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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ITALY

FROM 15 TO 26 APRIL 2013

IN ORDER TO EVALUATE THE CONTROL SYSTEMS FOR ORGANIC PRODUCTION AND LABELLING OF ORGANIC PRODUCTS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Italy, carried out between 15 and 26 April 2013 under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.

The objective of the audit was to evaluate the controls on organic production and labelling of organic products.

The supervision of the Control Bodies (CBs) by the Competent Authorities (CAs) is based on an appropriate number of office audits at the headquarters and regional offices of the CBs and review/witness audits at operators. The lack of co-ordination between the CAs and ongoing structural reforms within some CAs weakens the system for the supervision of the CBs. However, a new National Committee has been established in order to address this shortcoming.

Controls of the CAs and CBs are based on annual plans and risk criteria are sufficiently taken into account. The high number of samples taken by CBs at operators and controls of the CAs performed at market level allow the CAs to have a good overview of the compliance level in the area of organic production.

The system for import controls of organic consignments does not provide sufficient guarantees that consignments are verified in accordance with EU provisions. Therefore, there is a risk that non-compliant consignments are released for free circulation and enter the EU market via Italy.

Other shortcomings were found, in particular, with regard to the management of animals and derogations for the use of conventional fodder and the CBs met did not always verify all information as necessary.

The report makes a number of recommendations to the CAs, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AaA	Department of Agriculture *(Assessorato all'Agricoltura)*
ACCREDIA	National Accreditation Body (*Ente Italiano di Accreditamento*)
AGEA	Agency for Agricultural Payments (*Agenzia per le Erogazioni in Agricoltura*)
CA(s)	Competent Authority(ies)
CB(s)	Control Body(ies)
CFS	National Forest Service (*Corpo Forestale dello Stato*)
ENSE	National Seed Certification Institute (*Ente Nazionale Sementi Elette*)
EU	European Union
FVO	Food and Veterinary Office
ICQRF	Central Inspectorate for Quality Controls and Antifraud of Foodstuff and Agricultural Products (*Dipartimento dell'Ispettorato centrale della tutela della qualità e della repressione frodi dei prodotti agro-alimentari*)
MANCP	Multi Annual National Control Plan
MH	Ministry of Health (*Ministero della Salute*)
MIPAAF	Ministry of Agricultural and Forestry Policies (*Ministero per le Politiche Agricole e Forestali*)
MS(s)	Member State(s)
PPP(s)	Plant Protection Product(s)
PQA	Directorate-General for the Promotion of Agri-Food Quality (*Direzione generale per la promozione della qualità agroalimentare*)
PREF	Directorate-General for Preventing and Combating Agri-Food Fraud (*Direzione generale della prevenzione e del contrasto alle frodi agro-alimentari*)

SIAN	National Information System for Agriculture (*Sistema Informativo Agricolo Nazionale*)
SIB	Organic Information System (*Sistema Informativo Biologico*)
TC(s)	Third Country(ies)
VICO	Directorate-General for the Recognition of Control, Certification and Consumer Protection Bodies (*Direzione generale per il riconoscimento degli organismi di controllo e certificazione e tutela del consumatore*)

1 Introduction

This audit took place in Italy from 15 April to 26 April 2013. The audit formed part of the Food and Veterinary Office's (FVO) planned programme.

The audit team comprised three auditors from the FVO, two representatives from the Directorate for Agriculture and Rural Development (DG AGRI) and two national experts from Member States.

Representatives from the Ministry of Agricultural and Forestry Policies (MIPAAF - *Ministero per le Politiche Agricole e Forestali*) accompanied the FVO team for the duration of the audit.

An opening meeting was held on 15 April 2013 with the MIPAAF including the Central Inspectorate for Quality Controls and Antifraud of Foodstuff and Agricultural Products (ICQRF - *Dipartimento dell'Ispettorato centrale della tutela della qualità e della repressione frodi dei prodotti agro-alimentari*), the Directorate-General for the Promotion of Agri-Food Quality (PQA - *Direzione generale per la promozione della qualità agroalimentare*), the National Seed Certification Institute (ENSE - *Ente Nazionale Sementi Elette*) and the Agency for Agricultural Payments (AGEA - *Agenzia per le Erogazioni in Agricoltura*). Furthermore, representatives from the Department of Agriculture (AaA - *Assessorato all'Agricoltura*) of the Regions of Emilia-Romagna and Sicily and Customs participated in the opening meeting. At this meeting, the objectives of, and itinerary for, the audit were confirmed by the FVO team and the control systems were described by the authorities.

A closing meeting was held on 26 April 2013 with representatives from the Competent Authorities (CAs) including the Ministry of Health (MH - *Ministero della Salute*).

The report makes a number of recommendations to the CAs, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

2 Objectives

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

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

In pursuit of these objectives, the following sites were visited:

Table 1: Mission visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	3	Meeting with CAs at the opening and closing meeting. An additional meeting on 24 April with MIPAAF.
Regional	2	Meetings with ICQRF and AaA in the Regions Emilia-Romagna and Sicily.

Control Bodies (CBs)		
Control Bodies	4	Visit to the headquarters and of one of the regional offices of CB1 and CB2.
On-Site-Visits		
Region: Emilia-Romagna		Importer, retail shop (market control), wine processor, egg farm, fruit and vegetables, dairy farm.
Region: Sicily		Orange producer, processor of jam and fruit juices.

In terms of scope, the audit assessed the performance of the CAs, as well as the organisation of the controls carried out by the CBs including import controls, controls of operators producing, preparing and distributing organic products, controls on the labelling and marketing of organic products. The audit also addressed verification procedures and audits.

3 Legal Basis

The audit was carried out under the general provisions of EU legislation in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

EU legal acts quoted in this report refer, where applicable, to the last amended version. Full reference to documents quoted in this report is given in Annex 1.

4 Background

Between 1999 and 2004 the FVO carried out a total of 16 audits on organic farming in nine Member States (MSs) and seven Third Countries (TCs).

The FVO carried out an organic farming audit in Italy in 2000 (SANCO/1052/2000). The report of this audit has been published on the website of the Directorate-General for Health and Consumers (DG SANCO) (http://ec.europa.eu/food/fvo/ir_search_en.cfm).

The report concluded that the system of the supervision of the inspection and certification activities of the CBs by the CAs had, at the time of the audit, still been in a development phase. Furthermore, the report concluded that the co-ordination of the control activities of the Regions was not appropriate and that enforcement measures were only occasionally applied.

Based on a Memorandum of Understanding between the Directorate-General for Health and Consumers and the Directorate-General for Agriculture and Rural Development, the FVO is undertaking a new series of audits on organic production to MSs and TCs.

