operator, the certification body shall withdraw certification from the operator for a specified period.

IROCB[32]

Dealing with non conformities: certification decisions may include requirements for the correction of minor non-conformities (=breach of certification requirements other than standard – organic integrity of the product remains unaffected) within a specified time period. In case of major non-conformities (=breach of applicable standard), a certificate shall be withheld or suspended until implementation of corrective actions can be demonstrated. In serious cases certification shall be denied or withdrawn.

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31 International Organic Accreditation Service

32 International Requirements for Organic Certification Bodies

11. NOTIFICATION OF IRREGULARITIES AND INFRINGEMENTS BETWEEN MEMBER STATES AND THE COMMISSION

Article 92(2) of Regulation (EC) No 889/2008 requires a Member State that finds an irregularity (MS 1) concerning an organic product coming from another Member State to notify the Member State which designated the control body or control authority of the operator involved (MS 2) and the Commission.

According to the procedure that was developed for the purpose of these notifications[33], the MS 1 shall notify the irregularity immediately.

The MS 2 shall investigate the origin of the irregularity. It shall take an appropriate action immediately and it shall inform the MS 1 and the Commission of the result of the investigation and of the action taken by replying to the original notification. The reply shall be sent within 30 calendar days from the date of the notification.

In case the MS 1 is satisfied with the reply of the MS 2, it shall accept the reply of the MS 2 and the case is considered as closed. In case the MS 1 is not satisfied with the reply of the MS 2, it may ask the MS 2 for additional information. In any case, after receiving a reply from the MS 2, the MS 1 has to take an action (either accepting the reply or asking additional information).

The same procedure applies for replies to additional question.

All communication between the MS 1 and the MS 2 shall take place through the module "Irregularities" of the Organic Farming Information System (OFIS) and the standardized forms offered for this purpose by the OFIS shall be used.

This procedure applies only to notifications of irregularities between Member States. Cases originating in and found by the same Member State are not reported through this system. They are investigated by the competent authority of that Member State and reported by an e-mail to the Commission and Member States who may be concerned if the competent authority finds it appropriate.

[33] Procedure to follow-up notifications from Member States according to Article 92(2) of Regulation (EC) No 889/2008 on measures in case of infringements and irregularities. The latest version of the procedure was agreed by the Standing Committee for Organic Farming on 28-29 January 2009. It can be found at Circa, folder 4.

12. REPORTING REQUIREMENTS REGARDING OFFICIAL CONTROLS PERFORMED IN THE ORGANIC SECTOR

Regulation (EC) No 882/2004 on official food and feed controls (OFFC) also applies to the regime of controls, as provided in Article 27(1) of Regulation (EC) No 834/2007. Therefore the reporting requirements laid down by the OFFC Regulation apply also to the controls performed in the organic sector.

The organic sector has to be covered by the Multi-Annual National Control Plan (MANCP) prepared by Member States according to Articles 41-43 of Regulation (EC) No 882/2004. According to Article 44 of the same Regulation, Member States have to provide the Commission with an annual report on the implementation of the MANCP. The annual report has to be provided each year within six month of the end of the year to which the report relates, i.e. by 30 June. The Commission service responsible for receiving this report is the Food and Veterinary Office of DG SANCO.

The purpose of the annual report is to outline progress in the implementation of the MANCP and make an assessment of the effectiveness of the control arrangements and the control systems based on the results and outcomes of official controls in the relevant areas in the Member State.

There is no pre-defined template for the MANCP and the annual report. However, the Commission (DG SANCO) has adopted guidelines to assist Member States in preparing the MANCP and the annual report. These guidelines contain, amongst others, general guidance on content and format of the MANCP and the annual report which should be taken into account by Member States when drafting these documents.

