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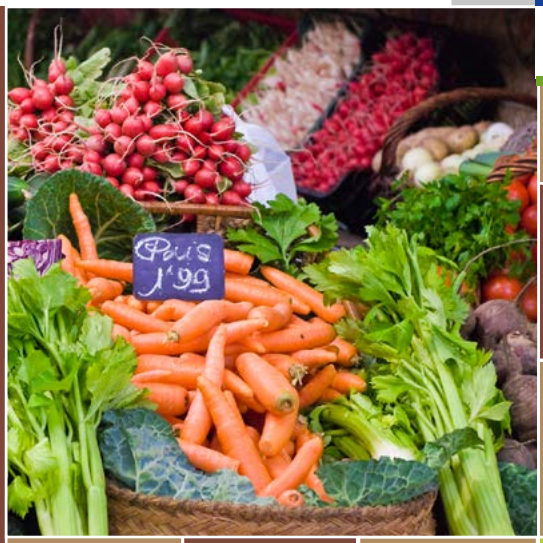

Food and Veterinary Office

OVERVIEW REPORT

Organic Production – Member States

FVO

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OVERVIEW REPORT
ON A SERIES OF FVO AUDITS ON ORGANIC PRODUCTION IN EU MEMBER STATES
2012-2014

Executive Summary

This is an overview report on 14 audits on organic production and labelling of organic products in Member States visited between 2012 and 2014 by the Food and Veterinary Office.

The objective of the audits was to evaluate the control systems for organic production and labelling of organic products.

All Member States visited had control systems in place with Control Bodies and/or Control Authorities entrusted with inspection and certification tasks. In most Member States these control systems were well organised although with some weaknesses. Significant shortcomings were identified in two Member States. Some Member States delegated to Control Bodies the competence to grant exceptions from certain production rules, contrary to EU requirements. Control systems in place ensure that organic operators are registered and are subject to control, although not all Member States published updated lists of operators. Deficiencies were also noted with regard to import controls and to the exemption of retailers from the control system.

The Control Bodies are generally subject to supervision by the Competent Authorities and/or the national accreditation body. However, controls in the framework of supervision were not always well planned and coordinated among Competent Authorities and the number of audits at Control Bodies was sometimes insufficient. In some cases the effectiveness of Competent Authorities supervision was deficient in that shortcomings in the quality of controls undertaken by the Control Bodies and Control Authorities at operators were not identified during the supervision process. In particular, supervisory activities did not adequately check the effectiveness of controls carried out by Control Bodies on operators to ensure that all relevant requirements were systematically verified and did not observe that Control Body staff was not sufficiently trained to fulfil their tasks.

Other significant shortcomings identified in the framework of supervision by Competent Authorities related to insufficient communication of irregularities detected at operators by Control Bodies to Competent Authorities, insufficient unannounced controls, the lack of updated information on operators, inadequate follow up of irregularities and the non-application of enforcement measures by Competent Authorities, Control Bodies and Control Authorities.

As regards the effectiveness of controls carried out by Controls Bodies at operators, significant differences were identified concerning the planning and prioritisation of controls mainly because not all relevant risk criteria were taken into account. There were significant variations in the quality and intensity of inspections at operators with regard to the verification of accounting documents, balance calculations of inputs and outputs, traceability systems, and precautionary measures taken by operators.

As a consequence of these shortcomings, irregularities were not always identified by Control bodies and appropriate enforcement measures were not imposed. Furthermore, in many

Member States, irregularities affecting the organic status of products, which were detected by the Control bodies, were not communicated to the Competent Authorities.

In a number of Member States thresholds were established for action in the case of detection of unauthorised substances, which is not foreseen in organic legislation. In addition, the analytical scope of laboratories used for testing was, in many cases, inadequate.

The audit series highlighted a range of good practices which could be transferable across Member States.

The individual reports contained recommendations to the Member States that are systematically followed up by the Commission.

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
AB(s)	Accreditation Body(ies)
CA(s)	Competent Authority(ies)
CB(s)	Control Body(ies)
CoI	Certificate(s) of Inspection
DG AGRI	Directorate-General for Agriculture and Rural Development
DG SANTE	Directorate-General for Health and Food Safety
EN	European Standard
EU	European Union
FVO	Food and Veterinary Office
ISO	International Organisation for Standardization
MoU	Memorandum of Understanding
MS	Member State(s)
PPP(s)	Plant Protection Product(s)
RCOP	Regulatory Committee on Organic Production
TC(s)	Third Country(ies)
Recognised CB(s)	Control Body(ies) recognised in accordance with Article 33(3) of Regulation (EC) No 834/2007
Recognised TC(s)	Third Country(ies) recognised in accordance with Article 33(2) of Regulation (EC) No 834/2007

1 INTRODUCTION

The overview on audits on organic production and labelling of organic products is issued in three separate reports covering audits in Member States (MS), audits in recognised Third Countries (TCs) and audits to recognised Control Bodies (CBs) operating in TCs, carried out by the Food and Veterinary Office (FVO) between 2012 and 2014.

