EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2018-6401

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
ITALY
FROM 05 JUNE 2018 TO 13 JUNE 2018
IN ORDER TO
EVALUATE THE SYSTEM OF OFFICIAL CONTROLS 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 DG Health and Food Safety audit in Italy, carried out from 05 to 13 June 2018, 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 report concludes that Italy has satisfactorily addressed the recommendation which remained open after the audit carried out in 2013 DG(SANCO)2013-6650. It also confirms that Italy continues to effectively apply most of the corrective actions which allowed for the closing of the rest of the recommendations. A number of improvements have been noted which include the issuance of new national provisions aiming at enhancing and harmonising controls on organic production.

Controls of operators are adequately planned and executed by control bodies, including a sufficient number of risk-based additional inspections and sampling. Annual supervision carried out by the competent authority is generally capable of detecting weaknesses in the performance of control bodies. However, follow-up made by control bodies in cases of severe irregularities and the measures taken against non-compliant operators are not always satisfactory. Control bodies are not required to immediately notify the competent authority of the detection of severe irregularities or their likelihood, which limits the possibility that the competent authority assesses the decisions taken by control bodies in such cases.

The report contains recommendations to the competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

Table of Contents

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ACCREDIA	National Accreditation Body *(Ente Italiano de Accreditamento)*
AGEA	Agency for Agricultural Payments *(Agenzia per le Erogazioni in Agricoltura)*
AaA	Department of Agriculture *(Assessorato all'Agricoltura)*
CA(s)	Competent authority(ies)
CB(s)	Control Body(ies)
CCA	Central competent authority
CREA	Council for Agricultural Research and Analysis of Agricultural Economy *(Consiglio per la ricerca en agricoltura e l´analisi dell´economia agraria)*
EU	European Union
ICQRF	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
MIPAAF	Ministry of Agricultural and Forestry Policies *(Ministero per le Politiche Agricole e Forestali)*
MS(s)	Member State(s)
OFIS	Organic Farming Information System
PPM	Parts Per Million (milligrams per kilogram)
PPP(s)	Plant Protection Product(s)
PREF	Directorate-General for Preventing and Combating Agri-Food Fraud *(Direzione generale della prevenzione e del contrasto alle frodi agro-alimentari)*
PQAI	Directorate-General for the Promotion of Agri-Food Quality *(Direzione generale per la promozione della qualità agroalimentare)*
SIAN	National Information System for Agriculture *(Sistema Informativo Agricolo Nazionale)*

Abbreviation	**Explanation**
SIB	Organic Information System *(Sistema Informativo Biologico)*
TRACES	Trade Control and Expert System
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

The audit took place from 05 to 13 June 2018. The team comprised 2 auditors from DG Health and Food Safety, one official from DG Agriculture and Rural Development and one national expert from a Member State (MS).

Representatives from the central competent authority (CCA) and regional Authorities accompanied the DG Health and Food Safety team for the duration of the audit. An opening meeting was held on 05 June with the competent Authorities (CAs) and representatives from the National Accreditation Body (ACCREDIA - *Ente Italiano di Accreditamento*). At this meeting, the objectives of, and itinerary for, the audit were confirmed by the DG Health and Food Safety team and the control systems were described by the authorities.

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 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 pursuit of these objectives, the following sites were visited:

Table 1: Mission visits and meetings

Visits/meetings		Comments
Competent authorities		
Central and Regional	4	Opening meeting with CCA and preliminary meetings and closing meeting with CCA and Regional CAs.
Control Bodies		

Control Bodies	2	Office audits
On-Site-Visits		
Region 1	2	One large processor and one medium-size livestock and crop producer.
Region 2	1	Retailer exempted from the control system

In terms of scope, the audit assessed the performance of the CAs, as well as the organisation of the controls carried out by control bodies (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 references to the EU acts quoted in this report are given in Annex I.

4 BACKGROUND

DG Health and Food Safety carried out an audit on organic farming in Italy in 2013 (audit report 2013-6650). The report of the audit is published on the website of the Directorate-General for Health and Food Safety:

http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3193

The report of this audit concluded that, although the supervision of the CBs by the CAs was in place, the lack of co-ordination between the CAs and ongoing structural reforms within some CAs weakened the system for the supervision of the CBs. A new National Committee had been established in order to address this shortcoming. Controls of the CAs and CBs were based on annual plans and risk criteria were sufficiently taken into account. The high number of samples taken by CBs at operators and controls of the CAs performed at market level allowed 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 did not provide sufficient guarantees that consignments were verified in accordance with EU provisions with the risk that non- compliant consignments entered 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.

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

1. Since the previous audit a critical change has taken place in relation to the relevant national legislation. Legislative Decree Number 20 (hereinafter referred as the Legislative Decree), which was published on 23 February 2018, is in force since March 2018. It integrates all the existent national provisions and describes:

    - the competences of the different CAs involved in controls of organic production and the sharing of information and coordination between them;
    - the obligations of CBs and operators as well as the sanctions to be applied against CBs which fail to fulfil their obligations and against non-compliant operators.
    - stricter conditions to improve compliance with criteria of impartiality and objectivity of CBs in the performance of their control activities.

2. The other new relevant legislative act is Ministerial Decree 8283/2018, which assigns a role to CBs in the framework of import controls (see paragraph 68).

Conclusions on Relevant National Legislation and Provisions

3. According to the information provided by the CCA, 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

Legal Requirements

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

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

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

Findings

4. The organisation of the control systems in Italy are described in its country profile, which can be found at the DG Health and Food Safety website: http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=IT

5. The Ministry of Agricultural and Forestry Policies (MIPAAF - *Ministero per le Politiche Agricole e Forestali)* is the CA responsible for the control system for organic production. Two departments of the MIPAFF are in charge of organic production:

    - 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 (PQAI - *Direzione generale per la promozione della qualità agroalimentare*). The PQAI is responsible for preparing national provisions and other instruments necessary to ensure that EU legislation on organic production is applied and for implementing the Organic Information System (SIB - *Sistema Informativo Biologico*), which forms part of the National Information System for Agriculture (SIAN-*Sistema Informativo Agricolo Nazionale*).

