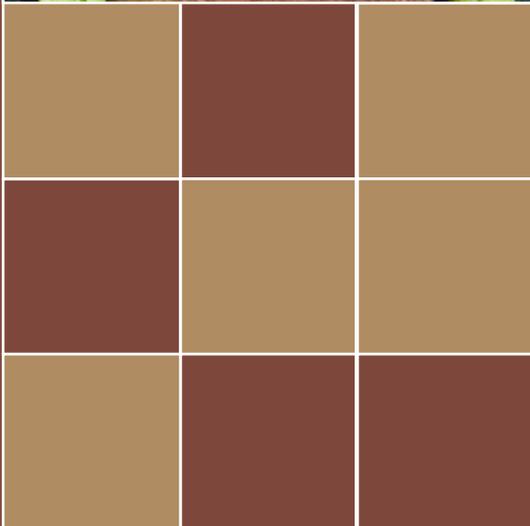




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Food and
Veterinary Office

OVERVIEW REPORT

Organic Production – Recognised Third Countries

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Luxembourg: Publications Office of the European Union, 2015

Electronic version
ISSN 2315-2168
ISBN 978-92-79-52979-5
doi:10.2875/471918
Catalogue number: EW-BC-15-040-EN-N

Paper version:
ISBN 978-92-79-52978-8
doi:10.2875/614543
Catalogue number: EW-BC-15-040-EN-C

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE) 2015-8951 - MR

OVERVIEW REPORT
ON A SERIES OF FVO AUDITS ON ORGANIC PRODUCTION IN
RECOGNISED THIRD COUNTRIES
2012-2014

Executive Summary

This report provides an overview on six audits on organic production in Third Countries between 2012 and 2014 carried out by the Food and Veterinary Office.

The objective of the audits was to evaluate the application of organic production rules and the effectiveness of the control system for organic production and the supervision carried out by the Competent Authority. The national standards for organic production of these Third Countries were recognised by the European Commission under the equivalency regime referred to in Article 33 of Regulation (EC) No 834/2007.

All six Third Countries visited had national organic production standards and control measures in place. Some Third Countries had not notified all new provisions to the European Commission.

In general, the CAs were designated in all TCs, with a clear division of tasks among them and they were empowered to enforce national provisions. Inspection and certification tasks were delegated in all six Third Countries to private Control Bodies and were adequately described and, in almost all TCs visited, good communication and co-operation were in place between CA's and CB's.

In all TCs visited, systems for the delegation of official controls to CBs were in place and CBs were accredited, where required. However, in almost all TCs some significant weaknesses were identified in the supervision of CBs mainly relating to the insufficient assessment of the effectiveness of CBs' control activities and the inadequate measures taken by the CAs against CBs in case of their failure.

At least one annual inspection of all operators is carried out by Control Bodies and relevant risk criteria were sufficiently taken into account for the planning of inspections. However in some cases these inspections were not always fully effective mainly because Control Bodies' inspectors did not adequately verify information at operators, and because checklists used did not cover all aspects.

Overall sampling arrangements were in place with some weaknesses found regarding the representativeness of the samples taken, the inadequate analysis capacity of laboratories used and the use of a threshold to trigger investigation. Shortcomings were also found with the application of exceptional production rules.

Traceability and export certification systems were in place in all Third Countries visited. In some Third Countries, these systems did not ensure that only products or ingredients produced in these countries are exported to the European Union.

Enforcement measures taken by the Control Bodies and/or Competent Authorities were generally effective in the Third Countries visited. In two Third Countries, measures taken were insufficient or ineffective due to delayed notification of irregularities. All Third countries visited followed up EU notifications of irregularities in an appropriate manner.

The audit series highlighted a range of good practices which could be transferable across Third Countries.

The individual reports contained recommendations to the Third Countries and these are systematically followed up by the Commission.

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Abbreviations and definitions used in this report

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

1 INTRODUCTION

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

This report provides an overview on six audits carried out by the FVO between October 2012 and December 2014 in India, Tunisia, Israel, Switzerland, Argentina and Australia.

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

The programme involved meetings with central and regional/local Competent Authorities (CAs) and CBs in the TCs visited. Representatives from the CA accompanied the FVO team for the duration of the audit. The programme also involved on-site visits to organic operators to witness inspections carried out by the CAs and CBs.