This report provides an overview on 14 audits carried out by the FVO in Portugal, Poland, Romania, Italy, Germany, United Kingdom, France, Spain, Greece, Slovak Republic, Finland, Czech Republic, Malta and the Netherlands.

Most audits were of two weeks' duration and usually consisted of a team of two auditors and one national expert from a MS Competent Authority (CA) and, in some instances, one official from the Directorate-General for Agriculture and Rural Development (DG AGRI).

The audit programme involved meetings with central and regional/local CAs, Control Authorities, CBs and Customs services. Representatives from the CAs of the MS visited accompanied the FVO team for the duration of the audits. The programme also involved on-site visits to organic operators to witness inspections carried out by the CBs and/or Control Authorities.

The report describes the main findings and conclusions of the individual audit reports, together with examples of good practices and recommendations made in order to rectify the shortcomings identified and to enhance implementation of the control measures in place and the effectiveness of the control system.

Details of the individual reports are provided in Annex and are available on Directorate-General for Health and Food Safety (DG SANTE) website: http://ec.europa.eu/food/food_veterinary_office/index_en.htm

It should be noted that the reports reflect the status of the control systems observed at the time of the audits.

2 OBJECTIVES AND SCOPE

The objective of the audits in MS was to evaluate the control systems in place for organic production and labelling of organic products and, in particular, the implementation of the requirements set out under Regulation (EC) No 834/2007 concerning:

- all stages of production, preparation and distribution of organic products, including controls at import, and
- the use of indications referring to organic production in labelling and advertising.

In terms of scope, the audits assessed the performance of the CAs, as well as the organisation of the controls carried out by CBs and/or Control Authorities, the performance of controls on operators producing, preparing and distributing organic products, of the import controls and

of the controls on the labelling and marketing of organic products. The audits also addressed verification procedures and audits.

3 LEGAL BASIS

Individual audits within this series were carried out based on Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

A full list of the legal instruments referred to in this report is provided in Annex 1 and refers, where applicable, to the last amended version.

4 BACKGROUND

Based on a Memorandum of Understanding (MoU) between DG SANTE and DG AGRI, the FVO initiated in 2012 a new series of audits on organic production and labelling of organic products in MS, as well as in TCs and CBs operating in TCs which are recognised in accordance with Article 33 of Regulation (EC) No 834/2007 for the import of organic products into the European Union.

Member States, recognised TCs and recognised CBs are selected based on priorities defined by DG AGRI.

The audits form part of the Annual FVO Work Programme published on DG SANTE's website:
http://ec.europa.eu/food/food_veterinary_office/index_en.htm

In addition to the audits referred to above, the FVO is currently undertaking a series of audits on pesticide residue testing in organic production. The main findings and conclusions of this series will be presented in an overview report planned for publication in 2016.

5 OVERVIEW OF MAIN FINDINGS AND CONCLUSIONS

This part summarises the main findings and conclusions of the individual audit reports.

5.1 RELEVANT NATIONAL LEGISLATION AND PROVISIONS

Legal Requirements

Article 291 of the Treaty on the functioning of the EU.

Findings

According to the information provided by the relevant CAs, all MS had adopted the measures of national law necessary to implement legally binding Union acts on organic production and labelling of organic products. In addition, most MS had issued guidelines and instructions on the implementation of EU organic legislation.

However, contrary to Article 27(7)(b) of Regulation (EC) No 834/2007 which stipulates that the competence to grant exceptions may not be delegated to CBs, three MS had national legislation delegating to CBs the responsibility for granting exceptions from certain production rules, in particular:

- the bringing-in of non-organically reared poultry or non-organically reared pullets for egg production;
- the renewal or reconstitution of a herd or flock with non-organic animals following high mortality caused by animal health problems or catastrophic circumstances.

Conclusions on Relevant National Legislation and Provisions

MS had national law to implement legally binding EU acts and most of them provided guidelines to facilitate the implementation of the organic rules. In some cases, legal power to grant certain exceptions to production rules was delegated to CBs contrary to EU requirements.

5.2 Organisation and Implementation of Controls

5.2.1 Competent Authorities, Control Authorities and Control Bodies

Legal Requirements

Article 4 and 6 of Regulation (EC) No 882/2004.

Article 27(1), 27(4), 27(14) and 31 of Regulation (EC) No 834/2007.

Article 92 of Regulation (EC) No 889/2008.

Findings

In the majority (nine) of MS visited, the CA delegated control and certification tasks to one or more CBs. All MS have designated authorities responsible for the approval and supervision of such bodies.

In three MS, the CA conferred its control competences to one or more Control Authorities.

In two MS, responsibility for control and certification tasks were spread across CAs, Control Authorities and CBs.

In general, staff of the CAs were trained and were suitably qualified. However, in five MS, staff of some CAs had not received appropriate training, in particular with regard to market and/or import controls.

CBs and CAs had generally adequate procedures for performing and reporting on controls and reports were drawn up after every control. However, in three MS, not all CAs had adequate documented procedures in place for controls of certain organic requirements, in particular, regarding import and market controls.