5 Findings And Conclusions

5.1 Relevant National Legislation and Provisions

Legal Requirements

Article 291 of the Treaty on the functioning of the EU establishes that MSs shall adopt all measures of national law necessary to implement legally binding Union acts.

Findings

Italy has established national and regional legislation for the implementation and application of EU legislation on organic production. Legislative Decree No 220/1995 and Ministerial Decree No 18354/2009 provide the legal framework for the application of Regulation (EC) No 834/2007 and specific decrees were subsequently issued by the MIPAAF.

Conclusions

According to the information provided by the MIPAAF all measures of national law necessary to implement legally binding Union acts relevant to this audit have been adopted in Italy.

5.2 Organisation and Implementation of Controls

5.2.1 Competent Authorities and Control Bodies

5.2.1.1 Competent Authorities

Legal Requirements

According to Article 27(1) of Regulation (EC) No 834/2007 MSs shall set up a system of controls and designate one or more CA responsible for controls in respect of the obligations established by this Regulation in conformity with Regulation (EC) No 882/2004. Article 27(4) of this Regulation lays down that CAs may confer its control competences to one or more other control authority or delegate control competences under certain conditions to one or more CB and shall designate authorities responsible for the approval and supervision of CBs.

Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available. Article 6 requires CAs to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

Article 27(4)(a) of Council Regulation (EC) No 834/2007 requires that control authorities offer adequate guarantees of objectivity and impartiality, and have at their disposal the qualified staff and resources necessary to carry out their functions.

Findings

The MIPAAF is the CA responsible for the control system for organic production. Two departments of the MIPAFF are in charge of organic production:

- The PQA is responsible for preparing national provisions and other instruments necessary to ensure that EU legislation on organic farming is applied and it oversees the updating of the National Information System for Agriculture (SIAN - *Sistema Informativo Agricolo Nazionale*). It is also responsible for issuing import authorisations for organic products from

TCs within the meaning of Regulation (EC) No 1235/2008.

- The ICQRF has two Directorate-Generals dealing with organic farming:
  - the Directorate-General for Preventing and Combating Agri-Food Fraud (PREF - *Direzione generale della prevenzione e del contrasto alle frodi agro-alimentari*) and
  - the Directorate-General for the Recognition of Control, Certification and Consumer Protection Bodies (VICO - *Direzione generale per il riconoscimento degli organismi di controllo e certificazione e tutela del consumatore*).

  The PREF is in charge of the market controls of organic products, fraud related investigations and, since September 2012, is responsible for the supervision of CBs. The VICO approves CBs based on accreditation by the National Accreditation Body (ACCREDIA - *Ente Italiano di Accreditamento*) and decides on the suspension and withdrawal of CBs.

  Up until 2012 VICO was supported by a committee consisting of representatives from other Ministries and from some Regions. As a result of the spending review of the public budget this committee was suspended.

  The ICQRF has 29 regional offices (including branch offices) with 790 employees. The MIPAAF stated that the re-organisation of the control system is still ongoing and that PREF, with regard to the supervision of the CBs is not yet fully operational. Therefore, PREF did not carry out any office audits at CBs between January 2013 and the time of the audit. The VICO continued to assess and approve procedures and files of new staff of the CBs.
- The ENSE manages the national database for organic seeds.
- The AGEA performs on-the-spot controls on 5% of organic operators receiving subsidies.

Customs carries out controls in relation to Article 13 of Commission Regulation (EC) No 1235/2008, including products imported under the provisions of Article 19 of the same Regulation, and endorses the certificate of inspection.

The Local Veterinary Services provide an opinion regarding certain operations referred to in Article 18(1) of Commission Regulation (EC) No 889/2008.

Other CAs are involved in the control system for organic production with regard to investigations on fraudulent activities (Carabinieri Health Protection Unit and Financial Guards).

The AaA of the Regions and the two autonomous Provinces are responsible for the registration of organic operators and the supervision of CBs.

Training of MIPAAF staff including staff from the territorial offices is organised at central level. In 2012 a training course on aquaculture and the new provisions for organic wine production was organised. The audit team noted that staff members from the territorial offices of ICQRF interviewed by the audit team were competent and familiar with EU and national provisions on organic production.

Inspectors from the territorial offices of ICQRF and from the AaAs have to have at least a high school or university degree in agriculture.

In Emilia-Romagna no specific training programme for organic production was in place at the time of the audit. The audit team checked the training file of an AaA inspector. This inspector had participated in the Better Training for Safer Food course on organic farming and was competent and familiar with organic production rules. The review audits at operators are carried out in Emilia-Romagna by staff from the National Forest Service (CFS - *Corpo Forestale dello Stato)*. These staff members had not received any specific training on organic production. However, the AaA

accompanies 20% of the inspections in order to verify that these inspections are effective and annual meetings are held with inspectors from the CFS.

The AaA of Sicily stated that in the last four years the system for the supervision of CBs had been affected by three structural reforms and a spending review. At the time of the audit the organisational structure regarding the supervision of CBs was in a transitional phase. A new co-ordinator was appointed and staff from the regional Plant Health Service were entrusted with the review of audits at operators. At the time of the audit these inspectors had not been trained in all aspects of organic production (e.g. animal husbandry) which is not in accordance with Article 6(a) of Regulation (EC) No 882/2004. The AaA of Sicily stated that the plant health inspectors would be supported by experienced staff members who had performed organic farming inspection up until 2010.

The Customs inspectors had not received specific training on import controls of organic products including the verification and endorsement of the certificate of inspection and the different types of import procedures as set out in Commission Regulation (EC) No 1235/2008. Customs stated at the closing meeting that training sessions also covering organic production had been held in the past. However, Customs did not provide sufficient evidence supporting this statement.

Controls of organic operators were delegated to 13 Italian CBs and three CBs with headquarters in another MS.

Conclusions

A system of controls is in place in accordance with Article 27(4) of Regulation (EC) No 834/2007 with designated CAs and inspection and certification tasks delegated to CBs. The division of tasks is clear although there is partly an overlap of responsibilities between the CAs.

Overall, staff from the CAs met by the audit team were competent in performing their tasks. However, no specific training had been provided to the plant health inspectors in Sicily and to staff members from Customs in order to allow them to undertake their duties competently and to carry out official controls in a consistent manner in accordance with Article 6(a) of Regulation (EC) No 882/2004.

5.2.1.2 Control Bodies: Accreditation, Approval, Supervision and Withdrawal

Legal Requirements

The CA may delegate control tasks to a particular CB only if the conditions laid down in Article 5(2) of Regulation (EC) No 882/2004 are met.

Articles 27(5) to (7) of Regulation (EC) No 834/2007 lay down the conditions under which the CA can delegate control tasks to CBs, the criteria which the CA has to take into account whilst approving CBs, the tasks that cannot be delegated and the situations in which CAs can withdraw the delegation to CBs.