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

Details of the individual reports are provided in Annex 3 and are available on Directorate-General for Health and Food Safety (DG SANTE) website: http://ec.europa.eu/food/food_veterinary_office/index_en.htm

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

2 OBJECTIVES AND SCOPE

The objectives of the audits in recognised TCs were to verify:

- that the production rules effectively applied are those notified to the European Commission and considered to be equivalent to those of the EU;
- that the control system notified to the European Commission, and considered to be of equivalent effectiveness to that of the EU, is effectively implemented.

In terms of scope, the audits focused on the organisation and performance of the CAs and the CBs, in particular, on the effectiveness of the control system in place covering the whole production chain of organic products to be exported to the EU and on the supervision of CBs carried out by the CA.s

3 LEGAL BASIS

Individual audits within this series were carried out under the general provisions of EU legislation and, in particular, Article 46 of Regulation (EC) No 882/2004 and Article 8 of Regulation (EC) No 1235/2008.

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

4 BACKGROUND

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

Recognised TCs are selected based on priorities defined by DG AGRI.

The audits form part of the Annual FVO Work Programme published on DG SANTE's website:

http://ec.europa.eu/food/food_veterinary_office/index_en.htm

Third Countries referred to above have been recognised by the European Commission as implementing (i) national standards on organic production that are equivalent to the production rules laid down in Titles II, III and IV of Regulation (EC) No 834/2007 and (ii) control systems of equivalent effectiveness to those of the EU (Title V of Regulation (EC) No 834/2007). TCs recognised as equivalent are included in Annex III of Regulation (EC) No 1235/2008.

All six TCs visited between October 2012 and December 2014 were recognised for the following categories of products to be imported into the EU:

- Category A (unprocessed plant products, except seaweed);
- Category D (processed agricultural products for use as food, except wine and yeast).
- Category F (vegetative propagating material and seeds for cultivation);

Ingredients used for category D products have to be produced in the TC of origin. Israel may use ingredients imported either from EU MS or from countries listed in Annex III of Regulation (EC) 1235/2008. Switzerland may also use ingredients imported from TCs having in place control systems recognised as equivalent by Switzerland.

Argentina was also listed for category B (live animals and unprocessed animal products) and Switzerland for category B and E (processed agricultural products for the use as feed). Ingredients used for category E products have to be produced under the same conditions as indicated for category D products.

The main products exported to the EU were:

- Sugar and sugar by-products, soybean and its products, basmati rice, tea and sesame from India;
- Olive oil, dates, fresh fruits and vegetables and processed cereals from Tunisia;
- Potatoes, carrots, sweet peppers, tomatoes, avocados, white grapefruit and dates from Israel;
- Chocolate, muesli, dairy products and cheese from Switzerland;
- Cereals and oil seeds (maize, soybean, wheat) and fresh fruits (mainly apples and pears) and vegetables (mainly onions) from Argentina;
- Vanilla paste and extract, dried organic green algae, macadamia kernels and oil, safflower oil, noodles and lemon myrtle tea from Australia.

5 OVERVIEW OF MAIN FINDINGS AND CONCLUSIONS

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

5.1 NATIONAL LEGISLATION AND NATIONAL STANDARDS

Article 46(1)(a) of Regulation (EC) No 882/2004.

Article 9(1)(a) of Regulation (EC) No 1235/2008.

Findings

All six TCs visited had national organic production standards and control measures in place, which were overall the same as those notified to the European Commission. However, not all countries had notified all amendments or implementing provisions:

- One TC did not notify its organic production implementing legislation, which was in force since 2008;
- One TC did not notify a minor change to its standard. Furthermore it has unilaterally extended its scope under the equivalency arrangement without recognition by the European Commission.
- One TC implemented a change to its production standards with regard to the use of organic yeast. However, the equivalence of the national provisions of this TC had not yet been formally declared by the European Commission at the time of the FVO audit.

Two TCs included in their national provisions lists of inputs authorised for use in organic production.

Conclusions on National Legislation and National Standards

All TCs audited had national organic provisions and control measures in place, the core of which had been notified to the European Commission. However, three of the TCs had not notified all national provisions or had implemented new provisions without having notified them to the European Commission. As a consequence, there is a risk that products exported

to the EU had not been produced in accordance with national standards on organic production recognised by the European Commission as being equivalent to those of the EU.