There was good communication and coordination between CAs and between CAs and CBs in eight MS.

Deficiencies regarding communication and coordination were found in four MS visited which were not meeting the requirements set out in Article 31 of Regulation (EC) No 834/2007 and Article 92 of Regulation (EC) No 889/2008 respectively. In three MS there was no exchange of information between the CAs and the paying agencies, responsible for making payments to the beneficiaries of support under the Common Agricultural Policy. In one case, there was no communication and coordination between the different Control Authorities and in another case, major shortcomings were found regarding the communication between the CBs and the CA.

Conclusions on CAs, Control Authorities and CBs

A system of controls was in place in accordance with EU provisions in all the MS visited. The CAs were designated and the tasks clearly distributed. There was an adequate exchange of information between CAs, Control Authorities and CBs and good communication and cooperation in the majority of MS. Deficiencies identified in some MS related to controls in the framework of supervision which were not always well planned and coordinated among CAs and the lack of communication of control results between the entities involved. Some CA staff had insufficient knowledge to appropriately fulfil all their tasks.

5.2.2 Control Bodies: Approval, Supervision and Withdrawal

Legal Requirements

Article 5(2), (3), (9) of Regulation (EC) No 882/2004.

Article 27(5) to (8), (14) of Regulation (EC) No 834/2007.

Article 92c of Regulation (EC) No 889/2008.

Findings

Most of the MS visited had delegated control tasks to CBs and systems in place for the approval, withdrawal and supervision of CBs. Evidence of the withdrawal of accreditation or approval of CBs by CAs when they no longer comply with the accreditation or approval conditions was seen in some MS visited.

CBs were accredited to European Standard (EN) 45011 or International Organisation for Standardization (ISO) Guide 65 (General requirements for bodies operating product certification systems)[1], in all the MS visited. However, in two MS visited some CBs were

[1] The ISO / IEC 17065: 2012 – Conformity assessment – Requirements for bodies certifying products, processes and services, was published in September 2012 and will replace ISO Guide 65 and EN 45011. In accordance with an International Accreditation Forum decision, the implementation of the new standard will be subject to a three year transition period.

approved before being accredited which is not in line with Article 27(5) of Regulation (EC) No 834/2007.

In the majority of MS visited, regular visits were carried out by the CA to supervise CBs. In one case, the CA did not carry out supervision of CBs and had not yet established an appropriate system for the verification of the effectiveness of the controls of CBs contrary to Article 27(9)(b) of Regulation (EC) No 834/2007.

Shortcomings found regarding the supervision in several MS, in particular, related to:

- Lack of inspections by CAs,
- Number of office and witness audits by CAs not appropriate;
- Supervision not effective as systemic issues had not been identified;
- Planning and coordination between CAs not appropriate;
- Lack of appropriate verification of available information in order to determine whether controls performed by the CBs are effective;
- Adequate training not provided to CB staff;

In one MS, supervision of CBs was not performed by the CA but by the accreditation body (AB) based on a MoU concluded between the CA and the AB.

From 1 January 2014, Regulation (EU) No 392/2013 amending Regulation (EC) No 889/2008 required CAs to organise an annual inspection of the CBs that have been delegated control tasks. In the MS visited in 2014, the FVO teams noted that office audits were carried out at least once a year in the headquarters (HQ) of CBs.

Conclusions on Approval, Supervision and Withdrawal of CBs

CBs were generally approved in accordance with the conditions laid down in EU legislation and are subject to regular supervision by the CAs and / or the national accreditation body. The effectiveness of the supervision by CAs was deficient in that shortcomings in the quality of controls undertaken by the CBs and Control Authorities at operators were not identified during the supervision process. In particular, CAs as part of their supervision did not adequately check the effectiveness of controls carried out by CBs on operators to ensure that all relevant requirements were systematically verified and did not observe that CB staff was not sufficiently trained to fulfil their tasks. In one case, the supervisory activities on controls carried out by CBs had not yet been implemented.

5.2.3 Registration of Operators

Legal Requirements

Article 1(2), 27, 28(1), 28(2), 28(5) of Regulation (EC) No 834/2007.

Article 92b of Regulation (EC) No 889/2008.

Findings

The control systems in place in all the MS visited ensure that organic operators are registered and submit their organic activities under the control system.

In the majority of MS, the designated CA made lists of registered operators publicly available. The lists were regularly updated to reflect any change in the organic status of the operators. These lists also included updated information on documentary evidence related to organic operators. The level of detail of the information provided on the activities and production of each operator enabled the public to be adequately informed.

However, three MS did not publish any list which is not in compliance with Article 92b of Regulation (EC) No 889/2008. In three other MS, the published lists did not include or contain the updated documentary evidence required by the same Article.

Most MS made use of the provisions of Article 28(2) of Regulation (EC) No 834/2007 and exempted operators who sell pre-packed products directly to the final consumer from controls. However, in three MS, the CAs exempted from controls operators that did not fulfil the requirements laid down in Article 28(2) of the same regulation.