6. The ICQRF has two Directorate-Generals dealing with organic production:

    - the Directorate-General for Preventing and Combating Agri-Food Fraud (PREF - *Direzione generale della prevenzione e del contrasto alle frodi agro-alimentari*);

    - 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*).

7. PREF is in charge of the market controls of organic products, fraud related investigations and is responsible for the supervision of CBs. VICO authorises CBs based on accreditation by ACCREDIA and decides on the suspension and withdrawal of CBs.

8. The Council for Agricultural Research and Analysis of Agricultural Economy (CREA – *Consiglio per la ricerca en agricoltura e l´analisi dell´economia agraria*)) is responsible for the management of the seed data base and the granting of derogations for the use of conventional seeds.

9. The Agency for Agricultural Payments (AGEA - *Agenzia per le Erogazioni in Agricoltura*) is responsible for the payments in the framework of rural development programs in 13 regions. It carries out inspections to 5% of operators receiving subsidies. AGEA receives the results of controls carried out by CBs through the database kept by ICQRF (described in paragraph 14). In addition to AGEA, regional payments agencies are also active in 8 autonomous regions and provinces. Regional paying agencies do not have direct access to the databank and therefore information on the results of controls must be communicated by the regional CAs. The CA provided evidence to the audit

team that results of controls are communicated by the regional and provincial CAs to the relevant paying agencies operating in those regions and provinces and that reduction of subsidies are applied to non-compliant operators.

10. Customs is the relevant MS authority responsible for the controls in relation to Article 13 of Regulation (EC) No 1235/2008. Customs endorses the certificates of inspection of consignments of organic products imported from non-EU countries. For the performance of its control duties, it may collaborate with CBs controlling the importers (see paragraph 68).

11. The departments of Agriculture (AaA - *Assessorato all'Agricoltura*) of the Regions and autonomous provinces are competent in their own regions for controls in organic production. Their responsibilities include the registration of operators and the supervision of CBs based in their regions.

12. The local veterinary services of the Ministry of Health are responsible for granting authorization for the management operations described in Article 18(1) of Regulation (EC) No 889/2008.

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

14. All CAs and CBs involved in controls of organic production have access to the database systems operating within the SIAN platform, in particular to the SIB managed by PAQI, which contains a summary of the control activities carried out by CBs and of the supervisory activities carried out by CAs. The files reviewed by the audit team during the present audit overall demonstrated a good communication and co-operation between the CAs involved in controls.

Conclusions on Competent Authorities and Control Bodies

15. The CAs responsible for official controls of organic production are designated with a clear division of tasks and overall good communication between them.

5.2.1.1 Control Bodies: Approval, Supervision and Withdrawal

Legal Requirements

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

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

Findings

16. At the time of this audit, controls of organic operators were delegated to 16 Italian CBs and three CBs with headquarters in other MSs. The audit team visited the headquarters

of two CBs (hereinafter referred as CB1 and CB2). The CB regional offices are entrusted with the inspection of operators while the final certification decision is taken by the Certification Committee at the CB's headquarters. The headquarters are usually responsible for the preparation of procedures, planning, co-ordination and supervision of regional offices. In some cases, the regional offices may be critical locations allocated with the responsibility of taking certification decisions.

17. Both CBs had procedures in place for the training of new inspectors. Before being allocated inspections, all new recruited inspectors have to undergo theoretical and practical training including tests before they are assessed by MIPAAF for approval. 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.

18. Accreditation of the CBs to ISO/IEC 17065 is a condition for the approval of the CBs by MIPAAF. 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 visited at least once within the four years of the accreditation cycle.

19. According to Article 3(4) of the Legislative Decree, MIPAAF, the Regions and the Autonomous Provinces of Trento and Bolzano, within their respective geographical areas, are the authorities responsible for supervising CBs. The annual supervision of CBs is carried out in coordination between ICQRF and the Regions. Co-ordination is ensured through a National Supervisory Committee, where the annual National Supervision Program is agreed. Supervision activities include office audits, which are usually carried out at the headquarters of the CBs by the ICQRF PREF territorial offices of the region where the headquarters are located. Office audits may be also carried out by the regional AaA departments at the CBs´ regional offices. Reports issued by ACCREDIA are taken into account by the central and regional CAs for the office audits.

20. During the office audit, the relevant CA extracts a risk-based sample of operators´ files which are distributed to the ICQRF territorial offices and to the AaA departments of the Regions where the operators are located. The number and location of operators selected for review audits are decided for each CB in the National Supervision Program taking into account the number of operators under control and their regional distribution. The relevant CAs (either ICQRF or AaA offices) then carry out direct inspections at the operators with the aim of comparing the outcome of these inspections with the inspections carried out by CBs. In addition to these review inspections, the CAs may also witness inspections carried out by CBs at operators. These witness inspections are not planned in the National Supervision Program but rather decided on an ad-hoc basis.

21. The offices of ICQRF and of the regions return the results of the reviews and witness audits to the office that made the selection of the files. According to the data provided by the CCA, all CBs received office audits and around 500 review audits and 17 witness

audits were carried out during 2017 in the regions. The audit team noted that the number of operators and their location is decided based on the regional distribution and that it covers all activities for which the CBs are approved. Supervision takes place based on documented procedures and checklists are used for the different supervisory activities (office audit, crop production, livestock production, processing, importing/trading activities).

22. It has to be noted that the implementation of the program is based in the loyal cooperation between the CAs. The central administration of ICQRF monitors the execution of the plan by the CAs responsible for supervision.

23. The office which made the selection of the files evaluates the results of supervision and issues the final supervision report to CBs. The supervision reports may contain the request of corrective actions to be applied by CBs. CBs must propose corrective actions within a deadline and submit them to the relevant office for assessment. If the corrective actions are accepted by the CA, they are verified during the next office audit in the subsequent year.

