

Food and Veterinary Office

OVERVIEW REPORT

Organic Production – Recognised Control Bodies in Third Countries

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

Executive Summary

This report provides an overview on five audits on organic production to Control Bodies in Third Countries visited between 2012 and 2014 by the Food and Veterinary Office.

The objective of the audits was to evaluate the application of organic production rules and the effective and permanent implementation of the control measures for which the Control Bodies were recognised by the European Commission under the equivalency regime referred to in Article 33 of Regulation (EC) No 834/2007.

All Control Bodies visited were accredited to EN 45011/ISO Guide 65 and their headquarters were subject to annual surveillance audits by an Accreditation Body.

In general, the Control Bodies visited applied the production rules and implemented the control measures for which they were recognised by the European Commission. However, in one case, the certification system put in place by the Control Bodies did not guarantee that only organic products were exported to the European Union and in another case, a product not covered by the equivalence recognition was certified and exported to the European Union. Some Control Bodies had not adapted in a timely manner their control measures to evolving requirements of the relevant EU legislation or did not correctly report to the European Commission the number and type of derogations granted to operators.

As regards the planning of controls of operators, in general, all Control Bodies visited had appropriate risk based systems in place. Inspections were performed in a structured manner and included checks of labels. Traceability exercises observed were generally satisfactory.

The effectiveness of control systems was reduced as Control Bodies did not always take into account all relevant factors, such as previous non-compliances, the risk of use of non-authorised substances and the appropriate timing of controls, when planning controls and sampling activities. Moreover, inspectors did not systematically check compliance with all requirements of the production rules and/or verify the information provided by the operators. Such weaknesses were seen, in particular, in the supervision by Control Bodies of grower/producer groups where there is an obligation to have a properly functioning Internal Control Systems, particularly because of inappropriate risk assessment of its members and the insufficient follow up of the implementation of corrective measures. Moreover, operators who manage grower groups did not have their certificates suspended or withdrawn in cases of recurrent or numerous failures by the members of the group.

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

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Abbreviation	Explanation
AB(s)	Accreditation Body(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
HQ	Headquarters
ICS	Internal Control System
ISO	International Organisation for Standardization
MoU	Memorandum of Understanding
MS	Member State(s)
OFIS	Organic Farming Information System
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 BC(s)	Control Body(ies) recognised in accordance with Article 33(3) of Regulation (EC) No 834/2007

Abbreviations and definitions used in this report

1 INTRODUCTION

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

This report provides an overview on five audits carried out by the FVO between 2012 and 2014 to recognised CBs operating in China, Turkey and Vietnam.

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

The audits comprised office audits at the headquarters of the CBs and visits to the CBs' branch offices and to operators certified by the CBs in the selected TCs. CBs' representatives accompanied the FVO audit teams for the duration of the audit.

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 control measures in place and the effectiveness of the control system.

Details on the specific reports are provided in the Annex 3 and are also 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 to recognised CBs were to verify:

- that the production rules applied by the CBs as regards the product categories listed in Annex IV of Commission Regulation (EC) No 1235/2008 are those for which the CBs have been recognised by the European Commission;
- that the control measures recognised by the European Commission as having equivalent effectiveness to that of the European Union (EU) have been permanently and effectively applied by the CBs.

In terms of scope, the audits focused on the organisation and performance of the CBs, in particular, on the effective implementation of the production rules and control measures in place covering the whole production, preparation and distribution chain of organic products intended for export to the EU.

3 LEGAL BASIS

Individual audits in this series were carried out under the general provisions of EU legislation and, in particular, Article 33(3) of Regulation (EC) No 834/2007 and Article 11(4) 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 CBs are selected based on priorities defined by DG AGRI.

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

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

Control Bodies referred to above have been recognised by the European Commission as applying in certain TCs (i) production rules equivalent to those laid down in Titles III and IV of Regulation (EC) No 834/2007 and (ii) control measures having equivalent effectiveness to those of the EU (Title V of Regulation (EC) No 834/2007). CBs recognised as equivalent are included in Annex IV of Regulation (EC) No 1235/2008.

The audits on recognised CBs provide an input to the European Commission's supervision of these Bodies under Article 33(3) of Regulation (EC) No 834/2007.