5.2 STRUCTURE AND ORGANISATION OF THE CONTROL SYSTEM

Legal Requirements and Relevant Standards

Article 46 of Regulation (EC) No 882/2004

Article 27(13), 30, 33(2), Title V of Regulation (EC) No 834/2007.

Codex Alimentarius guidelines CAC/GL 32-1999.

5.2.1 Competent Authorities: Designation, Cooperation and Communication

Findings

In all six TCs, the CAs were designated, with clear division of tasks among them and were empowered to enforce national provisions. The communication and co-operation among the CAs was adequate, except in one TC, where the system in place did not ensure appropriate and timely communication between the regional food safety authorities, the CBs and Central CA with regard to irregularities.

The inspection and certification tasks were delegated in all six TCs to private CBs. The system for the delegation of inspection and certification tasks was in general appropriate, but in one TC the description of the delegated tasks was not accurate.

Conclusions on CAs

Generally, the CAs were designated in all TCs, with a clear division of tasks among them and they were empowered to enforce national provisions. Control tasks delegated to CBs were adequately described and good communication and co-operation were in place between CAs, and between CAs and CBs, in almost all TCs visited.

5.2.2 Control Bodies: Accreditation, Approval, Supervision and Withdrawal

Findings

In all six TCs visited official controls of organic production and labelling were delegated to CBs. These CBs had been accredited, where required, by the national standards on organic production recognised by the European Commission as being equivalent to those of the EU.

In the TCs where the approval of CBs by CAs was a compulsory requirement, CAs had documented procedures in place establishing the conditions to be fulfilled in order to be approved to carry out delegated tasks. CBs must have documented procedures in place to carry out inspection and certification, to ensure competency, impartiality and objectivity of the personnel and to apply enforcement measures when irregularities are found at operators.

In all six TCs, the CAs must carry out an annual supervision in order to verify that the CBs continue to fulfil the conditions which they were authorised under.

Control Bodies maintain the delegation of tasks subject to a successful annual supervision by the CA. Annual re-approval is explicitly required in one TC. However, in the same TC, the approval was granted in 2013 based on the assessment of a mailed questionnaire and the renewal of CBs' approval was granted before compiling the conclusions of this assessment.

In one TC, office audits and witness audits were carried out to observe the performance of the CBs' inspectors. In two TCs verification audits were also carried out by the CA to 5% of operators, as the CAs keep the competence to directly inspect the operators. The inspections carried out by the CAs also serve to review the reports of the inspections carried out by the CBs.

Some significant weaknesses were noted with regard to supervision by CAs:

- In one TC, no witness audits were carried out in 2012 and 2013 due to budgetary constraints and no adequate follow up had been carried out on the irregularities detected in previous years.
- In two TCs the supervision did not cover all areas of activity in the scope of approval or accreditation of the CBs.
- In two other TCs there were no specific criteria in place to verify the effectiveness of the controls carried out by the CBs.
- In two TCs no adequate measures were taken against CBs where major non-compliances had been found by the CA in consecutive years.

No major issues were found with regard to the communication and co-operation between the CAs and CBs and among CBs. Reports on the outcome of the inspections are regularly communicated and major non-compliances are notified to the CAs within a short deadline. Working groups on different topics met regularly in one TC with the attendance of all CBs and the CA. In two TCs the CAs issued binding instructions to the CBs.

Conclusions on Accreditation, Approval, Withdrawal and Supervision of CBs

In all TCs visited systems for the delegation of official controls to CBs were in place and CBs were accredited, where required by national rules. However, in almost all TCs some significant shortcomings in the supervision of CBs were identified mainly relating to the insufficient assessment of the effectiveness of CBs' control activities and the inadequate measures taken by the CAs against CBs in case of their failure.

5.2.3 Organisation and Planning of Controls

Findings

In all TCs, at least one annual inspection of all operators is performed. Risk criteria were sufficiently taken into account for the planning of inspections, including operators' past irregularities and the risk of exchange of conventional and organic foodstuffs. In two TCs the CAs inspected directly 5% of operators in addition to the controls carried out by CBs.

Documented procedures were in place in all TCs as to ensure consistency and harmonisation of controls across CBs or between inspectors of the same CBs. However, in two TCs, checklists did not necessarily provide the inspectors with useful guidance on how to check and report some relevant requirements with the risk that important information is not provided to the CB staff responsible for the final decision on certification.