24. If the shortcomings in the performance of CBs are found to be severe or corrective actions proposed by CBs are unsatisfactory, PREF may transfer the supervision dossier to VICO for a decision to be taken. In recent years, VICO applied a partial limitation of the scope activity of some CBs following the detection of serious shortcomings in the performance of CBs. These measures were taken based on the previous legislation in force (Decree 220/1995). With the new Legislative Decree, VICO has now more measures available to act against CBs which fail to fulfil their duties. The new measures, which are described in Articles 7 and 8, include the suspension and withdrawal of the approval and the application of monetary sanctions to CBs.

25. The audit team identified some shortcomings in the performance of CBs, namely related to the inadequate planning of samples taken in 2017 by CB1 (see paragraph 52), to the inadequate follow-up of cases of irregularities notified by other MSs in 2017 and 2018 by both CBs (see paragraph 77) and to the lack of details of reports issued by CB1 (see paragraph 42). However, most of these shortcomings cannot be noted as a failure of the annual supervision by the CA as, at the time of the audit, supervision had not yet taken place for the activities carried out by CBs in 2017.

Conclusions on Control Bodies: Approval, Supervision and Withdrawal

26. CBs are approved by the CA and subject to annual supervision in line with EU rules. The CA supervision is overall capable to detect shortcomings in the performance of CBs and dissuasive enforcement measures are foreseen to be applied against CBs which fail to fulfil their duties.

5.2.2 Registration of operators

Legal Requirements

According to Article 28(1) (2) and (5) of Council Regulation (EC) No 834/2007

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

Findings

27. Italy has exempted from controls operators fulfilling the conditions of Article 28(2) of Regulation (EC) No 834/2007 and who in addition sell pre-packaged products only. The verification of the fulfilment of these requirements is made by ICQRF. All other operators must notify their activities to the CA and submit their undertakings to the control system. Notifications are made by operators to the Regional CA by using the IT tools available in the SIB database or in the database of the Regional CA. The applications include the choice of the CB selected for controls, which receive an automatic notification from the system. This is in line with Article 28(1) of Regulation (EC) No 834/2007.

28. CBs then have 90 days to finish the certification process and issue documentary evidence to new operators. The previous deadline was 120 days but the requirement was modified after the entry into force of the Legislative Decree. After verifying operators´ compliance with the requirements of EU Regulations, CBs issue documentary evidence related to the activities carried out, in line with Article 29 of Regulation (EC) No 834/2007. In the case that operators want to market organic products, an Annex (Conformity Certificate) to the documentary evidence is issued detailing all products covered by the certification. The audit team noted that CB1 and CB2 databases are updated on a daily basis, to include new operators and operators who quit the system. Changes in the certification status of the operators are also reflected in the database. This is in line with Article 28(5) of Regulation (EC) No 834/2007.

29. The documentary evidence and the operators´ control files are submitted to the Regional CAs for assessment before they are accepted for publication in the regional database list. Once the information on the new operators is uploaded onto the regional list, it is transferred to the national list kept in SIB. The transfer of the information is done on a daily basis.

30. The audit team was shown how the information about operators is kept in SIB. An advanced search function allows for specific lists to be generated (producers, processors, operators located in a given region, etc). Individual operators can also be searched by inserting the code which can be found on the labels of the products marketed. In all cases the information required by EU Regulation was found to available to the public, which is in line with Article 92b of Regulation (EC) No 889/2008. In this manner, Italy had addressed the recommendation that remained open after the audit carried out in 2013.

31. However, the audit team noted that although documentary evidence issued by CBs overall contains all information required, it does not always follow the model provided for in Annex XII of Regulation (EC) No 889/2008, as required by Articles 68 and 92b of the same Regulation. The fact that the model required by EU Regulation is not used makes more difficult the verification of the documentary evidence when controls are carried out outside Italy.

Conclusions

32. The system of registration of operators is satisfactory and the list of operators is kept publicly available and regularly updated. There CAs verifies that exempted operators fulfil the conditions for exemption. However, documentary evidence issued by CBs does not follow the model required by EU provisions.

5.2.3 Planning and Prioritisation of Controls

Legal Requirements

Articles 3 and 41 of Regulation (EC) No 882/2004

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

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

Findings

33. The Multi-annual National Control Plans and annual reports submitted by Italy to the European Commission contain sufficient information on the control system for organic production as required by EU provisions. According to Article 3(2) of the Legislative Decree, controls of certified operators are delegated to CBs. CBs have to prepare an annual control plan of the operators, in line with Article 5(1) of the Legislative Decree, which must be submitted to MIPAAF before 31 January of the year where controls have to take place.

34. Annual and additional controls of operators are therefore planned early in the year by CBs. Both CBs visited decide on the nature and frequency of controls based on risk

assessment. The audit team noted that the risk assessment applied by both CBs included all compulsory criteria of Article 65.4 of Regulation (EC) No 889/2008 and that the weighting allocated to each criteria was very similar. The representative of ACCREDIA stated that the assessment procedure has been established as an accreditation requirement and all CBs in Italy have to apply the same procedure.

35. Additional inspections are decided based on the results of the risk assessment. Operators placed in the highest risk category receive at least three inspections, one of which must be unannounced. The audit team verified the excel sheets kept by CBs with the list of all inspections carried out during 2017 and noted that both CBs carried out additional inspections to a number of operators under contract which was above the 10% set out in Article 92c(2)(b) of Regulation (EC) No 889/2008. At least 10% of the additional inspections were targeted taken into account the risk profile of operators, which is in line with Article 92c(2)(d) of the same Regulation. It was also noted that the total number of unannounced inspections carried out by both CBs was above the minimum 10% required by Article 92c(2)(c) of the same Regulation (14% by CB1 and slightly above 10% by CB2).

36. Both CBs require operators to submit before 31 January the schedule of crops, hectares grown and quantities expected, in line with national provisions. This is in line with Article 71 of Regulation (EC) No 889/2008. Management plans including the description of the unit and precautionary measures applied by operators to prevent or reduce the risk of contamination of organic products are requested by CBs when the first control arrangements are implemented. Operators do not need to notify the plans every year to CBs, but only when relevant changes take place (e.g. change of crops, new processing line). The audit team reviewed a number of files and noted that the information submitted was comprehensive enough for proper planning and preparation of the inspections. Inspections are planned at the most suitable time to verify operators´ compliance with organic requirements.