5 OVERVIEW OF MAIN FINDINGS AND CONCLUSIONS

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

5.1 ORGANIC PRODUCTION RULES AND CONTROL MEASURES

Legal Requirements

Article 10(2), 12(1)(a), Annex IV of Regulation (EC) No 1235/2008.

Findings

All CBs visited had notified their production rules and control measures to the European Commission in line with Article 12(1)(a) of Commission Regulation (EC) No 1235/2008.

However, one CB had certified steviol glycoside for export to the EU which was not covered by the equivalence recognition by the European Commission.

One of the two CBs visited in 2014 had not yet incorporated the new control requirements laid down in Regulation (EU) No 392/2013 into its procedures and the other CB had no sanction catalogue in place for the product categories it was listed for in the TC visited by the FVO audit team.

One CB did not correctly report to the European Commission the number and nature of derogations from production rules granted annually to operators certified by the CB in the TC visited as required by Article 12(1)(b) of Regulation (EC) No 1235/2008.

Conclusions on Organic Production Rules and Control Measures

In general, the CBs fulfilled the obligation to notify the European Commission of any changes made to the measures applied. However, shortcomings were identified concerning the certification and export to the EU of products not covered by the equivalence recognition, the timely implementation of the evolving requirements under EU legislation into the CBs organic standards, and the notification of derogations to the European Commission.

5.2 SURVEILLANCE AND RE-ASSESSMENT

Legal Requirements

Article 33(3) of Regulation (EC) No 834/2007.

Findings

All CBs visited were accredited to European Standard (EN) 45011/International Organisation for Standardisation (ISO) 65:1996 and were subject to annual surveillance audits by an accreditation body (AB) in accordance with Article 33(3) of Regulation (EC) No 834/2007.

CBs' branch offices in the TCs visited by the FVO audit teams had not yet been subject to surveillance audits except in one case, where the AB carried out witness audits in 2011 (the CB has no branch office in the TC concerned). CBs stated that ABs generally follow a risk based approach with regard to auditing CBs' branch offices in TCs. One CB stated that all its branch offices receive at least one surveillance visit by the AB within the accreditation cycle (5 years).

One CB was subject to a specific audit on shrimp production carried out by an AB at the request of the European Commission.

Another CB stated that it carries out internal audits to its branch offices following a risk assessment aimed at visiting each branch office at least once every 5 years. Branch offices considered as high risk are audited more often.

Conclusions on Surveillance and Reassessment

The headquarters (HQ) of all CBs visited by the FVO audit teams were subject to regular surveillance audits of their activities by an AB as required by EU legislation.

5.3 NATIONAL AUTHORITIES AND NATIONAL LEGAL REQUIREMENTS

Legal Requirements

Article 11(3)(d) of Regulation (EC) No 1235/2008.

Findings

All CBs had notified their activities to the national authorities and had taken measures to comply with national rules. One CB had no office in the TC concerned but nevertheless notified its activities to the national authorities.

Conclusions on National Authorities and National Legal Requirements

All CBs had notified their activities to the relevant national authorities and had taken measures to comply with national rules.

5.4 STRUCTURE AND ORGANISATION OF THE CONTROL SYSTEM

Legal Requirements

Article 33(1) and (3) of Regulation (EC) 834/2007.

5.4.1 Organisation and Planning of Controls

Findings

CBs generally had procedures in place for the recruitment, training and evaluation of inspectors and certification officers and implemented them. They trained newcomers and conducted regular trainings for their staff.

Newcomer inspectors had to pass a test before they were approved for specific areas of inspection (in two CBs) and certification officers were trained at the HQ (in one CB).

Inspectors of two CBs were supervised by the HQ and/or the branch office by means of inspection report reviews. Inspectors of two CBs had to undergo national training programmes and/or be registered/approved by national CAs.

All CBs had measures in place to prevent conflict of interest of their staff. Statements were generally signed by all staff and the inspectors. Rotation of inspectors for visits of operators was required by all CBs. In one TC, the CB did not apply its policy on rotation due to the very low number of operators. Inspectors were generally allocated according to their expertise.