Regarding the controls in the organic sector, it is recommended that the following items are included in the MANCP and in the Annual Report:

Multi-Annual National Control Plan

1) Information on the competent authority (CA) for the organic production

- which body is the CA
- resources available to the CA
- audit of the CA (how, by whom)
- CA has documented procedure in place

2) Description of the control system for organic production

- system of control bodies and / or control authorities
- all registered operators covered by the control system – minimum annual inspection
- how is the risk based approach applied
- announced / unannounced inspections

3) Information on control bodies / authorities

- which control bodies / authorities
- which tasks
- supervision of delegated control bodies (by whom and how)
- coordination of activities in case of more than one control body / authority
- training of staff performing the controls

Annual Report

1) Information on controls of organic operators

- number of registered operators
- number of annual visits
- number of additional risk based visits
- number of samples analysed
- type and number of non-compliances found

The above listed information is preferably to be divided between categories of "producers", "processors", "importers", "exporters" and "others".

2) Information on supervision and audits

- results of supervision of control bodies
- results of audits of the competent authority
- results of audits of control authorities

3) Conclusions on the control system for the organic production

- statement of overall performance of the control system for the organic production
- actions to ensure effective operation of the control system for the organic production (enforcement)

In most of the Member States usually the responsibility of co-ordinating and drafting the MANCP and the Annual Report lies within an institution dealing with food safety, health and consumer protection. Therefore it is very important that a good communication and co-operation between this institution and the competent authority for organic production is ensured.

A report on supervision that was submitted by Member States to the Commission (DG AGRI) according to Article 15 of Regulation (EEC) No 2092/91 is no longer required. Regulation (EEC) No 2092/91 was repealed by Regulation (EC) No 834/2007 as from 1.1.2009 and the requirement to provide annual report on supervision is not maintained by the new Regulation. The last supervision report according to Article 15 of Regulation (EEC) No 2092/91 was provided to DG AGRI by 1 July 2008. This report related to the control year 2007.

ANNEX

Notifications and transmissions of information to the Commission and to other Member States according to EU organic legislation[34] and Regulation No 882/2004 on OFFC

Note: The following tables list compulsory reporting requirements of Member States regarding organic sector deriving from the EU legislation. This information is included to provide Member States with an easily accessible overview, although the scope of the reported information is wider than the subject of the present document.

Table 1. Compulsory notifications and information to the Commission and to other Member States

Regulation	Article	Notified information	Special conditions	To whom?	When?	How?
834/2007 889/2008	35(a) 94(1)(a)	Name and address of **the competent authority**	Where appropriate the code numbers and the marks of conformity of the competent authorities shall be included	To the Commission	Before 1 January 2009 and afterwards at each modification	By e-mail *AGRI-H3@ ec.europa.eu*

[34] Regulations (EC) No 834/2007, No 889/2008 and No 1235/2008

Regulation	Article	Notified information	Special conditions	To whom?	When?	How?
834/2007 889/2008	35(b) 94(1)(b)	Lists of **control bodies and authorities** with code numbers and were appropriate marks of conformity as approved on 31 December of the previous year	The general format of the code number is as follows: AB-CDE-999	To the Commission	Each year by 31 March	By e-mail *AGRI-H3@ ec.europa.eu*
889/2008	55	**Summary report** covering all authorisations on the use of **non-organic seeds** and seed potatoes during the previous year		To the Commission and other Member States	Each year before 31 March	By e-mail *AGRI-H3@ ec.europa.eu*
889/2008 as amended by 1254/2008	27(4) 94(1)(c)	**National authorisations** on the traditional decorative **colouring** of the shell of boiled **eggs**.	Their use must respect general EU law.	To the Commission and other Member States	Before 1 July 2009 and afterwards at each modification	By e-mail *AGRI-H3@ ec.europa.eu*
889/2008	12(5) 94(1)(c)	Definition or a list of **slow-growing poultry strains**		To the Commission, other Member States and operators	Before 1 July and afterwards at each modification	By e-mail *AGRI-H3@ ec.europa.eu*