In five MS visited, retailers selling pre-packed products to the final consumers were not exempted by the CA. In two of these MS, although not exempted, retailers were not controlled, contrary to EU requirements.

Conclusions on Registration of Operators

Adequate systems for the registration of operators were in place and generally, they were effectively implemented, guaranteeing that operators are subject to controls. However, not all MS published updated lists of operators. Deficiencies were also noted with regard to the exemption of retailers from the control system.

5.2.4 Planning and Prioritisation of Controls

Legal Requirements

Article 3(a) to (d), 41 of Regulation (EC) No 882/2004.

Article 27(3) of Regulation (EC) No 834/2007.

Article 65(4), 92(c)(2), 92f of Regulation (EC) No 889/2008.

Findings

In the majority of the MS visited, the Multi Annual National Control Plan contained basic information on the control system for organic production and labelling on organic products.

In all MS but one, CBs and/or Control Authorities carried out annual inspections to all operators. Additional visits were also carried out in all MS. CBs in MS visited in 2014

complied with the new control requirements for additional and unannounced controls set out in Article 92(c)(2) of Regulation (EC) No 889/2008.

In the majority of MS, random additional controls to organic operators were announced contrary to Article 65(4) of Regulation (EC) No 889/2008. In several MS, prior notice was given to operators 24 hours ahead of the planned visit. These were considered unannounced visits by these MS.

Risk assessments carried out by the CAs or CBs for planning the inspections to organic operators were carried out in all MS visited. However, in a considerable number of MS, the risk assessment did not take into account all the criteria established in Article 27(3) of Regulation (EC) No 834/2007 and Article 65 of Regulation (EC) No 889/2008. In other cases the CBs/Control Authorities did not follow their own criteria to carry out the control visits to operators.

In the majority of MS, the CA provided instructions or guidance to CBs on planning and prioritisation of controls on organic operators and provided also guidance on criteria for the risk assessment. In two MS, the CAs had not given guidance to the CBs on how to perform a risk based analysis.

Conclusions on Planning and Prioritisation of Controls

In almost all MS, operators were subject to annual inspections and additional control visits. However, significant differences were identified concerning the planning and prioritisation of controls by the different CBs visited mainly because not all relevant risk criteria were taken into account mitigating the effectiveness of the control systems. Moreover, random control visits to organic operators were mainly carried announced contrary to EU requirements.

5.2.5 Controls of Operators

Legal Requirements

Articles 8, 9 of Regulation (EC) No 882/2004

Article 27, Titles II, III of Regulation (EC) No 834/2007.

Article 65, Title II, IV of Regulation (EC) No 889/2008.

Findings

Competent Authorities/Control Authorities/CBs performed physical inspections of all operators under their control at least once per year and additional inspections, in accordance with annual control programmes. In addition to these planned controls, inspections were also performed on an ad-hoc basis in case of complaints, suspicion or any external information related to operators under the control of the CBs.

In the majority of MS visited, Control Authorities/CBs were well organised and had written procedures in place to serve as guidance to the inspectors on how to perform the inspections

and how to report on the findings. Checklists for different activities (plant and animal production, processing, trade, imports) were used. Checklists including the documents and records to be prepared by operators and checked by inspectors were followed by the inspectors during controls. Official controls were carried out in accordance with documented procedures and reports were prepared and given to the relevant operators with at least a summary of the activities subject to inspection and the outcome of the inspection. Reports included a description of the deficiencies and non-compliances found.

In all the audits carried out, the FVO teams visited the HQs of the selected Control Authorities/CBs and witnessed inspections carried out by the Control Authorities/CBs on the ground at operators' premises.

In a large number of MS, inspections carried out by Control Authorities/CBs were not always effective to ensure compliance with EU requirements. This was not always noted by the CAs supervision of CBs (see chapter 5.2.2). The main problems observed were:

- Irregularities or non-compliances were not always identified during inspections
- Inspectors did not verify systematically the information provided by the operators;
- Inspections were conducted in a superficial manner;
- Input/output balances, and identity checks were not carried out systematically and, when they were carried out, inspectors did not always adequately verify the documentary accounts referred in Article 66 of Regulation (EC) No 899/2008;
- Insufficient verification of precautionary measures to be taken by operators to reduce the risk of contamination with unauthorised products/substances or mixing with non-organic products;
- Inappropriate measures taken in case of non-compliances;
- Traceability checks during inspections at operators were not always carried out in a systematic and adequate manner.

Conclusions on Control of Operators

Control Bodies/Control Authorities/CAs performed physical inspections in accordance with their annual control programmes and had adequate documented procedures in place to ensure consistency in the performance of official controls. There were however significant variations in the quality and intensity of inspections at operators with regard to verification of accounting documents, balance calculations of input and outputs, traceability system and precautionary measures taken by the operators.

5.2.6 Controls on Labelling and Traceability

Legal Requirements

Article 23, 24, 27(13) of Regulation (EC) No 834/2007.

Title III and IV of Regulation (EC) No 889/2008.