All CBs visited carry out a risk assessment of the operators they certified in order to determine the intensity and nature of annual inspections (including additional and unannounced controls).

All CBs visited used pre-defined risk criteria to classify the operators into different risk categories (low, medium, high). CBs visited generally took the following relevant risk criteria into account: inspection history, intensity of production, complexity of structure of operators, risk of contamination and internal controls systems and the appropriate timing for controls to take place, e.g. at farms before harvest, at processors after harvest.

All CBs visited, with one exception, applied group certifications requiring the groups to establish an Internal Control System (ICS). The other CB certified operators who could be an exporter or processor who subcontracted several hundreds of farmers (projects). In such cases, the CB required at least one annual control for each of the contracted farmers. And additional controls (sampling) were carried out on projects which were considered medium (additional announced visits) and high risk operators (additional unannounced visits).

One CB provided a risk assessment tool to its branch offices in all TCs for which it is listed in Annex IV of Regulation (EC) No 1235/2008 to be used for the annual planning of controls and sampling. The tool was flexible enough for specific national risks to be taken into account. The annual control/sampling plan was approved by the HQ. Sampling was considered an additional control.

Not all CBs had taken all relevant risk factors into account such as the high number of irregularities (one CB) or the unauthorised use of pesticides (glyphosate) as specifically requested by the European Commission to CBs operating in the TCs visited (two CBs). One CB did not oblige its processors to notify the start of processing or loading of containers which did not allow the CB to schedule the inspections at the most appropriate time. In another case, the operator's activity (processing step on the farm) was not considered processing and hence did not lead to an adequate risk assessment of the operator and an adequate control frequency. Another CB did not systematically control large farms which were members of grower groups at least once per year, contrary to the requirement in the CB procedures.

Increased control frequencies with regard to additional and unannounced controls as well as sampling were introduced by Regulation (EC) No 392/2013 (applicable as of 1.1.2014). One of the two CBs visited in 2014 had not yet incorporated the new control requirements into its procedures, but both CBs complied with the new requirements on additional and unannounced controls and, at least at global level, with the new requirement on sampling.

In one case, involving the transfer of an operator from one CB to another, the file of the operator including maps outlining the location of certified land parcels had not been transferred from the initial CB to the new CB and the new CB had no system in place to verify the status of all land parcels submitted by the operator.

Conclusions on Organisation and Planning of Controls

CBs visited had appropriate risk-based systems in place for the planning of the annual controls of operators (including additional and unannounced controls). Inspectors were allocated according to their expertise and a rotation policy was implemented. However, the effectiveness of the control system was reduced as when planning the controls CBs did not always take into account all relevant factors such as previous non-compliances, the risk of use of non-authorised substances, activities considered high risk and the appropriate timing of controls.

5.4.2 Off-farm Input Verification System

Findings

All CBs visited had procedures in place for the approval and verification of off-farm inputs.

Three CBs provided updated lists of approved products and all CBs required approval of new (not yet approved) input products before used by the operators. One CB (whose HQ did not provide such a list) advised its branch offices on product approvals which had to be requested in writing by the operator. The same CB required re-approval of products approved by other CBs prior to their use by the operator.

Operators generally pre-notified the use of input products to the CBs via the annual organic management plan and they had to keep records of the use of input products.

CBs inspectors verified off-farm input products and their use during inspections at the operators.

One CB authorised off-farm input products for aquaculture with reference to Article 95(11) of Regulation (EU) No 889/2008 although the condition set out in this Article was not met (national accepted organic rules in place before 1.1.2009).

Conclusions on Off-farm Input Verification System

In general, CBs visited had an appropriate system in place in order to verify that off-farm input products used in organic production were authorised for this purpose. In one case, an input product was authorised although relevant requirements were not fulfilled.

5.4.3 Handling of Derogations and Exceptional production rules

Findings

All CBs visited had granted derogations and exemptions with regard to production rules in accordance with their procedures.

One CB authorised the use of conventional juveniles beyond limits specified in the CB's production rules with reference to Article 95(11) of Regulation (EU) No 889/2008 although the condition set out in this Article was not met (national accepted organic rules in place before 1.1.2009).