Article 27(5)(b) of Council Regulation (EC) No 834/2007 requires that there is proof that CBs have the expertise, equipment and infrastructure required to carry out the tasks delegated to them and are impartial and free from any conflict of interest as regards the exercise of the tasks delegated to them.

Article 27(8) of Regulation (EC) No 834/2007 provides that, in accordance with Article 5(3) of Regulation (EC) No 882/2004, CAs delegating specific tasks to CBs shall organise audits or inspections of CBs as necessary. In addition, paragraph 9 of the same Article requires that the CA shall ensure that the controls carried out by the CB are objective and independent, verify the effectiveness of its controls, take cognisance of any irregularities or infringements found and

corrective measures applied and withdraw approval of that CB where it fails to satisfy the requirements.

Article 27(5)(b) of Council Regulation (EC) No 834/2007 requires that there is proof that CBs have the expertise, equipment and infrastructure required to carry out the tasks delegated to it, have a sufficient number of suitably qualified and experienced staff; and are impartial and free from any conflict of interest as regards the exercise of the tasks delegated to them.

Findings

The audit team visited the headquarters and one regional office of two CBs. Both CBs had more than ten regional offices. The regional offices are entrusted with the inspection and certification of operators. The final certification decision is taken by the Certification Committee at the CB's headquarters. The headquarters are responsible for the preparation of procedures, planning, co-ordination and supervision of regional offices.

Both CBs had procedures in place for the training of new inspectors and provided annual training courses for staff members. All staff members from the two CBs have to sign a declaration regarding an absence of conflict of interest every year and have to inform the CB of any other professional activity. The rotation of inspectors was ensured.

Accreditation of the CBs to EN 45011 is a condition for the approval of the CBs by the MIPAAF. The ACCREDIA stated that annual accreditation audits are carried out at all headquarters of the CBs and that critical locations (e.g. regional offices where certification decisions are prepared) are inspected at least once within the four years of the accreditation cycle. At the time of the audit ACCREDIA had sanctions against CB1 in place. CB1 was not allowed to accept and certify new operators. The reason for the sanction was in relation to an operator who had moved from one CB with open non-conformities to CB1. The national provisions allow operators to move to a new CB only when all non-conformities are rectified by the operator and subsequently closed by the initial CB. In 2012 another CB was suspended by ACCREDIA for four months and consequently approval was withdrawn by MIPAAF during this period.

In Italy the Regions are responsible for the supervision of CBs. Where a Region does not have the means to fulfil its obligations, the MIPAAF is, according to the principle of subsidiarity, authorised to carry out this task. According to the information provided by the MIPAAF about 49 office audits were performed by the CAs (Regions and MIPAAF) in 2011, 34 in 2012 and 58 are planned for 2013. The MIPAAF stated that these audits may not necessarily take place at the CB's office, but the CBs may be asked to submit documents (e.g. procedures and selected files of operators) to MIPAAF. About 869 review and witness audits at operators were carried out by the CAs in 2011, 809 in 2012 and 911 are planned for 2013. Most of these controls at operators were review audits. Usually 2 witness audits per CB are performed by the MIPAAF every year.

In 2012 four regions with seven or more CB offices did not carry out any office audits. The MIPAAF stated that there is a variation between Regions as some carry out more and others less intensive supervision of the CBs.

The representative from the Region of Emilia-Romagna stated that the AaA carries out annual office audits at all CBs with offices in their Region. Office audits might also be performed by the AaA of Emilia-Romagna at CB headquarters based in other Regions where a CB has many operators in Emilia-Romagna. Furthermore, the annual activity reports of the CBs and other relevant information (e.g. notifications of irregularities) are assessed.

Representatives from the Region of Sicily stated that in 2011 and 2012 the AaA did not perform review audits at operators, in particular, as the structural reforms of the administration did not permit them to do so. In 2011 and 2012 all offices of CBs in Sicily were audited by the Region and

it is planned to carry out office audits at all CB offices in 2013.

The MIPAAF has to approve the procedures and the annual inspection and sampling plan of the CBs. Since the end of 2012, as a result of fraud cases in organic production, the MIPAAF follows a stricter line. At the time of the FVO audit the MIPAAF checked files of the staff members of several CBs. In the case of CB2 the MIPAAF had suspended the approval of about 25% of the inspectors because of a potential conflict of interest.

No evidence was provided by MIPAAF that a coherent and appropriate system for the supervision of CBs is in place for the whole of Italy in particular, as there was no evidence of effective co-ordination of the CAs supervision activities (see section 5.2.8). The audit team checked the risk classification of operators of CB2 for 2012 and noted that a very low number of operators were in the high and medium risk classes. CB2 admitted that the observation made by the audit team was correct. The ACCREDIA had the same issue in 2012. None of the CAs supervising CB2 had detected this problem, although CB2 had applied this approach for the risk assessment for some years.

Conclusions

CBs are accredited to standard EN 45011 and approved as required by EU legislation by the MIPAAF.

A system for the supervision of CBs by the CAs is in place including a high number of office and review/witness audits, but there is a lack of co-ordination between the CAs (see section 5.2.8). Therefore, the system does not provide sufficient guarantees that all requirements as set out in Articles 27(8) and (9) of Regulation (EC) No 834/2007 are met. Furthermore, the continuous structural reorganisation of the AaA in Sicily and the ongoing reorganisation at MIPAAF weaken the control system.

Where a CB fails with its obligation, the MIPAAF withdraws or suspends the approval of the CB as required by EU provisions. In the case checked by the audit team the measures taken against a CB were appropriate.

5.2.2 Controls on Organic Production

5.2.2.1 Registration of operators

Legal Requirements

According to Article 28(1) of Council Regulation (EC) No 834/2007 any operator who produces, prepares, stores, or imports from a TC products within the meaning of Article 1(2) of the same Regulation or who places such products on the market shall, prior to placing on the market of any products as organic or in conversion to organic notify his activity to the CAs of the MS where the activity is carried out and submit his undertaking to the control system referred to in Article 27 of the same Regulation.

Article 28(2) of Regulation (EC) No 834/2007 provides that MSs may exempt from the application referred to in the same Article, operators who sell products directly to the final consumer or user provided they do not produce, prepare, store other than in connection with the point of sale or import such products from a TC or have not contracted out such activities to a third party.

Findings

All operators, except importers of organic products, have to submit their application for placing their activities under the official control system for organic production to the regional authorities.