Findings

Controls on the labelling of organic products were carried out at registered operators visited by the Control Authorities/CBs. Labels were, in most cases, in compliance with EU organic rules. However, in one MS, the CBs approved labels which were not in accordance with those rules.

In two MS, inspectors of CBs/Control Authorities were able to identify several labelling irregularities in a broad range of organic products.

In four MS, organic operators could only use labels that had been approved by the relevant CBs. In two MS, relevant CBs requested their operators to notify the composition of their organic processed products and issued an authorisation for each processed product.

In all the MS visited, the FVO teams asked the CAs to trace back to the producers a number of products selected in supermarkets by the teams. The outcome of the exercise was generally satisfactory in all MS but two. In four MS, irregularities were detected relating to ingredients used that were not organic.

In a large number of MS, deficiencies were found regarding verification of traceability systems and the balance of input/output during witness audits at operators. Only in a few MS, traceability checks were carried out by the inspectors at the operators visited. Such checks were often inadequate, in particular at processors: for example, inspectors did not link the final products with the incoming raw materials, or did not check records demonstrating the links between the different processing steps contrary to Article 66 of Regulation (EC) No 889/2008. Moreover, inspectors did not verify whether lots were identified during all processing steps to avoid mixtures or exchanges with non-organic products, which is not in line with Article 26(5)(d) of Regulation (EC) No 889/2008.

Conclusions on Controls on Labelling and Traceability

Labelling checks were regularly performed and overall effective. The traceability exercises carried out by MS during the FVO audits were generally satisfactory. However, weaknesses were identified in the majority of MS with regard to inspections at operators where the traceability of each product at all stages of production, preparation and distribution was not ensured.

5.2.7 Sampling and Laboratory Analysis

Legal Requirements

Article 12 of Regulation (EC) No 882/2004.

Article 65(2) of Regulation (EC) No 889/2008.

Findings

The majority of the MS visited had sampling plans in place and samples were taken in accordance with a standard procedure.

In a large number of MS, sampling was also carried out where the use of products not authorized for organic production was suspected.

However, shortcomings were noted in six MS regarding the analytical scope of laboratories. In three MS, it was noted that sampling was not properly carried out.

In a number of MS, CBs/Control Authorities either had no clear instructions on how to act when residues of non-authorised plant protection products (PPPs) were found in organic products or had established thresholds for non-authorised PPPs residues in organic products below or beyond which no actions were taken to identify the cause. This is not in compliance with Article 12(1)(h) of Regulation (EC) No 834/2007 and Article 91(2) of Regulation (EC) No 889/2008 respectively.

In all MS visited in 2014 with one exception, CBs complied with the new control requirement for sampling at least 5% of organic operators certified by them. However, in one MS, the Control Authority/CB did not take samples at organic operators or operators to be sampled were not selected based on the general evaluation of the risk of non-compliance with the organic rules, contrary to Article 65(2) of Regulation (EC) No 889/2008.

In three MS, laboratories were designated by the CA to carry out analysis on organic products. In all the MS visited laboratories were accredited to ISO/IEC 17025.

Conclusions on Sampling and Laboratory Analysis

In the majority of MS, sampling of organic products was in line with EU law. However, in a number of MS the selection of operators was not based on a general evaluation of risk of non-compliances with the organic production rules. Some MS had established a threshold for residues of unauthorised substances below or beyond which no measures were taken to identify the cause. Although laboratories used for the testing of samples were accredited, the analytical scope requested for the testing was not always adequate mitigating the reliability of testing results.

5.2.8 Exceptional Production Rules and Other Derogations

Legal Requirements

Article 22(2) of Regulation (EC) No 834/2007.

Article 29, Chapter 6 of Title II and Annex IX to Regulation (EC) No 889/2008.

Findings

In all the MS visited, exceptions from the production rules as referred to in Article 22 of Regulation (EC) No 834/2007 had been granted. In a large number of MS, the relevant CAs

had developed appropriate procedures for granting such derogations and administrative decisions were taken once applications were assessed. The most common exceptional production rules and other derogations granted by a large number of MS were as follows:

- Tethering of cattle on small holdings;
- Operations on animals such as de-horning, tail docking in sheep and tail docking and teeth trimming in piglets, beak trimming in poultry;
- Exceptions in case of catastrophic circumstances in order to ensure that organic production can be initiated or maintained on affected holdings
- Introducing non-organic animals to organic farms;
- Permitting non-organic ingredients of agricultural origin in processed organic food.

In four MS, the CAs delegated to CBs the assessment of individual requests and the final decision on granting some of the exceptions referred to in Article 22 of Regulation (EC) No 834/2007, contrary to Article 27(7) of that Regulation.

Irregularities related to the management of animals were noted in five MS. In particular, dehorning of animals was carried out routinely without asking for authorisation which is contrary to Article 18 of Regulation (EC) No 889/2008. In one MS, the CB did not verify the conditions under which dehorning was carried out by operators.

In two MS, the CAs granted derogations for the use of conventional feed after catastrophic weather conditions for a limited period and in relation to a specific area but not to individual operators which is not in line with Article 47(c) of Regulation (EC) No 889/2008.