In four TCs, additional visits were carried out unannounced while in two TCs, operators were given prior notice, which was not in line with national provisions. In one TC, the timing of the inspections was adequate, in particular with regard to some fruit crops as it took into account the expected harvesting period, which had to be authorised by the CA in advance.

Conclusions on Organisation and Planning of Controls

Planning of inspections ensured in all TCs that all registered operators were controlled at least annually, and documented procedures were in place to ensure consistency of controls. However, in two TCs, all visits were announced and the guidance provided to inspectors did not ensure that compliance with all relevant requirements of the national law was checked.

5.2.4 Sampling

Findings

All TCs visited had sampling arrangements for the detection of unauthorised plant protection products (PPPs) in line with the national standards on organic production recognised by the European Commission as being equivalent to those of the EU.

Sampling was carried out according to detailed documented procedures, except in one TC where the procedures applied by one CB did not contain enough information to provide the inspectors with adequate guidance on how to take representative samples and how to preserve perishable samples. In one TC, CBs did not follow the sampling protocols in place. The inspectors did not seal the bags and did not use cooling bags for the preservation of perishable samples.

The selection of operators to be sampled was risk-based in three TCs, taking into account several factors such as past irregularities of the operators, parallel production of conventional and organic products and volume of production. Overall, an adequate number of samples were taken. In particular, in one TC, a large number of samples was taken as national provisions required CBs to sample all operators visited. In addition, in the same TC, more than one sample was taken in cases of suspicion. Laboratories used by the CBs were generally accredited to ISO/IEC 17025. However, in three cases, the scope of analyses of the laboratories used was too limited and did not cover the relevant PPPs.

In four TCs, the detection of non-authorized PPP residues in organic products must be followed up by the CBs. One TC accepted a threshold below which, a positive result is not considered to affect the organic status of the product provided that the operator had addressed the potential risk of external contamination by implementing precautionary measures. In another TC, a threshold for a PPP was observed, below which the product was considered

compliant. This threshold was not described in the national standards on organic production recognised by the European Commission as being equivalent to those of the EU.

Conclusions on Sampling

Sampling arrangements and documented procedures were generally in place and adequately implemented and a satisfactory number of samples was taken.

In a number of TCs, shortcomings were detected with regard to the representativeness of the samples taken, their transportation to the laboratories and the analytical scope. Two TCs had established a threshold for PPP residues to trigger follow up actions.

5.2.5 Traceability and Export Certification System

Findings

Traceability systems were in place in all TCs visited. They generally allowed for tracking of foodstuffs throughout the food chain except in two TCs. In one TC, a web-based traceability system allowed for tracing all consignments from the exporter to the producer, as domestic certificates had to be issued for each sale of organic products.

Overall, export certification systems followed documented procedures in place, and certificates of inspections (CoI) issued were in line with national legislation. In one TC, a tamper-proof certificate pre-validated and registered by the CA had to be used for all commercial transactions and the CBs had to verify all relevant information provided by operators before the issuance of the CoI. In another TC it was noted that certificates were issued without adequate supporting documents having been received and assessed, and the inspection reports lacked comprehensive information to provide the certification officers with guidance on the certification decision. In addition, the certificates were not necessarily issued before the exported consignment left the premises of the exporter to which the organic certificate was issued. In two TCs the system in place did not ensure that only products produced in these countries or imported from countries included in Annex III of Regulation (EC) No 1235/2008 were exported to the EU. In one country, controls were not carried out in a timely manner and not all consignments were verified, contrary to national legislation.

Conclusions on Traceability and Export Certification System

Traceability and export certification systems were in place in all TCs visited. In three TCs, they were not always implemented so as to ensure that only products or ingredients produced in these countries are exported to the EU. In particular in one TC, export certificates were issued without adequate supporting evidence, weakening the reliability of the certification.

5.2.6 Enforcement Measures

Findings

In five TCs, a catalogue of sanctions was in place either issued by the CA or agreed between CBs and validated by the CAs. Only in one TC, there was no system in place at national level

to ensure that CBs apply enforcement measures in a consistent manner when the same types of non-compliances are found.

The CAs were adequately empowered to enforce the law. In two TCs, the CAs retained the competence to inspect directly the operators and therefore may directly apply sanctions without the need to receive the information on any non-compliances from CBs. Moreover, in one of these two TCs, the CAs had the power to withdraw any non-compliant operator from the system, with no possibility for the operator to move to a new CB.