Ministerial Decree of 1 February 2012, No 2049 introduces the Organic Information System (SIB - *Sistema Informativo Biologico*) which is an integral part of SIAN. Since 2012 operators are requested to submit their application to the regions via SIB. Importers address their application directly to MIPAAF. At the time of the audit, the system was still in transition as the interfaces with the regional databases were not fully in place. Therefore, the MIPAFF has to update the national list of organic operators including the certificates of conformity. The updated list for 2012 was in preparation at the time of the audit. The MIPAAF stated that the list of operators and the documentary evidence had not yet been updated in a timely manner, contrary to Article 92(a) of Commission Regulation (EC) No 889/2008. The MIPAAF also stated that most of the CBs also publish this information.

The audit randomly verified some names of organic operators whether they were contained in the SIB database or not and found that the list for 2011 as available at the time of the audit contained these operators and their certificates of conformity.

Italy has made use of the provisions of Article 28(2) of Regulation (EC) No 834/2007 about exempting operators who sell products directly to the final consumer from placing their activities under the control system where the conditions of the same paragraph are fulfilled.

Conclusions

A system for the registration of operators subject to the controls of organic production is in place. The information referred to in Article 92(a) of Commission Regulation (EC) No 889/2008 was made public by Italy but is not yet updated in a timely manner contrary to the provisions laid down in the same Article.

5.2.2.2 Controls of operators

Legal Requirements

Specific rules on production, processing, packaging, transport and storage of products are laid down under Title II of the same Regulation.

Title IV of Commission Regulation (EC) No 889/2008 provides, in accordance with Article 27 of Council Regulation (EC) No 834/2007 for general minimum control requirements as well as for specific control requirements for plants and plant products, livestock and livestock products, preparation of products, imports, units using contracts to third parties, units preparing feed.

According to Article 65 of Commission Regulation (EC) No 889/2008 control authorities or CBs shall carry out at least one physical inspection per year of all operators. Moreover, the control authority or control body shall carry out random control visits, primarily unannounced.

Findings

<u>General aspects of the controls</u>

Both CBs have checklists in place for different types of operators and the inspectors followed these check lists during the inspections observed by the audit team. Time did not usually permit the overseeing of a full inspection. Therefore, the audit team asked the inspectors to focus on certain aspects of the controls. The audit team also checked files of operators at the offices of the CBs.

Inspectors from both CBs have access to the physical file of the operators in order to prepare themselves for the inspection. The audit team noted that the inspectors upon arrival at the operators' premises already had a good knowledge of the operator' activities and past records.

The audit team noted that the files of the operators contained all relevant information as required by EU provisions including a plan of the premises and the production plan. Where information was missing this had been observed by the inspectors and was recorded in the inspection report.

The MIPAAF stated that in Italy, at the time of the audit, no harmonised lists with the commercial names of products authorised for use in organic farming were available. However, this is not required by EU provisions. The MIPAAF stated that it is planned to establish such a list for plant protection products (PPPs) and fertilisers in the near future. At the time of the audit the inspectors from the CBs had to check each product individually, e.g. for PPPs the database of the MH had to be consulted. Up until 2011 fertilisers for use in organic farming were approved by the authorities and products with approved labels were still on the market. Therefore, CB inspectors continued to rely on these approved labels.

CBs provide documentary evidence to any such operator who is subject to their controls and who in the sphere of his activities, meets the requirements laid down in this Regulation. Operators are allowed to sell their products only if the CB provides a certificate of conformity in addition to the documentary evidence. The certificate of conformity is more specific than the documentary evidence with regards to the products and has a shorter validity (documentary evidence 3 years and certificate of conformity 12 to 18 months). The MIPAAF stated that this system has been introduced in order to simplify the updating of the product categories covered by the certification. The CBs met stated that operators without a certificate of conformity are treated the same way as all operators including the risk assessment.

Producer

- The audit team visited a dairy farm and noted that the cows did not have horns as a result of veterinary treatments at a young age. The farmer, the inspector and the representatives from the Region of Emilia-Romagna stated that this is common practice in Italy and done on a regular basis contrary to Article 18(1) of Regulation (EC) No 889/2008. The disbudding of the animals was not recorded in the veterinary treatment records and the farmer did not require a derogation.

  The dairy farmer separated three animals, that had undergone veterinary treatments, from the herd and the milk from these cows was not marketed. This was ensured as each separated animal had a sensor fixed to the leg which sounded an alarm when entering the milking area. The inspector stated that usually the statement of the farmer that the withdrawal period is respected would be sufficient. Fluctuation in daily milk production was not cross-checked and was not foreseen in the checklist. This approach does not provide sufficient guarantees that the provisions as referred to in Article 22(5) of Commission Regulation (EC) No 889/2008 are complied with.
- The audit team visited producers of fruits and vegetables and one egg farmer of CB2 and noted that the inspectors from CB2 performed the inspection, as demonstrated, in accordance with the CBs procedures. The inspectors followed the CB's checklist.
- At the fruit producer visited in Sicily the operator and CB2 stated that not all documents were available due to a fire that destroyed some of the documentation in 2012 including the request for a derogation regarding the use of conventional material for the vegetative propagation of vine. The audit team asked ENSE for documentary evidence that the derogation had been granted. Based on the information provided by the MIPAAF no such derogation had been granted. The CB2 did not check this.
- The audit team noted that Emilia-Romagna set out the livestock unit equivalent to the 170 kg/ha limit based on relevant national/regional provisions adopted pursuant to Directive 91/676/EEC.

Processor

- The audit team visited a wine producer and a processor of organic jam, fruit juices and other products of CB1. The inspector from CB1 demonstrated a mass-balance exercise and label check. The audit team had no observations except that the CB could not provide evidence that checks are also performed at the jam processor when processing of organic products takes place.

Importer

- The audit team visited an importer of frozen fruits from Turkey. The products were imported up until July 2012 with an import authorisation. After this date the operator applied the procedures for equivalent imports as the CB had been listed in Annex IV of Commission Regulation (EC) No 1235/2008. At the beginning of the inspection, the inspector from CB1 identified some irregularities. The importer had not notified all imports to the CB and to MIPAAF and had not notified that the import authorisation was no longer used. The inspector informed the audit team of a recent import which had been accompanied by a certificate of inspection that deviated from the model as set out in Annex VI of Commission Regulation (EC) No 1235/2008. The audit team noted that Customs had endorsed this certificate of inspection.

Conclusions

Overall, the controls observed by the audit team covered the minimum requirements for controls as set out in Commission Regulation (EC) No 889/2008. However, for some control aspects the two CBs visited had no measures in place to ensure that operators comply with all EU organic production rules. Therefore, the system in place for the controls of operators does not always ensure that the controls are effective as CB1 could not ensure that inspections take place at the most appropriate time and CB2 did not verify and cross-check information as necessary.

5.2.2.3 Sampling

Legal Requirements

According to Article 65(2) of Commission Regulation (EC) No 889/2008 the control authorities or CBs may take samples. Samples shall be taken and analysed where the use of products not authorised for organic production is suspected.