37. In addition to the controls carried out by CBs, ICQRF inspectors also perform controls at certified and exempted operators. Such controls take place in the framework of food safety and quality controls, and target organic products. Controls include labelling checks and taking of samples. Italy reported 2563 checks carried out on organic products, of which 1152 related to samples taken for analytical tests. When analytical results indicate the presence of non-authorised substances, actions are taken by the CAs (see paragraph 78). When CA inspectors detect operators who are under control system but do not fulfill conditions of exemption, this is noted as a non-conformity and the operators are requested to submit their undertakings to the control system. The audit team was shown examples of enforcement measures taken by the CCA, including monetary sanctions, applied in these cases.

Conclusions on Planning and Prioritisation of Controls

38. Controls carried out by CBs are adequately planned based on risk criteria harmonised at national level, with a sufficient number of additional and unannounced inspections carried out.

5.2.4 Controls of operators

Legal Requirements

Titles II and III of Regulation (EC) No 834/2007

Titles II and IV and Article 65 of Commission Regulation (EC) No 889/2008 .

Article 8 and 9 of Regulation (EC) No 882/2004

Findings

39. The audit team observed inspections carried out by both CBs. The inspection by CB1 took place at a large processor and the inspection by CB2 at a medium sized livestock producer. The latter also had plant production for own consumption and a processing plant fully dedicated to transform the meat from his animals. The number of inspections decided by the CBs was proportional to the risk identified for the different activities carried out. For example, the livestock activity had been identified by CB2 as medium risk while the plant production and processing were low risk. In 2017, the annual inspection had covered the three activities (on different dates) and the additional inspection covered the livestock activity.

40. Inspections observed took place based on documented procedures. Both inspectors had access to all relevant documents pertaining to previous inspections as well as information submitted by operators before inspections. The audit team noted that checklists were overall comprehensive and served as guidance for inspectors to cover most relevant requirements of the EU Regulations. All premises were physically visited during the inspections and all relevant records and supporting documents were requested to operators.

41. However, inspection reports issued by CB1 did not contain detailed references to records verified during inspections. This is not fully in line with Article 9 of Regulation (EC) No 882/2004 as it raises concerns on how records are verified by inspectors. For example, the audit team noted that the manner in which both CBs verified the records kept by operators at reception of organic products was not fully adequate. Both CBs require that supporting documents (such as updated documentary evidence of the supplier) are present at the time of inspection, but there is no control measure in place to verify that they were present and updated at the time of reception. The lack of this verification cannot ensure that operators comply with the requirement of Article 66(2) of

Regulation (EC) No 889/2008. The audit team found out that at least in two cases of severe irregularities reviewed, the verification made by operators at reception was not capable to detect that the incoming products were not organic (see paragraph 76).

Conclusions on Control at Operators

42. Controls carried out by CBs take place based on documented procedures and overall cover in an effective manner the minimum requirements of EU Regulation. However, verification of some records kept by operators is not adequate and reports issued by CBs do not always contain sufficient evidence of how such verification takes place.

5.2.5 Controls on Labelling and Traceability

Legal Requirements

Articles 5, 23, 24 and 27(13) of Regulation (EC) No 834/2007

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

Article 18 of Regulation (EC) No 178/2002

Findings

43. The audit team observed the inspection carried out by two ICQRF inspectors at an exempted retailer. A specific checklist containing the labelling requirements set out in Articles 23 and 24 of Regulation (EC) No 834/2007 serves the inspectors as guidance for the verification of compliance of labels applied on the products. The inspectors walked the premises and verified the labelling of a large number of products in different sections. The audit team noted that the labels checked overall complied with EU provisions although some of them were not in line with Article 58 of Regulation (EC) No 889/2008. For example, in one label there was no indication of the code number of the CB (but the name instead), and the indication of the place where the agricultural raw materials had been farmed was placed in the reverse of the label instead of below the organic logo.

44. Four products (eggs, bananas, olive oil and a package of rice) were selected by inspectors to be formally verified (one checklists was filled in for each product) and reported to the operator, who was required to collect the documents necessary to trace the products back to the organic suppliers of the products. Samples of these products were also taken to be sent to the ICQRF laboratory for analysis. The inspection also included checking whether loose products were sold, which would not be compatible with the retailer being exempted from controls.

45. Two products were selected by the audit team from a supermarket on 5 June for a traceability exercise to be carried out by the CCA. In one case (olive oil in a biscuit) it was difficult to trace the ingredients back to the producers as there were many

intermediate traders and processors. However, the documents provided by the CCA were sufficient to establish the organic origin of the products. All delivery notes bore reference to the organic status of the products and internal batches were recorded in the processing sheets to establish a link between incoming raw materials and final products.

46. The audit team was informed by the CAs that the Legislative Decree (Article 9(l)) sets out the obligation of operators to submit regularly to their CBs information on organic and in-conversion products placed on the market. A new databank has been created for this purpose, and operators have to declare all transactions of products such as cereal grain, tomatoes, rice or olive oil, which are considered to be high-risk products involved in past cases of fraud. The CCA stated that for the moment operators submit these declarations on a voluntary basis and it will only become obligatory once the databank is placed in SIAN. The declarations of all transactions would, in principle, greatly facilitate cross-checks made by CBs on quantities produced and sold by operators under their control. In fact, the audit team was aware of several cases where CBs collaborated to carry out cross-checks on information and documents provided by operators. This collaboration helped, in certain instances, to detect serious irregularities and identify risk of fraud.

Conclusions on labelling and traceability

47. An appropriate system is in place to ensure traceability of the products at all stages and to ensure that the labelling of the products complies with EU provisions.