Overall, enforcement measures applied in TCs were effective except in two cases. In one TC, irregularities were notified with a substantial delay between CBs/CAs or between CAs, thus not allowing for measures to be taken to avoid the marketing of the non-compliant products. In the same TC, measures on the non-compliant products already marketed were taken only when food safety issues arose. In one TC, enforcement measures taken having regard to the severity of the irregularities, were found to be insufficient and inconsistently applied by CBs.

Conclusions on Enforcement Measures

Enforcement measures were in place in almost all of the TCs visited, and were generally applied effectively. Shortcomings detected related to the inadequacy of enforcement measures taken by CBs in case of major irregularities, with the risk that non-compliant products might be exported to the EU.

5.3 REGISTRATION OF ORGANIC OPERATORS

Legal Requirements and Relevant Standards

Article 28, 32(2), Title V of Regulation (EC) No 834/2007.

Findings

In all TCs, producers and processors of organic products (hereinafter "organic operators") were required to register and submit their activities under the control system. However, in one TC, not all organic operators were registered for all the operations they carried out, namely trading activities including export. Nevertheless, controls also covered the non-registered activities. In one TC, not all traders and exporters were required by the CAs to submit their undertakings to the control system, contrary to the requirements of the national standards on organic production recognised by the European Commission as being equivalent to those of the EU.

Lists of registered organic operators were kept by CBs and transmitted to the CAs. These lists were updated at least when changes in the organic status of the operators occurred, and published on the CA's website. In one TC, these lists were updated every two weeks. However, in one TC, the list had not been published since 2010 due to budgetary constraints. In another TC, the information provided by the list was not fully adequate, as the type or range of products was not indicated in the certificate of organic operators contrary to national requirements.

Conclusions on Registration of Organic Operators

In all TCs visited, a system for registration of organic operators was in place and included lists of operators that were published and updated. However, since not all organic operators' activities have to be notified and registered in all TCs, there is a certain risk that these operators were not controlled.

5.4 CONTROL ON ORGANIC PRODUCTION

Legal Requirements and relevant standards

Article 23, 24, 25, 27, 32(2), Titles II, III and IV of Regulation (EC) No 834/2007.

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

5.4.1 Control of Operators

Findings

In all TCs visited, documented procedures were in place to ensure harmonisation and consistency of controls carried out by the CBs' inspectors. Checklists were used by inspectors as a supporting document to perform the inspections. Previous reports and other relevant information concerning the establishment (e.g. maps, lay-out of the premises, operators' management plans and quality control systems) were also taken into account for the preparation of the control visits.

Knowledge and competence of the inspectors was adequate. Inspections observed by the FVO audit teams were generally well structured and inspectors followed checklists produced by the CBs. However, in two TCs, inspections were effective at producer's level but less effective at processor level. In one TC, inspectors focused on the organic processing and did not pay equal attention to the conventional processing, as required by the national legislation. Some shortcomings in the performance of the inspectors were recurrently noted during witness audits, in particular:

- In two TCs, inspectors did not adequately verify the information provided by the operators. In one of these TCs, the inspectors simply noted down the responses given by the operators without further verification of the accuracy of the statements.
- Not all relevant requirements were checked by the inspectors in four TCs. Inspectors did not check records kept by operators regarding separation of the operations (processing) between conventional and organic batches, inputs used were not verified and not all storage and processing facilities were visited by the inspectors.

In all TCs, derogations on the use of conventional input and exceptional production rules were granted in line with the national standards on organic production recognised by the European Commission as being equivalent to those of the EU. The most common derogations were:

- Use of conventional, untreated seeds, where no organic seeds were available.
- Shortening of the conversion period of new lands dedicated to organic farming.

- Introduction of new conventional animals into an organic farm for the renewal of a herd or flock.
- Use of conventional feed in cases of fodder losses.
- Mutilations of animals and use of antibiotics for veterinary treatment.

The conditions under which derogations were granted were adequately documented. CBs generally verified the fulfilment of the conditions by operators during inspections. Only in two TCs, shortcomings were noted which related to the inadequate shortening of the conversion period (three years were recognised retrospectively by one CB, contrary to the national legislation) and the inappropriate verification of the use of untreated seeds.