According to Article 12 of Regulation (EC) No 882/2004 the CA shall designate laboratories that may carry out the analysis of samples taken during official controls.

Findings

Both CBs visited had procedures for sampling in place and the annual sampling plans of the CBs had been approved by the MIPAAF. Both CBs take samples at operators classified as high risk (including all operators where in the previous year a positive sample had been taken), 25% of medium risk operators are randomly sampled. Samples are also taken where there is a suspicion of use of unauthorised products.

The audit team observed sampling of products performed by both CBs. The audit team noted that both CBs take four samples; one sample remains with the operator, two counter samples with the CB and one sample is for the laboratory. The samples were sealed and were properly marked.

The selection of the laboratory and the analytical scope of the analysis is the responsibility of the CB. The MIPAAF stated that no instructions or guidelines had been issued at national or regional level in this regard. The only requirement is that laboratories have to be accredited but there is no

requirement to use official laboratories designated by the CA contrary to Article 12(1) of Regulation (EC) No 882/2004.

The audit team checked laboratory results and noted that the two CBs visited had given clear instructions to the laboratories regarding the scope of the analysis. The laboratories selected by the CBs were accredited and had an appropriate analytical scope for pesticide residues with Liquid chromatography–mass spectrometry and Gas chromatography-mass spectrometry as well as for single residue testing where requested by the CB. The sampling plan of both CBs covered testing for pesticide and medical residues for the presence of genetically modified organism.

CB1 took 2 194 samples (equal to 17% of controlled operators) in 2012. More than 10% of the samples were positive. CB2 took 715 samples (equal to nearly 7% of operators controlled) in 2012. More than 6% of the samples were positive with regional variations of up to 20% of samples tested positive.

Ministerial Decree D.M. 309 of 2009 defines an action level of 0.01 ppm above which organic products cannot be marketed even when the cause of the residues is accidental contamination (e.g. spray drift). This is not in compliance with Article 12(1)(h) of Regulation (EC) No 834/2007 which does not allow the establishing of such limits for pesticide residues.

Conclusions

The CBs visited had appropriate sampling procedures and sampling plans in place. The testing of the samples from the two CBs is performed by accredited laboratories and the analytical scope of the testing is appropriate. Italy has not designated laboratories for testing samples taken by the CBs. This is not in compliance with Article 12 of Regulation (EC) No 882/2004.

Italy has established an action level for pesticide residue levels in organic products. This is not in compliance with Article 12 (1) (h) of Regulation (EC) No 834/2007.

5.2.3 Controls on Labelling and Traceability

Legal Requirements

Article 23 of Regulation (EC) No 834/2007 provides for the use of terms referring to organic production and according to paragraph 5 of the same Article, MSs shall take the necessary measures to ensure compliance with this Article.

Compulsory indications concerning the use of the terms as referred to in Article 23(1) of Regulation (EC) No 834/2007 are laid down in Article 24 of the same Regulation.

Article 27(13) of Council Regulation (EC) No 834/2007 provides that MSs shall ensure that the control system as set up allows for the traceability of each product at all stages of production, preparation and distribution in accordance with Article 18 of Regulation (EC) No 178/2002.

Labelling requirements for organic products are laid down in Title III of Commission Regulation (EC) No 889/2008.

Findings

Operators who sell packaged products can only use labels that have been approved by the CB. The audit team noted that the inspectors had samples of the approved labels on file and verified them against the labels found during the inspection.

At a wine producer the audit team noted that the labels on the bottled wines, which had been approved by CB1, were not in accordance with EU provisions. The inspector did not note this during the inspection. The label referred to “Italy” and not to “Italy Agriculture” as required by

Article 24(1)(c) of Regulation (EC) No 834/2007.

Controls at market level are carried out by the territorial offices of ICQRF based on a national plan which is co-ordinated with the MH. The Regions are informed at the beginning of the year of the number of controls to be carried out and of any specific products to be checked and sampled. In total, all territorial offices carried out 588 controls on marketing and labelling of organic products in 2010, 1150 in 2011 and 897 in 2012. For 2013 nearly 1 600 controls are planned. The inspectors from MIPAAF took 424 samples (8 tested positive) in 2010, 583 (10 tested positive) in 2011 and 655 (39 tested positive) in 2012. The MIPAAF stated that 6 non-compliances were found at market level in 2010 and 8 in 2011. However, MIPAAF stated that these figures are underestimated. The draft report on market controls for 2012 indicated in the category "organic" that at around 6% of operators' irregularities had been found.

Controls usually start at retail level. If a chosen organic product originates from an operator of the Region where the territorial office is located further checks on the product are performed at that operator.

The audit team observed a market control at a retailer carried out by two inspectors from the territorial office of MIPAAF in Emiliga-Romagna. One inspector checked labels of a broad range of products and identified several irregularities.

The audit team selected two organic products at a retailer on the first day of the audit (biscuits and blueberry drink). The MIPAAF successfully carried out the traceability exercise and provided the audit team with relevant supporting documentation.

Conclusions

An appropriate system is in place to ensure the traceability of products at all stages. However, a minor non-compliance regarding the approval of labels by CB1 were found with regard to organic wine.

5.2.4 Exceptional Production Rules, Derogations and Authorisations

Legal Requirements

Where an ingredient of agricultural origin is not included in Annex IX of Commission Regulation (EC) No 889/2008, that ingredient may only be used in its non-organic form for the preparation of organic processed products and only under certain conditions as set out in Article 29 of the same Regulation. A MS shall immediately notify the other MSs and the Commission of authorisations of such use of non-organic ingredients.

Sections 2 to 4 of Chapter 6 of Title II of Commission Regulation (EC) No 889/2008 provide for exceptional production rules related to non-availability of organic farm inputs, specific management problems in organic livestock, use of specific products and substances in the processing and catastrophic circumstances in accordance with Article 22(2)of Regulation (EC) No 834/2007.

Findings

Overall the number of derogations granted for organic production is relatively low in Italy compared with other MSs including derogation for non-organic ingredients and movements of non-organic female mammals brought onto the holding for the renewal of the herd. In most cases the Regions are responsible for granting derogations.

The audit team checked in Emilia-Romagna one derogation granted with regard to Article 47 (c) of Commission Regulation (EC) No 889/2008 (use of non-organic feed due to catastrophic circumstances) and one with respect to Article 36 (2) (shortening of conversion period) and noted

that:

- the derogation granted by Emilia-Romagna in 2012 for the use of non-organic feed applied to the whole territory of the Region and did not identify individual operators contrary to EU provisions,
- the farmer had to provide the expertise of a registered agriculture expert to be assessed by the CB before approval by the Region and the derogation for the shortening of the conversion period was granted in accordance with EU provisions.