Conclusions Handling of Derogations and Exemptions

CBs generally granted derogations and exemptions to production rules in accordance with their procedures. However, in one case the CB granted an exemption to production rules although the relevant legal requirement was not met.

5.4.4 Sampling

Findings

CBs visited had sampling plans in place which were based on a risk assessment of the operators certified by the CBs.

All CBs visited sampled a minimum of 5% of the operators they certified (on a global level). However, one CB had not taken any samples up to 2014 in the TC visited, and had only taken a low number of samples in 2014 primarily aimed at detecting fraud.

Three CBs (in one TC) had taken a relatively high number of samples in 2012: in one case samples were taken at 100% of operators and in another case at 25% of operators; in another TC, consignments intended for EU export were systematically sampled and certificates were issued only after confirming results were available.

All CBs visited had sampling procedures in place. Sampling procedures / Codex guidelines were however not always respected by CBs' inspectors. In some cases, inspectors lacked either the appropriate equipment (sufficient number of bags, seals, cooling boxes for transport of samples to laboratories) or did not take representative samples, contrary to requirements in CBs' procedures / Codex guidelines.

All laboratories used by the CBs visited were accredited under an officially recognised quality management and assurance programme equivalent to international standards, such as ISO/IEC 17025.

Control Bodies mainly used laboratories in Europe with a sufficient analytical scope covering more than 200 active analyses.

For testing of routine samples one CB in one TC had used an accredited laboratory with an insufficient analytical scope (100 active substances); in two other cases, CBs had not asked for the testing of pesticides not authorised in organic production such as glyphosate but which are widely used in the country concerned.

Conclusions on Sampling

All CBs visited had sampling plans in place based on risk assessment of the operators they certified. At global level, all CBs sampled a minimum of 5% of their operators. In one TC, the number of samples taken was relatively low and the type of samples inadequate for confirmation of compliance with organic rules. Sampling procedures were not always respected by the CBs' inspectors and the analytical scope for testing requested by the CBs was not always adequate.

5.5 LIST OF ORGANIC OPERATORS

Legal Requirements

Article 11(3)(e) of Regulation (EC) No 1235/2008.

Findings

All CBs visited published lists of operators on their webpage which provided the relevant information as set out in Article 11(3)(e) of Regulation (EC) No 1235/2008. The lists were regularly updated by three CBs. One CB had not updated the lists to reflect recent changes and another CB had still operators on the list which were suspended during the two preceding years and a third CB had procedures in place which did not require the continuous updating of the list.

One CB highlighted suspended operators in the list and deleted the operators who were no longer certified. For each operator, an annex to the documentary evidence of the operator was provided which listed all product categories covered by the certificate and the validity of the certification (usually 12 months); the annex also indicated subcontracted activities.

All CBs visited, with one exception, applied group certifications. In one TC, one CB issued single certificates for operators who subcontracted activities including farming, processing and export (projects). The number of farmers in such projects could go up to several hundreds.

Conclusions on List of Organic Operators

All CBs published on their websites the lists of operators subject to their controls. Two CBs however did not regularly update these lists undermining their reliability when certifying or renewing certifications of organic operators.

5.6 CONTROLS ON ORGANIC PRODUCTION

Legal Requirements

Article 23, 24, 25, 27(13), 33(1) and (3) of Regulation (EC) 834/2007.

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

Codex Alimentarius guidelines CAC/GL 32-1999.

Findings

5.6.1 Controls of Operators

The FVO audit teams witnessed in total 20 inspections which included 11 inspections at grower/producer groups/projects located in the three TCs visited. Witness audits were selected based on the size and complexity of operators, identified irregularities in past inspections, importance of product categories.

The inspectors observed by the FVO audit teams were generally competent, well prepared and well equipped with laptops and internet access. Procedures and detailed checklists were available to them. Inspectors informed operators about the objective and scope of the inspection in the beginning, checked relevant documents (production plan, purchases, sales, transport records) and updates to the organic production plan, previous non-compliances and corrective actions. CBs' inspectors carried out on-site inspections to check premises and the implementation of precautionary measures such as cleaning records, identification/separation, as well as buffer zones. At grower groups/producer groups, inspectors checked the setting up and implementation of the ICS. At the end of the controls, operators were informed about non-compliances and an inspection report was issued which was signed by the inspector and countersigned by the operator or the grower group/producer group.