Conclusions on Control of Operators

All TCs had documented procedures including checklists in place aimed at harmonising controls implemented by CBs. CBs' inspectors were generally experienced and conducted well-structured controls. However, in most of the TCs visited, shortcomings related to the inadequate verification by inspectors of information provided by the operators, with the risk that non-compliant products were exported to the EU.

All TCs granted derogations and exceptional production rules in line with national rules. These grants were adequately documented. Weaknesses related mainly to the inappropriate shortening of the conversion period and insufficient verification of derogations during the inspections.

5.4.2 Labelling

Findings

Labelling provisions were in place in all TCs and checks were regularly carried out by CBs. In two TCs, CBs requested their operators to send the labels for approval before they were used. Labels were found to bear all the compulsory indications established in the EU Regulations when the EU logo was used, except in one TC.

Conclusions on Labelling

Labelling provisions were in place and adequate checks were carried out in the TCs visited. When the EU logo was used, it was ensured that products exported to the EU bore labels with information in line with EU Regulations, except in one TC.

5.5 FOLLOW UP OF EU NOTIFICATIONS OF IRREGULARITIES

Legal Requirements and Relevant Standards

Article 46(1)(h) of Regulation (EC) No 882/2004.

Findings

All TCs visited had a system in place for the follow up of EU notifications. All TCs visited, with one exception, had been notified of irregularities by the EU. In most cases, the notifications related to residues of PPPs found in samples taken in EU MS. The CA notified the CBs in charge of controls of the operators involved, and requested them to carry out follow up activities. In all cases, control visits were carried out to the operators involved, both at producer and at processor level. In two TCs, the whole food chain was sampled in order to identify the possible origin of the residue. The measures taken were considered adequate by the FVO audit teams. The outcome of the follow up actions was notified in all cases to the European Commission.

Conclusions on Follow up of EU Notifications of Irregularities

In all TCs EU notifications checked by the FVO audit teams were adequately followed-up and the results were communicated to the European Commission.

6 EXAMPLES OF GOOD PRACTICE

The following examples of good practice were found in the TCs covered by this report:

- Two TCs (Israel and Australia) included in their national provisions lists of inputs authorised for use in organic production, which served as a good guidance for both CBs and operators.
- The CA carried out witness audits in one TC (Israel) to observe the performance of the CBs' inspectors. In two TCs (Israel and Argentina) verification audits were also carried out by the CA to 5% of operators to review the reports of the inspections performed by the CBs.
- Working groups on different topics met regularly in one TC (Switzerland) with the attendance of all CBs and the CA, and in two TCs (Switzerland and Argentina) the CAs issued regularly binding instructions to the CBs.
- In one TC (Argentina), CBs planned the timing of the visits to operators growing certain fruits taking into account the expected harvesting period as authorised by the CA.
- In one TC (Israel), a large number of samples was taken for the detection of PPPs, as national provisions required CBs to sample all operators visited. In addition, in the same TC more than one sample was taken in cases of suspicion.
- Two TCs (Israel and Argentina) had a specific approval and control system in place for laboratories involved in testing organic farming samples including a good analytical scope required from the laboratories. One TC (Argentina) required that samples for the testing of PPPs and GMOs may only be taken by personnel of CBs or accredited laboratories.

- In one TC (India), the web-based traceability system in place allowed the CA to trace back in real time the chain of custody of a product and of the quantities transferred between operators, as domestic certificates have to be issued for each sale of organic products. In another TC (Argentina), a tamper-proof certificate pre-validated and registered by the CA was used for all commercial transactions, and the CBs had to verify all relevant information provided by operators since the issuance of the previous certificate
- In two TCs (Argentina and Israel) the CA kept the competency to inspect directly the operators and therefore may directly apply sanctions without the need to receive the information on non-compliances from CBs. Moreover, in one of these two TCs the CA had the power to withdraw any non-compliant operator from the system, with no possibility for the operator to move to a new CB.
- In one TC (Israel) the lists of registered operators were updated every two weeks.
- In two TCs (Argentina and Australia), CBs requested their operators to send the labels for approval before they were used.

7 MATTERS FOR CONSIDERATION BY RECOGNISED THIRD COUNTRIES

In total, the FVO audit teams raised 41 recommendations to the CAs of the recognised TCs concerned. The majority of recommendations related to the notification requirements regarding legislation, the supervision of CBs by CAs, CBs' controls of operators, sampling and certification of organic products for export to the EU:

The most important recommendations are summarised below:

National Legislation and National Standards

- Ensure that any changes made to the measures in force or their implementation and in particular to its control system are notified to the Commission as required by Article 9(1)(a) of Regulation (EC) No 1235/2008.