Authorisations by the CAs as referred to in Articles 18(1) and 39 of Commission Regulation (EC) No 889/2008 are regulated by Ministerial Decree D.M.18354/2009. Disbudding of calves is allowed under the supervision of a veterinarian. In the case of tethering of animals the national provisions specify that this applies to small holdings, with no more than 30 animals. The CAs may collect information in relation to these derogations only when performing audits at the CBs. In Italy there is no requirement to notify these authorisations and the CA has no overview of the situation.

The dairy farmer visited by the audit team stated that veterinary treatment of the horn is performed at a young age of the animal in order to avoid further growth. The farmer, CB2 and the representative from the Region stated that this is common practice in Italy and it is not considered to be dehorning. Therefore, no entry into the veterinary treatment register is needed. This is not in accordance with Article 18(1) of Commission Regulation (EC) No 889/2008 and this is a de-facto dehorning.

Conclusions

The system in place for derogations and authorisations of certain management practices is not fully in compliance with EU provisions as it allows disbudding of calves on a regular basis. The treatment of the horn of young animals is a de facto dehorning and this is not in accordance with Article 18(1) of Commission Regulation (EC) No 889/2008 and derogations granted under Article 47 (c) of Commission Regulation (EC) No 889/2008 do not always refer to individual operators.

5.2.5 Imports of Products from Organic Production

Legal Requirements

A product imported from a TC may be placed on the EU market as organic if it fulfils the requirements for compliant products as laid down in Article 32 of Regulation (EC) No 834/2007 or the requirements for products providing equivalent guarantees as laid down in Article 33.

Commission Regulation (EC) No 1235/2008 provides detailed rules for the implementation of Council Regulation (EC) No 834/2007 with regards to the arrangements for the imports of organic products from TCs. Chapter 3 of title III of Commission Regulation (EC) No 1235/2008 provides provisions on the release for free circulation of products imported in accordance with Article 33 of Regulation (EC) No 834/2007. Models of the documentary evidence, the certificate of inspection and the extract of the certificate of inspection are provided in Annexes II, V and VI respectively. A list of TCs and relevant specifications referred to in Article 7 of Commission Regulation (EC) No 1235/2008 are contained in Annex III.

Article 19 of Regulation (EC) No 1235/2008 lays down transitional rules on equivalent imports of products not originating in listed TCs. It establishes the conditions under which MSs may authorise importers and when the authorisations must be withdrawn. It also requires MSs to inform other MSs and the Commission of each authorisation granted, including information on the production standards and control arrangements concerned.

Findings

Customs is the CA responsible for the verification of organic consignments and the endorsement of the certificate of inspection in accordance with Article 13(1)(b). A representative from Customs stated at the opening meeting, that, where the import of an organic product is notified to Customs, the information contained in the certificate of inspection is assessed against the accompanying documents.

The audit team found certificates of inspection at one importer which had been endorsed by Customs in box 17. The organic products were imported from a TC under the import procedures referred to in Article 19 of Commission Regulation (EC) No 1235/2008. The importer from this company stated that the original import authorisation did not need to be presented to Customs and that only a copy of the document is required. The audit team noted that:

- One certificate of inspection did not follow the model contained in Annex V of Commission Regulation (EC) No 1235/2008. Customs had endorsed this document and did not suspect that the certificate of inspection may have been falsified.
- The certificates of inspection checked had not been endorsed in box 16 although the conditions of Article 13(7)(c) of Regulation (EC) No 1235/2008 did not apply.
- Customs had outdated procedures in place (see section 5.2.1.1).

The audit team checked a file of an import authorisation granted under Article 19 of Commission Regulation (EC) No 1235/2008. The MIPAAF stated that import authorisations are granted based on the certificate of conformity issued by an accredited CB and that where needed, inspection reports and additional information may be requested. However, the MIPAAF admitted that the standard applied by the CB is not assessed as to whether it is equivalent to EU production rules contrary to the provisions referred to in Article 19 of Commission Regulation (EC) No 1235/2008.

Conclusions

A system for the control of imports of organic products is not in compliance with EU provisions and there is a risk that non-compliant products enter the EU markets via Italy. The shortcomings found by the audit team have their root-cause in outdated procedures and training for Customs inspectors (see section 5.2.1.1).

The system in place for granting import authorisations is not fully in accordance with EU provisions as no equivalence assessment of the standard applied by the CB in the TC is carried out. However, the MIPAAF takes inspection reports and additional information into account.

5.2.6 Planning and Prioritisation of Controls

Legal Requirements

Article 41 of Regulation (EC) No 882/2004 requires MSs to prepare a single integrated Multi-Annual National Control Plan (MANCP).

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency, taking account of (a) identified risks; (b) the food business operators' past record with regard to compliance; (c) the reliability of any self checks that have already been carried out; and (d) any information that might indicate non-compliance. In addition, Article 27(3) of Regulation (EC) No 834/2007 requires that the nature and frequency of the controls shall be determined on the basis of an assessment of the risk of occurrence of irregularities and infringements as regards compliance with the requirements laid down in this Regulation and that all operators, with some exceptions, shall be subject to verification of

compliance at least once a year.

According to Article 65(4) of Commission Regulation (EC) No 889/2008 control authorities or CBs shall carry out, in addition to the annual physical inspections referred to in paragraph 1 of the same Article random control visits, primarily unannounced, based on the general evaluation of the risk of non-compliance with organic production rules, taking into account at least the results of previous controls, the quantity of products concerned and the risk for exchange of products.

Findings

Every year MIPAAF establishes general guidelines for controls regarding the marketing and labelling of organic products which are then interpreted by the territorial offices of MIPAAF into operational control plans. In the planning process, various factors are taken into account at central and regional level, including:

- the economic importance of the various commodity sectors;
- the characteristics of the productive and commercial organisation of the various sectors;
- movements of organic products from MSs and TCs;
- trends in production and market prices;
- past records.

The territorial offices of ICQRF carry out review audits based on a national programme by MIPAAF. The annual programme of MIPAAF sets out for the territorial offices of ICQRF where CBs have their headquarters a minimum number of controls at operators, basically all review audits but also two witness audits per CB. The ICQRF first carry out a preliminary assessment based on information available, and visits the headquarters of the CB based in their jurisdiction in order to check some procedures and to select operator files for the review audits. Where possible, at least 50% of the selected operators should have had infringements.

The Regions of Emilia-Romaga and Sicily prioritise the review audits at operators and take information gained from office audits at the CBs and other information into account. The review audits are planned in order to cover different types of operators.

The MIPAFF has an annual plan for controls of organic products at market level in place which, if needed, following interception, identifies specific products considered to be of higher risk.

The MANCP 2011-2014 has been published on the website of the MH (http://www.salute.gov.it). It provides sufficient information on the control system for organic production and labelling of organic products.