Conclusions on Exceptional Production Rules and Other Derogations

Systems in place for the granting of derogations and exceptional production rules were generally in line with EU requirements. However, some MS have delegated the power to grant derogations to CBs contrary to EU requirements. Deficiencies were found in the implementation of the system in a number of MS, in particular with regard to the management of animals and granting of generalised exemptions.

5.2.9 Imports of Organic Products

Legal Requirements

Article 32, 33 of Regulation (EC) No 834/2007.

Article 7, 13, 19, Chapter 3 of Title III, Annexes II, III, V and VI of Regulation (EC) No 1235/2008.

Findings

All the MS visited had a system in place to control organic product imports.

In the majority of MS, the relevant CAs released organic consignments for free circulation after they had verified the consignment and endorsed the certificate of inspection (CoI).

Relevant CAs generally verified that importers of organic products were registered and that the CoI was issued by the CB recognised for the relevant product category and TC in accordance with Annex III and IV of Regulation (EC) No 1235/2008. After verification of the consignment, the CAs endorsed the certificate in box 17 of the CoI and the original CoI was returned to the importer.

In most MS, the procedures followed for the verification of imported consignments were carried out in line with Articles 2(5) and 13 of Regulation (EC) No 1235/2008.

In four MS, shortcomings were found regarding the verification of CoIs (not all certificates were endorsed by the CA, lack of information in some fields, etc).

Other deficiencies related to the lack of training of import inspectors (in two MS), to the lack of notification of import authorisations to the Commission (in one MS) or to the non-performance of physical checks on import consignments (in one MS).

Import authorisations under Article 19 of Regulation (EC) No 1235/2008 had been granted by all MS visited. In a number of MS, the procedures for granting import authorisation were not in compliance with EU requirements. Shortcomings noted related, in particular, to the lack of sufficient verification of the equivalence of the standards and control measures applied by the CBs in the TCs concerned.

Conclusions on Imports of Organic Products

Import control systems for organic products were in place in the majority of the MS visited. Deficiencies identified in a number of MS related to the verification of CoIs and procedures to grant import authorisations under Article 19 of Regulation (EC) No 1235/2008 with a risk that non-organic products are imported to the EU.

5.2.10 Measures in cases of Irregularities and Infringements

Legal Requirements

Article 54, 55(1) of Regulation (EC) No 882/2004.

Article 27(5)(d), 30 of Regulation (EC) No 834/2007.

Article 91, 92 of Regulation (EC) No 889/2008.

Findings

The majority of MS visited had a system in place for the application of sanctions in case of irregularities. The obligation to have a catalogue of measures in place for irregularities and infringements was complied with by all MS visited in 2014 with one exception. In that MS, the catalogue of measures had not yet been adopted at the time of the FVO audit.

In half of the MS visited, the CA or the CBs/Control Authorities did not take proper actions or impose sanctions on operators when irregularities were detected. Moreover, in some of these MS the follow up of irregularities was inappropriate.

A large number of MS had procedures in place requiring that non-compliances affecting the organic status of the products must be notified by the CBs to the CAs without delay. However, in eight MS, irregularities or infringements affecting the organic status of a product were not immediately communicated by the CBs to the CAs contrary to Articles 30 of Regulation (EC) No 834/2007 and 92(4) of Regulation (EC) No 889/2008.

Conclusions on Measures in Case of Irregularities and Infringements

The majority of MS visited had systems in place to handle irregularities and infringements. However, the effectiveness of the systems to prevent non-compliant products from being placed on the market are substantially weakened in many MS as major irregularities were often not immediately notified to CAs and enforcement measures and sanctions taken were often inappropriate.

5.3 SEED DATA BASE

Legal Requirements

Article 48 to 56 of Regulation (EC) No 889/2008.

Findings

The CAs in all MS but one had established seed databases with the species and varieties of organic seeds available in their respective countries. These databases were available to the public and were kept up-to date. Data available contained *inter alia*, the amount of seed available, the list of suppliers and the list of application submitted.

Conclusions on Seed Data Base

Seed databases had been established by the CAs as required by Article 48 of Regulation (EC) No 889/2008 in all MS visited but one.

6 EXAMPLES OF GOOD PRACTICE

Several examples of good practice were found in the MS covered by this report, for instance:

- Harmonisation of the risk assessment of operators at national level (Italy);
- Harmonisation of the sanction catalogue at national level before 1.1.2014 [as it is an obligation since 1.1.2014] (Italy, Romania, Portugal);
- National lists of commercial products allowed to be used in organic production (Germany);
- Operators can only use labels that have been approved by the relevant CBs (Italy, Spain, Czech Republic, France);

- CBs requires processors to report on a regular basis on incoming materials, production quantities and sales, which allowed for better preparation prior to the inspection (Greece);

- CBs inspector have to pass written exams and have accompanied senior inspectors on audits (Czech Republic);

- Operator produced records of own-checks carried out at the arrival of imported consignments, including pictures of the labels and packages (Slovakia);

- CBs provided lists of commercial farm input products and a table with reference yields for different crops (Spain).