Control Bodies: Accreditation, Approval, Supervision and Withdrawal

- Ensure that the system in place for the approval, supervision and withdrawal of CBs allows the CA to verify the effectiveness of controls carried out by CBs. In particular ensure that supervision covers all areas of the CB's activity and that appropriate actions are taken if the CB fails to properly carry out the tasks delegated to the CB.

Organisation and Planning of Controls

- Ensure that appropriate documented procedures are in place to ensure uniformity and consistency of controls, and in particular to provide guidance for inspectors on appropriate verification of precautionary measures (separation, cleaning) and

appropriate reporting of inspection results to ensure that sufficient information is provided to the CB certification officer.

- Ensure that additional visits to operators are carried out unannounced and on a risk basis, as established by national provisions.

Sampling

- Ensure that samples taken are representative and adequately stored in particular in cases of perishable products and that laboratories used for the testing of organic products provide an adequate scope allowing the detection of the non-authorised substances.

Traceability and Export Certification System

- Ensure that organic products to be exported to the EU contain only organic ingredients that have been grown in the country or have been produced in the countries mentioned in Annex IV of Regulation (EC) No 1235/2008.

Controls of Operators

- Ensure that the CBs effectively check all relevant requirements during inspection at operators, in particular that precautionary measures to separate conventional and organic products and related records are checked, and that all premises are physically inspected.

8 ACTIONS TAKEN OR ENVISAGED BY THE COMMISSION SERVICES

8.1 FOLLOW UP OF AUDIT RECOMMENDATIONS FOR RECOGNISED THIRD COUNTRIES

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

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

The European Commission regularly monitors the progress on the actions undertaken by the CAs in recognised TCs to address the recommendations.

8.2 ENFORCEMENT

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

As regards recognised TCs, the Commission services reviewed the scope of the equivalency arrangements or agreements for which the audit findings, together with the results of the European Commission's supervision, showed that the equivalency was not fulfilled (restriction in scope of equivalency for one TC in 2013, conditional extension of equivalency for another TC in 2013 and 2014).

8.3 DISCUSSIONS WITH MEMBER STATES AND EXCHANGE OF GOOD PRACTICES

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

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

8.4 TRAINING

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

A specific training module under the BTSF initiative was designed for staff involved in official controls for organic production and labelling of organic products. Ten workshops were held in the period from 2013 to 2015, in Warsaw (Poland); Sofia (Bulgaria) and Bristol (the UK) and attended by 307 participants, 250 from EU Member states and 57 participants from countries outside the EU.

8.5 LEGISLATION

On 24 March 2014, the European Commission adopted a legislative proposal for a new Regulation of the European Parliament and of the Council on organic production and labelling of organic products¹.

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

¹ COM(2014)180 final.

As regards the control system, the proposal:

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

The proposal is currently under Inter-institutional discussions.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 834/2007	OJ L 189, 20.7.2007, p. 1-23	Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91
Reg. 889/2008	OJ L 250, 18.9.2008, p. 1-84	Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control
Reg. 1235/2008	OJ L 334, 12.12.2008, p. 25-52	Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries

ANNEX 2 - STANDARDS QUOTED IN THIS REPORT

Reference	Title	Publication
ISO/IEC Guide 65:1996	General requirements for bodies operating product certification systems	http://www.iso.org/
ISO/IEC 17065:2012	Conformity assessment -- Requirements for bodies certifying products, processes and services	http://www.iso.org/
Codex Alimentarius guidelines CAC/GL 32	Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods	http://www.codexalimentarius.org/standards/list-of-standards/
Codex Guidelines CAC/GL 50-2004	General Guidelines on sampling	http://www.codexalimentarius.org/standards/list-of-standards/

ANNEX 3 - DETAILS OF INDIVIDUAL AUDITS

Third Country	Dates of Mission	SANTE Reference Number
India	15-26/10/2012	2012-6571
Tunisia	26/11-07/12/2012	2012-6769
Israel	24/02-07/03/2013	2013-6697
Switzerland	09-19/09/2013	2013-6700
Argentina	17-28/03/2014	2014-7096
Australia	16-27/06/2014	2014-7122

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