Inspectors did not always systematically verify the information provided by the operators during on-site inspections such as pesticides and seeds on stock, type of farm-inputs used, nature and quantity of manure used, harvest yields/estimations or cleaning records. Inspectors of four CBs did not sufficiently verify whether appropriate measures were in place for the identification and separation of organic and non-organic raw material and end products stored at operators visited. One CB did not require the operators to record data and information on parallel processing and hence this was not checked and verified by the inspectors.

As regards group certification, one CB did not require growers groups to implement an ICS contrary to the CB's procedures. Other weaknesses were related to inappropriate verification of information provided by the certificate holder such as the appropriate record keeping, correctness of maps for land and the use of fertilizer, cleaning records for storage facilities at a subcontracted warehouse.

In one TC, the CBs inspectors had not noticed that the risk assessment undertaken by the producer groups did not take into account the fact that prohibited off-farm input (rotenone, saponine) had been used and that organic management plans were either missing or if available, addressed food safety issues rather than ensured compliance with organic rules. Large farms in grower groups were not controlled once per year contrary to the CB procedures.

5.6.2 Labelling

All CBs' inspectors checked labels during inspections. CBs generally approved labels before their use by the operators. Labels checked during the audits contained all information necessary for the traceability exercise (CB number, lot number, addresses).

5.6.3 Traceability

Traceability exercises were generally conducted in a satisfactory manner during the inspections observed by the FVO audit teams. Product lots were randomly selected and traced from the field to the processors. One CB issued handwritten labels on boxes brought to the collection points (wild collection) which allowed the tracking of the products to the field/plot.

Four CBs issued domestic transaction certificates (which were required by national law) when products were sold or moved between operators certified by different CBs.

Conclusions on Controls on Organic Production

Inspectors were competent and prepared when carrying out inspections. Procedures and checklists were available to inspectors. Labels were checked and traceability exercises were well performed by CBs inspectors.

The effectiveness of the controls was however weakened by the fact that CBs' inspectors did not always check all requirements of the CBs' organic production rules or did not systematically verify the information provided by the operators.

As regards grower groups, weaknesses were identified with regard to the supervision obligation by CBs. CBs did not always require or verify the setting up of an ICS which led CBs inspectors to overlook the risk assessment and management plans set up by the grower groups in the ICS and to corrective measures that were inappropriate to ensure compliance with the CBs' organic production rules.

5.7 EXPORT CERTIFICATION SYSTEM

Legal Requirements

Article 33(2) and (3) of Regulation (EC) No 834/2007.

Article 13 of Regulation (EC) No 1235/2008.

Findings

All CBs had procedures in place for the issuance of Certificate of Inspection (CoI) in line with Article 13 of Regulation (EC) No 1235/2008 and used the EU model. All CBs visited, with one exception, had experience with the issue of CoIs for the export of organic products to the EU at the time the FVO audits were carried out.

CoIs were issued by the HQ of the CBs visited (except in one TC). The branch offices sent the draft CoI to the HQ after they had satisfied themselves that the consignments were organic by checking relevant documents requested from the exporters and, if considered necessary, by conducting physical checks. The HQ returned the signed original CoI to the importer and a copy to the branch office in the TC.

Exporters in one TC sent for each consignment/transaction labels and supporting documents to the CB branch office. In case of farming projects, the CB requested and verified the list of approved farmers and compared the quantity sold with the harvest estimates registered in the CB database. The credibility of the operator's declaration was verified during the next inspection visit.

One CB operated a computerised system which allowed the blocking of non-compliant consignments by the certification officer to prevent the issue of a CoI by the CBs HQ.

However, the system failed and CoIs were issued for non-compliant products because the certifying officer had not received all relevant documents from the CB's inspectors to launch such an alert in the system.

Conclusions Export Certification System

Most of the CBs visited issued certificates for organic products for export to the EU in line with EU requirements. The export certification system put in place by one CB did not guarantee that only products fulfilling the requirements of the CB organic standard were exported to the EU.