5.2.6 Sampling and laboratory analysis

Legal Requirements

Article 12 of Regulation (EC) No 882/2004

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

Findings

48. The Italian CCA has designated the laboratories that must be used by CBs in the framework of official controls in organic production. The obligation for the CBs to use the designated laboratories is set out in Article 6(1)(q) of the Legislative Decree as well as in Article 2(2) of Ministerial Decree 2593/2014. The audit team confirmed during the office audits that both CBs use only the designated laboratories. The list of laboratories is published on the website of the MIPAAF and is regularly updated. The most recent list of the laboratories can be found here:

    https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/7620

49. The scope of laboratories is verified during the office audits carried out by the CAs in the framework of supervision of CBs and also during the ACCREDIA audits. The audit team also reviewed a number of analytical reports and confirmed that the methods used by laboratories were accredited, also for single residue methods used for substances such as Glyphosate or Fosetyl-Aluminium. CB1 informed the audit team that the last substance, which had not been previously requested by CB1 to its laboratories, had been included in the sampling planning for 2018.

50. The number of samples taken by both CBs is significantly above the 5% of operators under contract required by Article 65(2) of Regulation (EC) No 889/2008. As regards the planning of samples, operators are selected by both CBs based on results of risk assessment. CB2 has a very good overview of the samples taken and the percentage of positive results in recent years, broken down by type of products and regions. The trend in the positive results was a factor used to decide on the number and type of samples to be taken in the different regions.

51. Ministerial Decree 309/2011 sets out the obligation to decertify products in which the analytical results show the presence of unauthorised substances above a limit of 0.01 parts per million (ppm). This was considered as non-compliance in the audit report 2013-6650 as no threshold is foreseen in the EU Regulations. However, during the follow-up of the actions proposed by Italy, the CCA clarified that the limit of 0.01 ppm cannot be considered as a threshold below which no actions are taken by CBs. The interpretative note No 13349/2011 was issued to provide clarifications on this issue. According to the note, CBs are required to investigate any presence of unauthorized Plant Protection Products (PPPs) below the limit indicated in the Ministerial Decree and also in the cases where the presence leads to the decertification of the products. The audit team requested both CBs to prepare an excel sheet with all the details of the samples which have been considered as non-compliant in 2017 and noted that, overall, CBs took actions in all cases of confirmed positive results.

52. However, CB1 had recently changed the products to be targeted for sampling, moving from a process-oriented approach (sampling from soil or leaves) to a product-oriented approach (sampling from edible products). The reason for this change is that, according to the CB, the Ministerial Decree 309/2011 only allows for decertification of edible products, and the detection of an unauthorised substance on soil or leaves above the 0.01 ppm level does not allow the CB to decertify the crop. This is not in line with Article 65(2) of Regulation (EC) No 889/2008, as the samples are neither taken at the most suitable time to detect non-conformities nor at all stages of the food chain. This inadequate approach was confirmed by the lower percentage of positive results obtained during the 2017 campaign, which dropped in relation to previous years.

53. In addition, the procedure to accept that an analytical result is a false positive is not consistently applied by CBs. The CCA and CB2 stated that a negative result of the counter-sample will lead to the closing of the file with no further investigation to determine whether the substance was used by operators. CB1 stated that in the case that

the results of the first sample and the counter sample differ, a third sample would be needed to settle the discrepancy. If the result of the third sample is positive, CB1 would consider it as an established irregularity. This inconsistent approach does not ensure that all possible irregularities are treated in the same manner by all CBs in Italy.

54. Although the Ministerial Decree 309/2011 requires CBs to investigate the presence of residues of substances not authorised for organic production, the audit team noted that it does not happen in all cases. For example, for certain substances which are not even authorised for conventional agriculture (e.g. Dieldrin), the de-certification of products would only take place above the Maximum Residue Levels defined in food safety Regulations. In addition, ACCREDIA issued guidelines to CBs which accept the presence of certain substances (e.g. phosphonic and phosphorous acid) below a threshold (for instance, 60 ppm in case of wine and related products) without requiring any further action from CBs and with no impact on the certification of the product. This distinction between actions to be taken for substances not included in the Annex II of Regulation (EC) No 889/2008 and for substances not even allowed for conventional agriculture is not foreseen in EU Regulations. Article 12(1)(h) of Regulation (EC) No 834/2007 requires that only the substances authorized for use in organic production under Article 16 of the same Regulation may be used.

55. Both CBs follow the compulsory instructions issued by the CA for sample collection. Analytical results can be interpreted by CBs taking into account the information compiled from the declarations received from operators as well as from information gathered during inspections. For example, in some files reviewed by the audit team, the presence of unauthorised PPPs in samples taken at producers was explained as spray-drift from the conventional neighboring plots. However, such theory could be demonstrated only if the results of samples taken from different spots (closer and further to the neighboring plot) would differ (e.g. no presence or lower concentration of the relevant PPP in the furthest spot). The audit team noted that the information on the samples sheets was very basic and did not contain information on how samples were collected, thus not allowing the CB to assess the analytical results obtained.

Conclusions on Sampling and laboratory analysis

56. CBs take a large number of samples for the detection of unauthorised substances and use accredited laboratories designated by the CCA. However, samples are not necessarily planned at the most suitable time to detect the use of unauthorised substances, and not all detections of such substances lead to further investigation by CBs or to decertification of the products involved. In addition, CBs are not always in the position to assess the analytical results as relevant information on the circumstances of sampling is generally missing on the samples sheets.

5.2.7 Exceptional production rules and other derogations.

Legal Requirements

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

Annex IX and Article 29 of Commission Regulation No 889/2008

Sections 2 to 4 of Chapter 6 of Title II of Commission Regulation (EC) No 889/2008

Findings

57. According to the information provided by the CCA, the most frequent derogations granted in Italy relate to the retroactive recognition of the conversion period, the management operations of Article 18 of Regulation (EC) No 889/2008 and derogations on the use of conventional seeds.

58. As regards the retroactive recognition of a previous period as part of the conversion period, the procedure in place only foresees two cases where derogations can be granted (where the land was not in agricultural use or where applicants were under Rural Development Scheme). In the latter case, operators have to produce records of the off-farm inputs applied in the land during the last three years for the assessment of the CAs (usually the AaA departments of the Regions). In some cases, operators may also attach technical reports issued by third parties.