The risk assessment of operators by the CBs is harmonised in Italy. ACCREDIA issues a technical document (RT-16) providing binding requirements for the CBs including risk assessment. It defines three risk categories (low, medium, high) and provides guidance regarding risk assessment. In the case of CB1 the risk assessment is carried out by the certifier and approved by headquarters and in the case of CB2, headquarters carry out the risk assessment. The audit team checked several files at CB1 and noted that all operators were classified according to risk. However, in the case of CB2 the audit team noted that the number of operators in the high and medium class was very low (see section 5.2.1.2).

Both CBs plan the number and type of inspection at operators according to the risk assessment. Low risk operators are inspected routinely once a year, medium risk operators receive two inspections of which one may be unannounced and high risk operators receive more than two inspections with at least one inspection unannounced. CB1 stated that, in most cases the operator is informed of the unannounced inspection with short notice (one day prior to the inspection). This is

not in accordance with Article 65(4) of Commission Regulation (EC) No 889/2008.

Conclusions

The CAs perform supervision of CBs based on annual plans. The operational plans of the CAs are risk based as required by EU provisions.

The CBs visited have annual control plans in place and are approved by MIPAAF. The risk criteria are harmonised by ACCREDIA document RT16. The announcement of inspections planned as unannounced inspections of operators by CB2 is not in accordance with Article 65(4) of Commission Regulation (EC) No 889/2008 with the risk that the inspections do not achieve the envisaged result.

5.2.7 Procedures for Performance and Reporting of Control Activities

Legal Requirements

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of the above Regulation requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the control methods applied, the results obtained and any action to be taken by the business operator concerned.

According to Article 65(3) of Commission Regulation (EC) No 889/2008 control authorities or CBs shall draw up a control report after each visit, countersigned by the operator of the unit or his representative.

Findings

The MIPAAF has procedures in place for import controls and for the supervision of CBs. Ministerial Decree No 16954/2010 establishes provisions on the minimum requirements for sampling procedures for organic products for analysis. These guidelines are also binding for the CBs.

The MIPAAF also has procedures in place for the supervision of CBs. These procedures are established and updated in the form of circular letters sent to the territorial offices of the ICQRF.

Both Regions visited had procedures in place for the supervision of CBs. In the case of Sicily these procedures were not very detailed.

The two CBs visited had a set of guidelines for the organisation of the CB (e.g. staff related issues and conflict of interest) and the preparation and performance of controls including forms and checklists in place. The audit team randomly checked some of the procedures.

Customs provided the audit team with a circular letter sent in 2003 to the customs offices with instructions regarding the import procedures for consignments of organic products. The audit team noted that the procedures were outdated and did not refer to Commission Regulation (EC) No 1235/2008.

The state veterinarians entrusted with the approval of operations referred to in Article 18(1) of Commission Regulation (EC) No 889/2008 had not received any guidance or instructions from the MIPAAF or the MH in order to ensure that the principles of organic farming are respected when approving such operations.

Inspectors from the CAs and CBs met by the audit team issued a report to be signed by the inspector and the operator's representative.

Conclusions

Official controls are carried out by the CAs and CBs in accordance with documented procedures and reports are draw up as required by EU provisions. However, Customs had outdated procedures for import controls (see section 5.2.5).

5.2.8 Communication, Co-ordination and Co-operation

Legal Requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination between CAs.

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a CA, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

Article 27(5)(d) of Regulation (EC) No 834/2007 provides that CBs communicate the results of the controls carried out to the CA on a regular basis and whenever the CA so requests. Furthermore, Article 27(5)(e) requires that there is effective co-ordination between the delegating CA and the CB.

Article 27(14) provides that control authorities and CBs shall transmit to the CAs each year by 31 January a list of the operators which were subject to their controls of the previous year and by 31 March a summary report of the control activities carried out during the previous year.

Article 30(2) provides that Information on cases of irregularities or infringements affecting the organic status of a product shall be immediately communicated between the control bodies, control authorities, competent authorities and Member States concerned and, where appropriate, to the Commission. The level of communication shall depend on the severity and the extent of the irregularity or infringement found.

Findings

The CBs notify every two weeks all irregularities to the MIPAAF and to the Regions. The MIPAAF enters the information into a database which is also accessible by all territorial offices of ICQRF. The CBs met also fulfil their reporting requirements and submit their annual control programme and annual activity report to the CAs.

Both Regions stated that the results of the supervision of the CBs are communicated to the MIPAFF and that this requirement was established by Ministerial Decree D.M of 16 February 2012 which came into effect in 2013. The same Ministerial Decree established a new National Committee regarding the supervision of CBs. This committee had, at the time of the audit, held one meeting. The audit team also received whilst in Emilia-Romagna documentary evidence of the communication between the Regional and ICQRF regarding the controls of organic operators.

The audit team noted that at the time of the audit no effective measures were in place to ensure a co-ordinated approach with regard to the supervision of the CBs by the CAs (see section supervision 5.2.1.2). The PREF stated that the aim of the new Committee is to address this weakness. As the Committee only started its activities in early 2013 the PREF expects that the measures will become effective as of 2014.

The audit team checked one file of an OFIS notification and noted that there was good and timely communication between the MIPAAF, including the territorial office of ICQRF, and the CB involved.

AGEA enters the results of its inspections at operators receiving EU agricultural subsidies into a database which is accessible to other CAs. The regional services met stated that this information is

used in order to plan inspections at operators where irregularities were found, if appropriate.

Conclusions

Overall there is appropriate and timely communication between the CBs and CAs. However, all irregularities, including cases of irregularities or infringements affecting the organic status of a product, are communicated once every two weeks by CBs to the CAs and not immediately as required by Article 30(2) of Regulation (EC) No 834/2008.

Italy has established good communication structures regarding the exchange of information on the results of the supervision of CBs by the CAs. However, there is a lack of coordination between the CAs with regard to the supervision of the CBs (see section 5.2.1.2) which weakens the control system.

5.2.9 Irregularities and Enforcement measures

Legal Requirements

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

According to Article 55(1) of Regulation (EC) No 882/2004 MSs shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

According to Article 27(5)(d) of Regulation (EC) No 834/2007 CBs shall, if the results of the controls indicate non-compliance or point to the likelihood of non-compliance, immediately inform the CA.

Article 30 of the same Regulation sets out measures in cases of infringements and irregularities. Paragraph 2 of this Article requires that information about cases of irregularities or infringements affecting the organic status of a product shall be immediately communicated between the CBs, control authorities, CAs and MSs concerned and, where appropriate, to the Commission.

Article 91 of Commission Regulation (EC) No 889/2008 provides further specification on measures in cases of suspicion of infringements and irregularities.