5.8 FOLLOW UP OF EU NOTIFICATIONS OF IRREGULARITIES

Legal Requirements

Article 30, 33(3) and (1) of Regulation (EC) No 834/2007.

Annex IV of Regulation (EC) No 1235/2008.

Findings

All CBs visited, with one exception, had procedures for the handling of non-compliances and sanction catalogues in place. These classified non-compliances according to their severity and corresponding enforcement measures to be applied. One CB had its sanction catalogue only partially in place but not for the product category which was subject to the audit by the FVO.

In case of suspicion, CBs generally took measures in line with their procedures in order to establish irregularities Enforcement measures were taken in a timely manner and certificates were suspended or withdrawn in cases of severe irregularities.

Weaknesses were identified with regard to grower groups/producer groups/projects. Sanctions were unlikely to be imposed by the CB on certificate holders in cases where several irregularities or recurrent non-compliances were detected during controls of group members, e.g. when farmers repeatedly failed to comply with organic rules (lack of maps, missing records).

In one case internal inspectors of grower groups had not always reported non-compliances nor had they imposed any enforcement measures. Although the CB's inspectors noted and suspended the certificate of the grower groups involved, these non-compliances were noted again during the FVO audit.

At the same grower group, neither the CB inspectors nor the internal inspectors had noted that the grower group had continued to sell products to a processor during the time when its certificate was suspended. The processor, who was a member of the same producer group, accepted them and exported them to the EU as organic.

Open EU notifications of irregularities in the Organic Farming Information System (OFIS) were checked by the FVO audit teams with regard to two CBs. There were either no or no

open EU notifications for the other CBs and TCs visited at the time of the audits. CBs had uploaded in OFIS the results of the investigations carried out in a timely manner, except in one case where technical problems prevented the uploading of the information.

Conclusions on follow up of EU Notifications of irregularities

All CBs visited, with one exception, applied their procedures on handling infringements and irregularities and implemented their sanction catalogues. The effectiveness of the control systems was weakened by the fact that operators who manage grower groups did not have their certificate suspended or withdrawn in the case of recurrent or numerous failures by the members of the group. One CB's sanction catalogue was only partially in place not allowing for an effective enforcement of the CB's organic production rules. EU notifications of irregularities (OFIS) were generally followed up in a satisfactory manner.

6 NON-EXHAUSTIVE LIST OF EXAMPLES OF GOOD PRACTICE

- Newcomer inspectors had to pass a test before they were approved for specific areas of inspection (two CBs in China and Turkey) and certification officers were trained at the HQ (one CB in Turkey).
- One CB (Turkey) provided a risk assessment tool to all branch offices in all TCs for which it is listed in Annex IV of Regulation (EC) No 1235/2008 to be used for the annual planning of controls and sampling. The tool was flexible enough to allow taking into account specific national risks.
- One CB (Turkey) systematically sampled consignments intended for EU export and CoIs were only issued after confirming results were available.
- One CB (China) highlighted in the list the suspended operators and the operators who were no longer certified. For each operator, an annex to the documentary evidence of the operator was provided which listed all product categories covered by the certificate and the validity of the certification (usually 12 months); the annex also indicated subcontracted activities.
- One CB (China) issued labels on boxes from workers brought to the collection points which allowed the tracking back of the goods to the field/plot.
- Four CBs (China and Turkey) issued domestic transaction certificates (required by national law) when products were sold or moved between operators certified by different CBs.
- One CB (Turkey) requested and verified the list of approved farmers and compared the quantity sold by them with the harvest estimates registered in the CB database.

7 RECOMMENDATIONS TO RECOGNISED CONTROL BODIES

In total, the FVO raised 33 recommendations to the CBs concerned. The majority of the recommendations were related to the planning of controls, the controls of operators, sampling and the follow up of irregularities.

The most important recommendations are summarised below:

Organic Production Rules and Control Measures

• Ensure that new control requirements are incorporated into the CB's control measures (three CBs)

Organisation and Planning of Controls

• Ensure that the nature and frequency of the controls are determined on the basis of an assessment of the risk of occurrence of irregularities and infringements and, in particular that all relevant criteria are taken into account for the planning of additional inspections and that inspections are carried out at the most appropriate times (four CBs).