59. The file assessed by the CA must also include the inspection report issued by the relevant CB to which the applicant is under control. Derogations are only granted if there is a favorable report by the CB and the records provided by operators do not indicate the use in the previous three years of any substance not authorised in organic production. The audit team reviewed several files and noted that the procedure was followed. In one case the CA refused the application as the records showed that unauthorised substances had been used in July 2016. The CB decided to extend the duration of the conversion period accordingly.

60. The audit report 2013/6650 issued a recommendation as regards the operations of management of animals described in Article 18(1) of Regulation (EC) No 889/2008. At the time of the 2013 audit, operations such as disbudding of the calves were systematically carried out without prior derogation being granted by the CAs. In order to address the recommendation, Italy decided to transfer the competence to grant the derogations to the local Veterinary offices of the Ministry of Health. The audit team was shown a number of files where the local offices received and assessed applications from farmers. Some of them were granted but there were refusals as well.

61. CREA is the department responsible for the granting of derogations for the use of conventional seeds. At the time of this audit, CREA received above 80.000 applications per year for the use of conventional seeds. However, due to the manner in which the applications are submitted (email, fax, post, etc.) and the lack of staff resources (only

one person responsible for the assessment and reply), CREA cannot handle them all and only replies to a few number of the applicants. This is not in line with Article 45 of Regulation (EC) No 889/2008. The CCA stated that administrative silence is considered as a positive reply to the applicant and that this procedure is regulated by Ministerial Decree 18354 of 27 November 2009, Annex 5, paragraph 2.4.

62. The CCA stated that they were aware of this weakness, and that in order to address it, a new seed database was being developed at the time of the audit, in line with the requirements of Ministerial Decree 15130/2017. The seed database will categorise the seeds in three groups: green (seeds which have not been available in the market in recent times and for which derogation will be automatically granted), red (seeds that are currently available and for which applications will be automatically refused) and yellow (seeds with limited availability and for which and assessment is needed). Applications will be submitted by operators in SIAN, which will be linked to the seed database.

63. The audit team raised its concerns on the issue of infant formulas and baby food which are labelled as organic but may contain ingredients (such as vitamins and minerals) incompatible with organic certification. Such situation had not led in the past to the CCA taking any enforcement measure or notification in the Organic Farming Information System (OFIS). The CCA stated that PQAI had recently issued an interpretative note on certification of baby food which was submitted to the ICQRF territorial offices. The CCA does not accept that baby food containing such ingredients may continue being certified as organic. The CCA stated that the correct implementation of the note by CBs during 2018 controls will be verified by ICQRF and the Regions during the 2019 supervision.

Conclusions on exceptional production rules and other derogations

64. Derogations are generally granted in line with EU requirements, except for the granting of derogations for the use of conventional seeds.

5.2.8 Imports of Products from Organic Production

Legal Requirements

Articles 32 and 33 of Regulation (EC) No 834/2007

Articles 2(5) and 7, Chapter 3 of Title III and Annexes II, IV and VI of Commission Regulation (EC) No 1235/2008

Findings

65. According to Article 3(2) of the Legislative Decree, Customs is the relevant MS authority for carrying out controls required by Article 13 of Regulation (EC) No 1235/2008. Following the audit report 2013-6650, the CCA had ensured continuous training of the Customs staff in order to be able to adequately perform its duties. The

actions implemented by the CCA were assessed by the European Commission as satisfactory and the recommendation closed accordingly.

66. With the administrative circular No 13 of 2 August 2013, Customs made aware to all its offices the requirements concerning the import of organic products. These instructions were subsequently supplemented with specific notes following the updates of Regulation (EC) No 1235/2008 and the adoption of the IT support system to carry out such controls in TRACES (Trade Control and Expert Sytem). The aforementioned instructions are permanently present in a specific section of the INTRANET available to customs personnel.

67. Customs carries out documentary checks of all consignments of organic goods imported into Italy. Physical checks may be carried out based on risk assessment, although no specific assessment is made for organic products based on the countries of origin or type of products received. This is not fully in line with Article 2(5) of Regulation (EC) No 1235/2008. In cases of doubt, customs offices may contact the CB of the importer to obtain additional information. According to the figures provided by Customs during the closing meeting, this communication took place in 12 cases during 2017, where a total of 26 samples were taken from organic consignments.

68. In addition to the checks carried out by Customs, 142 samples were taken by CBs from imported consignments in 2017, of which 42 were taken at Customs warehouses and the rest at the premises of the first consignee. The Ministerial Decree 8283/2018, in force since 18 February 2018 formally allocated responsibilities to CBs in the framework of import controls. According to Article 5, importers have to notify in SIB to the CCA and to Customs three days in advance of the arrival of organic consignments. Article 6 requires CBs to take samples from the consignments based on the results of specific risk assessment which must take into account several criteria defined in the same Article. Samples must be taken from the consignments at Customs warehouses before they are released for free circulation, and Customs to be informed of the results of the samples before signing the certificates of inspection in TRACES. However, at the time of the audit, CBs had not implemented a specific risk assessment in line with Article 6 of the Ministerial Decree. Therefore it could not be guaranteed that physical checks carried out for the verification of the consignment referred to in Article 13(1)(b) of Regulation (EC) No 1235/2008 are risk-based, as required by Article 2(5) of the same Regulation.

69. As regards checks carried out from consignments coming from Ukraine and neighboring countries, the CCA provided the figures on samples taken by CBs at Customs warehouses. According to these figures, samples were taken from 26 out of 27 consignments containing products mentioned in the guidelines issued by the European Commission for this purpose. The CCA explained that one of the checks was not carried out by the relevant CB due to an administrative mistake as it was the first time that the CB received an import from Ukraine and the product was not available in the first consignee upon arrival of the inspector. This case had been noted by the CCA as a shortcoming of the CB and noted to be reviewed during the 2018 supervision. However,

the CCA could not provide statistics on the total number of consignments imported from the higher-risk countries, and therefore it could not be demonstrated that samples are taken from the consignments in all cases.