Findings

The CA gave the audit team an update regarding the fraud case called "*Gatto con gli Stivali*" and two recent fraud cases regarding (i) non-organic olive oil fraudulently marketed as organic and (ii) products fraudulently imported from India, Moldova and Ukraine via an Italian company based in Malta and traded to Italy. In the latter case the investigation and seizure of documents and products took place only a few days prior to the start of the audit and had yet to be notified to the Commission. The olive oil case was notified in October 2012 to the Commission with an update of the situation in February 2013. However, the CA stated that due to the ongoing investigation detailed information cannot be released. All cases are still with the prosecutor and by law the CA is not allowed to release further information without prior approval of the judge in charge of the criminal offence proceedings.

The CA stated that there are no specific legal provisions in place to fine or penalise operators who do not comply with organic farming legislation. However, the legal provisions regarding labelling and fraud permit the imposition of administrative fines or to launch criminal offence proceedings.

The audit team checked several operator files at both CBs visited and noted that the CBs had taken

appropriate measures in cases where irregularities were found.

The CBs have procedures in place to follow-up irregularities. For irregularities the operator has to provide evidence of corrective action taken within 30 days. In the case of an infringement, a case by case decision on follow-up is taken and where needed, precautionary measures are put in place. The audit team checked some files at the CBs offices which confirmed this approach. In all cases the CBs had taken appropriate measures where non-compliances were found at operators.

The audit team checked one file of an OFIS notification and noted that the CB and territorial office had carried out investigations.

Since February 2013, the territorial offices of ICQRF have to follow-up irregularities found by them during the review audits at operators. Before, the CBs were informed and had to follow-up the irregularities. Where the Regions find irregularities during review audits the CBs are asked to follow-up the irregularity and to report back to the Regions.

Conclusions

The system in place for the follow-up of irregularities and for measures taken in case of irregularities is appropriate.

5.3 Seed Data Base

Legal Requirements

According to Article 48 of Commission Regulation (EC) No 889/2008 MSs shall ensure that a computerised database is established for the listing of the varieties for which seed or seed potatoes obtained by organic production methods are available within its territory. Articles 49 to 56 of the same Regulation provide further requirements on the registration and information to be kept in the database as well as on the access to this information and reporting on the authorisations.

Findings

ENSE is the CA in charge of managing the seed database and of derogations for the use of conventional seeds in organic production. Producers have to submit on a monthly basis all relevant information regarding the availability of certified organic seeds and vegetative propagating material to ENSE. If a seed producer has not submitted data he is deleted from the register. ENSE stated that the number of entries in the seed database is limited and the number of entries decreases from year to year. Operators have to submit their derogation request at least 30 days (in case of horticulture 10 days) prior to sowing, by fax, email or registered mail to ENSE which assesses the request and only in the case of refusal replies to the operator and the CB. Nearly 30 000 derogations for use of non-organic seeds and vegetative propagating material are granted every year.

Conclusions

A seed database is in place and derogations for the use of non-organic seeds are granted in accordance with EU provisions.

6 Overall Conclusions

The supervision of the CBs by the CAs is based on an appropriate number of office audits at the headquarters and regional offices of the CBs and review/witness audits at operators. The lack of co-ordination between the CAs and ongoing structural reforms within some CAs weakens the system for the supervision of the CBs. However, a new National Committee has been established in order to address this shortcoming.

Controls of the CAs and CBs are based on annual plans and risk criteria are sufficiently taken into account. The high number of samples taken by CBs at operators and controls of the CAs performed at market level allow the CAs to have a good overview of the compliance level in the area of organic production.

The system for import controls of organic consignments does not provide sufficient guarantees that consignments are verified in accordance with EU provisions. Therefore, there is a risk that non-compliant consignments are released for free circulation and enter the EU market via Italy.

Other shortcomings were found, in particular, with regard to the management of animals and derogations for the use of conventional fodder and the CBs met did not always verify all information as necessary.

7 Closing Meeting

A closing meeting was held on 26 April 2013 with representatives from the CAs. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit.

The representatives from the CAs offered some initial comments and disputed, in particular, the findings regarding the delayed communication of irregularities affecting the organic status of products, the lack of co-ordination between the CAs and the shortcomings identified with regard to import controls. The MIPAAF stated that EU legislation is not clear and that a delay of two weeks is considered “immediate”. Further explanation was not provided with regard to the other points.

8 Recommendations

The CAs are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within 25 working days of receipt of this audit report. The CA s should:

N°.	Recommendation
1.	Ensure that all staff from the CAs performing official controls, including Customs inspectors, receive appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner in accordance with Article 6(a) of Regulation (EC) No 882/2004.
2.	Ensure efficient and effective co-ordination between all the CAs involved in the supervision of the CBs as required by Article 4(3) of Regulation (EC) No 882/2004 in order to ensure requirements as set out by Articles 27(8) and (9) of Regulation (EC) No 834/2007 are met.
3.	Ensure that the information referred to in Article 92(a) of Commission Regulation (EC) No 889/2008 is made available to the public and is updated in a timely manner.
4.	Ensure that controls are effective and appropriate as required by Article 4(2)(a) of Regulation (EC) No 882/2004 and, in particular, that CBs perform controls at operators at the most appropriate time and that measures are in place to verify relevant information as necessary.

N°.	Recommendation
5.	Ensure that testing of samples is performed by designated laboratories as required by Article 12 of Regulation (EC) No 882/2004.
6.	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.
7.	Ensure that labels of organic products, in particular of bottled wine, are in accordance with Article 24(1)(c) Regulation (EC) No 834/2007.
8.	Ensure that dehorning shall not be carried out routinely in organic farming as required by Article 18(1) of Commission Regulation (EC) No 889/2008 and that official veterinarians receive instructions in this regard when authorising such measures.
9.	Ensure that the use of non-organic feeding stuffs is authorised by the CAs only for a limited period and, in particular, in relation to a specific area by individual operators, in accordance with Article 47(c) of Commission Regulation (EC) No 889/2008.
10.	Ensure that organic products are released for free circulation in accordance with Article 33 of Regulation (EC) and Article 13 of Commission Regulation (EC) No 889/2008 and, in particular, that Customs inspectors receive documented procedures regarding import controls of organic products in accordance with Article 8(1) of Regulation (EC) No 882/2004.
11.	Ensure that imports of organic products in accordance with procedures referred to in Article 19 of Commission Regulation (EC) No 1235/2008 are only authorised if the importer provides sufficient evidence showing that the conditions referred to in Articles 33(1)(a) and (b) of Council Regulation (EC) No 834/2007 are satisfied.
12.	Ensure that CBs carry out random control visits in accordance with Article 65(4) of Commission Regulation (EC) No 889/2008 and in particular that unannounced visits take place without prior notice.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6650

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