Off-farm Input Verification System

• To ensure that off-farm inputs used by any organic operator are authorised in line with the provisions of the Organic Standard and/or the EU legislation (one CB).

Handling of Derogations and Exemptions

- Ensure that reporting obligations set out in Article 12(1)(b) of Regulation (EC) No 1235/2008 are fully complied with, in particular with regards to derogations (one CB).
- To ensure that the stocking of ponds with conventional juveniles does not exceed the limits laid down in the CB production rules and that wild caught and non-organic aquaculture animals are kept under organic management for the minimum periods defined in the CB production rules (one CB).

Sampling

- Ensure that the sampling plan covers all products certified by the CB and all countries where the CB is active, and that matrix and analyses are targeted to detect possible specific infringements to organic production rules (one CB).
- Ensure that the CB's sampling procedures are respected/effectively applied and, in particular, that the sealing, cooling and transport of the samples is appropriate (three CBs).
- Ensure that the scope of the laboratories is adequate to guarantee the detection of non-authorised substances (two CBs).

List of Operators

• Ensure that the published list of operators subject to the control system is regularly updated to reflect any changes in their certification status by Regulation (EC) 1235/2008 (three CBs).

Controls of Operators

- Ensure that the CB's procedures regarding grower groups are effectively applied and, in particular, that grower groups have an adequate internal control system (three CBs).
- Ensure that controls are effective and that inspectors verify the information provided by the operators (3 CBs), including the implementation of adequate precautionary measures by operators to avoid the mixing of organic and non-organic products (one CB).

Export Certification System

- Ensure that only products are certified that are covered by the equivalence recognition (one CB).
- Ensure that all relevant information (including details concerning the batches forming the consignment) is provided to, and checked by, the certifying officer before signing the certificate, and that a risk-oriented evaluation of the credibility of the operator's declaration is carried out (one CB).

Follow up of EU Notifications of Irregularities

• Ensure that, in case of irregularities, appropriate actions are taken to identify the cause of the presence of non-authorised substances and that appropriate enforcement measures are applied to respective operators, and in particular with regard to certified operators who manage producer groups (four CBs).

8 ACTIONS TAKEN OR ENVISAGED BY THE COMMISSION SERVICES

8.1 Follow up of Audit Recommendations for Recognised Control Bodies in Third Countries

FVO audits of recognised CBs with activities in TCs provide an input to the European Commission's supervision of the CBs under Article 33(3) of Regulation (EC) No 834/2007.

For each audit a copy of the final audit report is sent to the CB 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 CBs is analysed. Where it is considered that a response does not address the issues raised, the Commission services actively pursue the matter with the CBs concerned (see also point 2.1).

8.2 Enforcement

The recognition of CBs with activities in TCs in accordance with Article 33(3) of Regulation (EC) No 834/2007 is regularly reviewed. In case appropriate measures are not taken following the results of an audit, CBs may be suspended and/or withdrawn from the list of recognised CBs by the responsible Commission services for export of organic products into the EU.

8.3 DISCUSSIONS WITH MEMBER STATES AND EXCHANGE OF GOOD PRACTICES

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

The 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 CAs in MS - and open to participants from TCs and CBs - so as to keep them up-to-date with all relevant aspects of EU food and feed law and contribute to official controls being carried out in a uniform, objective and adequate manner.

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

¹ COM(2014)180 final.

fair competition for farmers and operators and allowing the internal market to function more efficiently, 3) maintaining or improving consumer confidence in organic products.

As regards the control system, the proposal

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

The proposal is currently under Inter-institutional discussions.

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	

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 2 - STANDARDS QUOTED IN THIS REPORT

Control Bodies in	Dates of Mission	SANTE Reference Number
China	9-21/10/2013	2013-6951
China	10-23/10/2013	2013-6952
China	9-21/10/2013	2013-6953
Turkey	11-20/03/2014	2014-7123
Vietnam	17-28/11/2014	2014-7097

ANNEX 3 - DETAILS OF THE INDIVIDUAL AUDITS

The reports on individual missions are available on the DG SANTE's Website: <u>http://ec.europa.eu/food/fvo/ir_search_en.cfm</u>

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