Regulation	Article	Notified information	Special conditions	To whom?	When?	How?
834/2007 889/2008	36 93	**Statistical information**	The statistical information shall comprise: (a) Number of producers, processors, importers and exporters (b) Organic crop production and crop area under conversion and under organic production (c) Organic livestock in numbers and organic animal products (d) Data on organic processing – type and activities	To the Commission (Eurostat)	Each year before 1 July	Directly to Eurostat
889/2008	48(3)	Authority or private **body** designated to manage the **national seed database**		To the Commission and other Member States	Before 1 July 2009 and afterwards at each modification	By e-mail *AGRI-H3@ ec.europa.eu*

Regulation	Article	Notified information	Special conditions	To whom?	When?	How?
882/2004	44	**Annual report** on implementation of **official controls** in the previous year	The report shall indicate: (a) Any amendments made to multi-annual national control plans; (b) The results of controls and audits conducted; (c) Type and number of cases of non-compliances identified; (d) Actions to ensure the effective operation of multi-annual national control plans, including enforcement action and its results.	To the Commission (DG SANCO)	Each year by 1 July (by 1 July 2008 for the first time)	Directly to DG SANCO
889/2008	36(4)	**Compulsory disease or pest control measures**		To the Commission and other Member States	Immediately	By e-mail *AGRI-H3@ ec.europa.eu*

Regulation	Article	Notified information	Special conditions	To whom?	When?	How?
889/2008	29(2) 29(3) 29(5)	• **National authorisations of non-organic food ingredients** of agricultural origin and their prolongations	Notification shall include : • Date of authorisation and where prolonged date of first authorisation; • Name, address, phone and if possible fax, e-mail of the company and name, address and contact point of the granting authority; • Name and if necessary precise description and quality requirements of the ingredient; • Type of products or preparation that needs the ingredient; • quantities required and its justification; • Why and expected storage time; • Date of notification.	To the Commission and other Member States	Immediately	In OFIS
		• **Contestation** of national authorisations granted by other Member State	In case sufficient supplies of an ingredient are available		Within 15 working days following the receipt of the contestation	
		• **Reply to the contestation** of the Member State who granted the authorisation	Reply should contain measures taken or envisage to be taken			

Regulation	Article	Notified information	Special conditions	To whom?	When?	How?
834/2007	30(2)	**Irregularities or infringements** affecting the organic status of a product	The level of communication shall depend on the severity and the extent of the irregularity or infringement.	Communication between the control bodies and authorities, competent authorities and Member States and , where appropriate, to the Commission	Immediately	*AGRI-H3@ ec.europa.eu*
889/2008	92	**Irregularities or infringements** concerning a product **from another Member State** **Reply** to such notifications		To the Commission and other Member States	Immediately Within 30 days	In OFIS
1235/2008	19(2)	Information on each **import authorisation** granted	Including information on the production standards and control arrangements concerned	To the Commission and other Member States	Consequently after each authorisation granted	In OFIS
834/2007	16(4)	**National rules on the use of products and substances** for purposes ***other*** than plant protection; fertilising and soil conditioning; animal nutrition; feed additives and processing aids; cleaning and disinfecting of ponds, cages, buildings and installation for animal production	Their use must be subject to objectives and principles laid down in Title II of Reg. 834/07 and the general and specific criteria in paragraph 2 of Art. 16 of Reg. 834/07 and respect general EU law.	To the Commission and other Member States	Every time new rules are issued	by e-mail *AGRI-H3@ ec.europa.eu*

Regulation	Article	Notified information	Special conditions	To whom?	When?	How?
889/2008	47	**Granted exceptions on the use of non-organic feedingstuff** in connection with catastrophic circumstances		To the Commission and other Member States	Within one month from its approval	By e-mail *AGRI-H3@ ec.europa.eu*

Table 2: Information on request

Regulation	Article	Information
834/2007	31	**Exchange of information on results of controls** between control bodies, control authorities and competent authorities upon request or on their own initiative
889/2008	56	**Detailed information on authorisations on the use of non-organic seed** shall be made available to the other MS and to the Commission upon request from a MS or the Commission
882/2004	42(1)(c)	Upon request Member States shall provide the Commission with the latest version of the **multi-annual national control plan**