Conclusions on Import Controls

70. An appropriate system is in place for import controls is in place in Italy with a large number of samples taken from organic consignments. However, the consignments to be sampled are not necessarily selected based on risk assessment. In addition, Italy could not demonstrate the fulfilment of the increased control measures decided by the European Commission for consignments originated in Ukraine, Russian Federation and Kazakhstan.

5.2.9 Measures in cases of irregularities and infringements

Legal Requirements

Articles 54 and 55(1) of Regulation (EC) No 882/2004

Articles 27(5)(d) and 30 of Regulation (EC) No 834/2007

Article 91, 92, 92a and 92(d) of Commission Regulation (EC) No 889/2008

Findings

71. Italy adopted a catalogue of measures to be taken by CBs in cases of detection of non-conformities at operators. This catalogue was established to address the requirement of Article 92d of Regulation (EC) No 889/2008. However, the audit team noted that some non-compliances were vaguely described and some of the measures to be applied by CBs seemed not to be dissuasive to avoid the repetition of the non-compliance (e.g. CBs can issue a caution during two consecutive years even in cases of serious non-compliance with no impact on the certification status until the third year, which does not encourage operators to apply corrective actions). This is not in line with Article 55(1) of Regulation (EC) No 882/2004. The CCA stated that the catalogue was under revision, to incorporate the sanctions foreseen in the Legislative Decree.

72. According to Article 6(1)(b) of the Legislative Decree, CBs have to notify to the CA without delay the detection of severe irregularities at operators. This requirement in the national provision aimed to address one of the recommendations made in the audit report 2013-6650. Article 6(1)(e) requires CBs to notify to the CA any measures taken against operators. This notification is made by CBs by uploading the relevant file to the databank in SIB referred to in paragraph 14. However, the audit team noted that in practice CBs only notify the CA after the measure has been decided and not at the time of detection. This process includes the notification to operators and the assessment of operators´ appeal, which may take several weeks. In one file reviewed by the audit team, the CA was informed three weeks after the detection of the irregularity.

73. Moreover, CBs do not notify the likelihood of irregularities either. The lack of immediate notification of irregularities or their likelihood is not in line with Articles 27(5)(d) and 30(2) of Regulation (EC) No 834/2007 and prevents the CAs to have an overview of the state of play as regards detection of irregularities by CBs in Italy. It also prevents the CAs to assess the decisions and actions taken by CBs and react as necessary to avoid the marketing of non-compliant products.

FOLLOW-UP OF NOTIFICATIONS MADE BY MSs in OFIS

74. Italy issued a procedure to follow-up cases of irregularities notified by MSs through OFIS. The issuance of this procedure, published in the Decree 14458/2011, sets out the deadlines for the CBs to take actions and send the first reply (15 days after notification) as well as the channel of communications to be used.

75. The audit team reviewed at the offices of CB1 and CB2 a number of files pertaining notifications of non-compliant products made by MSs through OFIS. The actions taken by CBs were discussed with both CBs and with the CCA. It has to be noted that in all cases CBs inspections were performed at the premises of the operators involved and samples when products of the same batches notified were available. The audit team noted that the CA was actively involved in the follow-up of the OFIS cases, in particular with regard to remind the CBs to fulfil the deadlines. Some of the cases may be reviewed by the CAs during the subsequent supervision planned for the following year.

76. However, the audit team noted that in some cases the actions taken by CBs/CAs were not fully adequate:

- CBs were not always able to find the root cause of the problem which had caused the irregularity (e.g. inadequate verification made by one operator at reception of organic goods, organic quantities sold exceeding the maximum capacity of production) even if the information was available at the time of the inspections;

- Unjustified delays were observed during the follow-up of the cases (e.g. up to two-three weeks between subsequent steps). The audit team noted that, in one of the OFIS cases, the origin of the problem was the fraudulent sale of organic products made by a supplier, who used faked documentary evidence to sell the product. One company under control of CB2 notified its suspicions on the supplier to CB2. However, it took CB2 almost one month to carry out an inspection at the premises of the suspected operator and about three months to reply to the operator who had made the complaint;

- Samples were only taken in cases by CBs where products of the same batch involved in the OFIS notification were available. This approach is not correct as it means that CBs limit the investigation to the batches involved and do not try to find out whether there could be a systematic problem which may provoke the marketing of more non-compliant products;

- All follow-up inspections took place announced, even in cases of complaints or where there could be a suspicion against operators;

- Even if samples taken by CBs confirmed that the remainders of the batches involved were non-compliant, this did not prevent their marketing in all cases. The quantities marketed to the notifying country were decertified and sold as conventional. However, quantities of the same batch were still sold as organic to different MSs;

- No, or inadequate measures were taken by CBs against non-compliant operators, but only on products involved. In some cases operators had been warned by their clients long before the formal notification was made in OFIS, with no communication made to their CBs. This lack of fulfilment of Article 91.1 of Regulation (EC) was not noted by CB1 and CB2 as a non-conformity;

- In some of the cases reviewed there was a lack of proper communication to the CAs or CBs of the MSs where the non-compliant products were marketed;

- The actions taken and replies submitted by CBs were in some cases endorsed by the CA and uploaded into OFIS without an explicit assessment being made.

77. The audit team noted that there is no immediate assessment by the CA of measures taken by CBs in cases of irregularities. It was the cases in a file reviewed where a sample taken by the CA tested positive to the presence of an unauthorised PPP. The case was handed out to the CB controlling the operator, which sent a reply to the CA only ten months later describing the measures taken. This file was selected by the CA for the next supervision (which always take place for the activities carried out by CBs during the previous year) and a non-conformity was issued to the CB for the delay of the reply.

78. However, at supervision stage the CA can only verify the appropriateness of the actions taken by the CB but cannot react to avoid the marketing of non-compliant products. The audit team reviewed the file and noted that it did not contain sufficient evidence to demonstrate that the non-compliant products had not been marketed as organic and that the decision of not downgrading the land to undergo the conversion period was not fully justified.