7 RECOMMENDATIONS TO MEMBER STATES

In total, the FVO raised 133 recommendations to the CAs of the MS concerned. The majority of the recommendations related to the planning of controls, measures in cases of irregularities and infringements and sampling.

The most important recommendations made are summarised below:

Competent Authorities and Control Bodies

- Ensure that all staff of the CAs performing official controls receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner as required by Article 6 of Regulation (EC) No 882/2004.

- Ensure efficient and effective co-ordination between all the CAs involved in the supervision of the CBs and that the effectiveness of CBs' controls is regularly verified in accordance with Article 27(8) and (9) of Regulation (EC) No 834/2007.

Registration of Operators

- Ensure that updated list of operators, as referred to by Article 28(5) of Regulation (EC) No 834/2007, and updated documentary evidence related to each operator are made available to the public as required by Article 92(b) of Regulation (EC) No 889/2008, and using the model set out in Annex XII to that Regulation.

- Ensure that operators (retailers) who are not exempted from controls as provided for in Article 28(2) of Regulation (EC) No 834/2007 notify their activity to the CAs and submit their undertakings to the control system.

Planning and Prioritisation of Controls

- Ensure that the risk assessment of operators applied by CBs serves as an adequate basis to determine the nature and frequency of controls, as established in Article 27(3) of Regulation (EC) No 834/2007 and take into account at least the results of

previous controls, the quantity of products concerned and the risk for exchange of products.

- Ensure that additional visits are carried out primarily unannounced, in line with Article 65(4) of Regulation (EC) No 889/2008 and that no prior notice is given in case of unannounced visits.

Control of Operators

- Ensure that controls carried out by CBs are effective, as required by Article 27(8) of Regulation (EC) No 834/2007, and in particular that inspectors adequately verify information provided by operators with regard to the control arrangements and undertakings as laid down in Article 63 of Regulation (EC) No 889/2008, accounting documents and the balance between inputs and outputs as referred to in Article 66 of Regulation (EC) No 889/2008.

Labelling and Traceability

- Ensure that CBs carry out effective traceability controls and adequate checks of measures put in place by the operator to ensure identification of products at all stages of production (including reception of goods), processing and distribution in order to avoid mixtures or exchanges of organic products with non-organic products.

Sampling and Laboratory Analysis

- Ensure that CBs select the operators to be sampled based on the general evaluation of the risk of non-compliance with the organic production rules, in line with Article 65(2) of Regulation (EC) No 889/2008.

- Ensure that the sealing, storage and transport of the laboratory samples for pesticide testing is performed in accordance with point 4.6 of Directive 2002/63/EC.

Exceptional Production Rules and other Derogations

- Ensure that the competence to grant exceptions, as referred to in Article 22 of Regulation (EC) No 834/2007, is not delegated to CBs, as required by Article 27(7) of the same regulation.

- Ensure that the use of non-organic feeding stuffs is authorised by the CA only for a limited period and, in particular, in relation to a specific area by individual operators, in accordance with Article 47(c) of Regulation (EC) No 889/2008, and that operations such as attaching elastic bands to the tail of sheep, the trimming of peaks and de-horning are not carried out routinely and are only carried out after having been authorised by the CA as required by Article 18 of the same regulation.

Imports of Products from Organic Production

- Ensure that consignments of organic products imported are verified by the relevant MS authority and that the certificate of inspection is endorsed as established by Article 13 of Regulation (EC) No 1235/2008 before release for free circulation into the EU market.

- Ensure that imports of organic products under Article 19 of Regulation (EC) No 1235/2008 are only authorised if the importer provides sufficient evidence that the conditions referred to in Article 33 of Regulation (EC) No 834/2007 are satisfied.

- Ensure that procedures for import controls of organic products are established in accordance with Article 8 of Regulation No 882/2004.

Measures in cases of Irregularities and Infringements

- Ensure that information on irregularities or infringements affecting the organic status of the products is immediately communicated between the CBs, Control Authorities, CAs and MS concerned, and where appropriate to the Commission, in accordance with Article 30(2) of Regulation (EC) No 834/2007.

- Ensure that in cases of suspicion of infringements and irregularities measures are taken and are adequate to prevent the fraudulent use of the organic indications as established in Article 91(2) and (3) of Regulation (EC) No 889/2008. In particular, ensure that appropriate actions are taken in all cases when analytical results of samples show the presence of products or substances not authorised in organic production.

- Ensure that only PPPs authorised for use in organic production are used in accordance with Article 12(1)(h) of Regulation (EC) No 834/2007 and, in particular, that no action level for pesticide residue levels in organic products is established.

8 ACTION TAKEN OR ENVISAGED BY THE COMMISSION SERVICES

8.1 FOLLOW UP OF RECOMMENDATIONS FOR MEMBER STATES

For each audit a copy of the final report is sent to the CAs in the MS concerned with a request for an action plan indicating the steps envisaged to address the recommendations made in the audit report.

A deadline is set for the receipt of these plans and the response of the CAs of MS is analysed. Where it is considered that a response did not address the issues raised, the European Commission services actively pursued the matter with the authorities concerned (see also point 8.2).

The European Commission regularly monitors the progress on the actions undertaken by the CAs in MS to address the recommendations. The outcome of this monitoring activity is described in the MS Country Profiles which can be found at the following website:

http://ec.europa.eu/food/fvo/audit_reports/index.cfm

8.2 ENFORCEMENT

In addition to the follow-up of the audits, the Commission services took, and are regularly taking action, with a view to enforcing the EU legal provisions on organic production and labelling of organic products.

Specifically, the Commission services instructed EU Pilot proceedings[2] against 20 MS where audit findings showed issues linked to the incorrect application of EU legislation on organic production and labelling of organic products. Those proceedings were closed when assurances were received from the CAs that measures had been taken to ensure compliance with the requirements.

8.3 DISCUSSIONS WITH MEMBER STATES AND EXCHANGE OF GOOD PRACTICES

A Committee on Organic Production (COP), comprising representatives of all EU MS and chaired by a European Commission representative, ensures close cooperation with the authorities in charge of organic production and labelling of organic products.

The Commission services presented to the COP the approach and scope of this series of audits on organic production and labelling of organic products (February 2012 and September 2014 as regards the annual work programme) and discussed the main findings of the audits carried out, with regard to both identified shortcomings and examples of good practices (September 2013 and December 2014).

8.4 TRAINING

"Better Training for Safer Food" (BTSF) is a Commission initiative aimed at organising a EU training strategy in the various areas of food and feed law. Training is designed for staff in charge of official control activities in the CAs in MS - and open to participants from TCs and CBs - so as to keep them up-to-date with all relevant aspects of EU food and feed law and contribute to official controls being carried out in a uniform, objective and adequate manner.

A specific training module under the BTSF initiative was designed for staff involved in official controls for organic production and labelling of organic products. Ten workshops were held in the period from 2013 to 2015, in Warsaw (Poland); Sofia (Bulgaria) and Bristol

2 EU Pilot is the tool for exchanging information and problem solving between the Commission services and the MS. The EU Pilot system is based on a structured dialogue giving MS the opportunity to provide further factual or legal information and/or to submit acceptable solution in compliance with EU law. EU Pilot is thus the first compulsory step before an infringement proceeding.

(the UK) and attended by 307 participants, 250 from EU Member states and 57 from countries outside the EU. A new cycle of training activities will resume in 2016.

In 2016, a BTSF workshop based on the present overview report is planned and aims at the exchange of experience and good practice examples with regard to the implementation of the organic legislation in EU MS.

8.5 LEGISLATION

On 24 March 2014, the European Commission adopted a legislative proposal for a new Regulation of the European Parliament and of the Council on organic production and labelling of organic products[3].

The proposal aims at improving the existing legislation with the objectives of 1) removing obstacles to the sustainable development of organic production in the Union, 2) guaranteeing fair competition for farmers and operators and allowing the internal market to function more efficiently, 3) maintaining or improving consumer confidence in organic products.

As regards the control system, the proposal:

- integrates all control-related provisions into a single legislative text under the Commission proposal for a regulation on official controls in food and feed;
- aims at enhancing controllability of the rules by the clarification, simplification and harmonisation of the production rules and the removal of a series of possible exceptions to such rules;
- seeks to do away with the possibility to exempt certain type of retailers, which led to different interpretations and practices across MS and made management, supervision and control more difficult;
- reinforces the risk-based approach to controls by removing the requirement for mandatory annual verification of compliance of all operators and making it possible to adapt the control frequency;
- introduces specific provisions for enhanced traceability and fraud prevention and for harmonised action to be taken when non-authorised products or substances are detected in organic products.

The proposal is currently under Inter-institutional discussions.

[3] COM(2014)180 final.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	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
Reg. 834/2007	OJ L 189, 20.7.2007, p. 1-23	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
Reg. 889/2008	OJ L 250, 18.9.2008, p. 1-84	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
Reg. 1235/2008	OJ L 334, 12.12.2008, p. 25-52	Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries

ANNEX 2 - DETAILS OF INDIVIDUAL AUDITS

Member State	Dates of Mission	SANCO Reference Number
Portugal	29/05-08/06/2012	6449/2012
Poland	11-21/09/2012	6569/2012
Romania	08-19/04/2013	6871/2013
Italy	15-26/04/2013	6650/2013
United Kingdom	13-23/05/2013	6744/2013
Germany	10-21/06/2013	6747/2013
France	09-20/09/2013	6880/2013
Spain	14-25/10/2013	6652/2013
Greece	11-22/11/2013	6645/2013
Slovak Republic	05-14/05/2014	7098/2014
Finland	11-19/09/2014	7101/2014
Czech Republic	07-17/10/2014	7099/2014
Malta	14-17/10/2014	7300/2014
The Netherlands	03-13/11/2014	7105/2014

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