79. The CCA described to the audit team some measures which have been decided to be implemented to combat fraud. The measures include, *inter alia*, the establishing of the transaction databank referred out in paragraph 47, the application of the monetary sanctions to operators and the sampling of fertilizers for the detection of unauthorised, undeclared substances. The latter had not yet been implemented at the time of the audit due to lack of budgetary resources.

Conclusions on measures in cases of irregularities and infringements

80. CBs are not required to notify immediately to the CAs the occurrence of severe irregularities or their likelihood, which limits the possibility that the CA can assess the decisions and actions taken by CBs and intervene, if necessary, in a timely manner, to avoid that non-compliant products are placed on the market.

81. Actions are taken in all cases to follow-up OFIS cases notified by other MSs, and the replies submitted within the legal deadlines. However, the lack of systematic assessment made by the CA does not ensure that actions taken by CBs are always effective.

82. Italy has issued a catalogue of measures to be applied by CBs in cases of detection of irregularities at operators. However, measures are generally not dissuasive to avoid the repetition of the non-compliance.

5.3 SEED DATA BASE

Legal Requirements

Article 48 and 49 to 56 of Commission Regulation (EC) No 889/2008

Findings

83. The audit report 2013/6650 did not identify any shortcoming as regards the management of the seed database. At the time of that audit, a seed database was in place and the number of applications for the use of conventional seeds could be handled by CREA. The list contains the varieties for which seeds obtained by organic production methods are available within Italian territory. However, the CCA informed the audit team that a new database will be operative as from September 2018 in order to respond to the current necessities (see paragraph 62).

84. The decision of implementation of the seed data base is contained in the Ministerial Decree 15130/2017. It designates PQAI as the CA responsible for the management of the seed database and for the granting of derogations for the use of conventional seeds. It also describes the functioning of the database, the conditions for derogations to be granted as well as the role of CBs in the process of granting derogations. The database will be integrated in SIB, which will be accessible though SIAN:

    https://mipaaf.sian.it/portale-mipaaf/home.jsp

Conclusions on Seed Database

85. A seed database is established in accordance with Article 48 of Regulation (EC) No 889/2008. Arrangements are being made to establish a new database in response to current necessities.

6 OVERALL CONCLUSIONS

Italy has satisfactorily addressed the recommendation which remained open after the audit carried out in 2013 DG(SANCO)2013-6650. It also confirms that Italy continues to effectively apply most of the corrective actions which allowed for the closing of the rest of recommendations. A number of improvements have been noted which include the issuance of new national provisions aiming at enhancing and harmonising controls on organic production.

Controls of operators are adequately planned and executed by CBs, including a sufficient number of risk-based additional inspections and sampling. Annual supervision carried out by the CA is generally capable of detecting weaknesses in the performance of CBs. However, follow-up made by control bodies in cases of severe irregularities and the measures taken against non-compliant operators are not always satisfactory. The detection of substances not authorised in organic production is not investigated in all cases and this is endorsed by the CCA. CBs are not required to immediately notify the CA of the detection of severe irregularities or their likelihood, which limits the possibility that the competent authority assess the decisions taken by CBs in such cases.

7 CLOSING MEETING

A closing meeting was held on 13 June with representatives from the CAs and ACCREDIA. At this meeting, the DG Health and Food Safety team presented the main findings and preliminary conclusions of the audit.

The representatives of the CAs offered some initial comments and provisionally accepted the findings.

8 RECOMMENDATIONS

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

No.	Recommendation
1.	Ensure that documentary evidence issued by CBs to operators who meet the requirements of the Regulation follows the model of Annex XII of Regulation (EC) No 889/2008, as required by Articles 68 and 92b of the same Regulation *Recommendation is based upon conclusion No 32* *Associated findings No 31*
2.	Ensure that: • checks carried out by CBs cover the verification of records kept by operators, in particular at reception of organic goods, as required by Article 66(2) of Regulation (EC) No 889/2008; • inspection reports issued by CBs provide details of such verification having taken place, in line with Article 9 of Regulation (EC) No 882/2004. *Recommendation is based upon conclusion No 42* *Associated findings No 41*
3.	Ensure that sampling is adequately planned and implemented and its results followed-up by CBs, and in particular that: • samples are taken by CBs at the most suitable time to detect the use of unauthorised substances and at all stages of the food chain, in line with Article 65(2) of Regulation (EC) No 889/2008; • harmonised rules are followed by the CA and CBs when deciding when analytical results are to be considered as being false positives; • CBs take actions in all cases where the analytical results show the presence of unauthorised PPPs to confirm that operators are compliant with Article 12(1)(h) of Regulation (EC) No 834/2007; • Sample sheets used by CBs contain valuable information on the circumstances of collection of samples, to allow the CBs to assess the analytical results obtained.

No.	Recommendation
	Recommendation is based upon conclusion No 56 *Associated findings No 52, 53, 54 and 55*
4.	Ensure that a system is in place to guarantee that operators use conventional seeds only after derogations are granted in line with Article 45 of Regulation (EC) No 889/2008. *Recommendation is based upon conclusion No 64* *Associated findings No 61 and 62*
5.	Ensure that: • physical checks for the verification of organic consignments required by Article 13(1)(b) of Regulation (EC) No 1235/2008 are carried out based on risk assessment, in line with Article 2(5) of the same Regulation; • samples are taken from all consignments originating from Ukraine, Russian Federation and Kazakhstan, as required by the increased control measures decided by the European Commission for these countries. *Recommendation is based upon conclusion No 70* *Associated findings No 67, 68 and 69*
6.	Ensure that: • CBs notify immediately the occurrence of severe irregularities or their likelihood, in line with Article 27(5)(d) and 30(2) of Regulation (EC) No 834/2007, for the CAs being able to assess the actions taken by CBs and intervene if necessary; • dissuasive and proportionate measures are applied to non-compliant operators, as required by Article 55(1) of Regulation (EC) No 882/2004. *Recommendation is based upon conclusions No 80, 81 and 82* *Associated findings No 71, 72, 73, 76, 77 and 78*

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2018-6401

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