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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
CONTROL BODIES
FROM 24 JANUARY 2018 TO 01 FEBRUARY 2018
IN ORDER TO
EVALUATE THE IMPLEMENTATION OF THE ORGANIC PRODUCTION
STANDARDS AND CONTROL MEASURES APPLIED BY A RECOGNISED CONTROL
BODY OPERATING IN THE DOMINICAN REPUBLIC

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 carried out between 24 January and 1 February 2018 in order to evaluate the application of the organic production standards and control measures applied by a recognised control body in the Dominican Republic.

The report concludes that the control body has a documented control system in place that covers operators certified by the control body. Control body inspectors are subject to regular training and evaluation. Control body inspections are generally effective and include traceability checks, and the system for export is in general in line with European Union rules.

However, the control body's control and sampling plans are not based on an adequate risk assessment of its certified operators. The control body does not carry out annual visits at all of its operators and does not carry out additional visits to at least 10% of operators. This reduces the effectiveness of the control system in place as it cannot guarantee that all operators comply with the organic production standards, in particular high risk operators, who are not necessarily subject to sampling and additional visits.

In addition, the control body does not take any action in most cases where the analytical results show the presence of unauthorised plant protection products. As a consequence, products are marketed as organic without the control body taking any action to investigate the use of the substances by operators. Moreover, the control body does not have a procedure for granting derogations on the retroactive recognition of the conversion period to ensure that such derogations are only granted when the control body has satisfactory proof that all conditions are met by operators.

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

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AB	Accreditation Body
CB(s)	Control Body(ies)
CoI	Certificate of Inspection
EU	European Union
ICS(s)	Internal Control System(s)
ISO	International Organisation for Standardization
MRL	Maximum Residual Limit
OFIS	Organic Farming Information System
OSP	Organic System Plan
PG(s)	Producer Group(s)
PPP(s)	Plant Protection Product(s)

1 INTRODUCTION

The audit took place from 24 January to 1 February 2018 in order to evaluate the application of the organic production standards and control measures applied by a recognised Control Body (CB). The CB was selected for the audit by the Directorate-General for Agriculture and Rural Development based on a risk assessment. The audit formed part of the DG Health and Food Safety's planned programme.

The audit comprised an office audit at the headquarters of the CB located in a non-EU country and visits to operators certified by the CB in the Dominican Republic.

An opening meeting was held on 24 January at the CB headquarters. At this meeting, the objectives of, and itinerary for, the audit were confirmed by the audit team and the control systems were described by the CB.

The audit on the CB will provide an input to the European Commission's supervision of the CB under Article 33(3) of Regulation (EC) No 834/2007.

2 OBJECTIVES AND SCOPE

The CB is recognised by the Commission for applying in non-European Union (EU) countries equivalent production rules as foreseen in Titles III and IV of Regulation (EC) No 834/2007 and control measures having equivalent effectiveness to that of the EU (Title V of Regulation (EC) No 834/2007).

Therefore, the system should give assurances that organic products exported to the EU have been produced in accordance with the CB's organic production rules and control measures.

The objectives of the audit were:

- to verify that the production rules applied by the CB as regards the product categories listed in Annex IV of Commission Regulation (EC) No 1235/2008 are those for which the CB has been recognised by the Commission as competent to carry out controls for the purpose of equivalence.
- to verify that the control measures recognised by the Commission as having equivalent effectiveness to that of the EU have been permanently and effectively applied by the CB.

In pursuit of this objective, the following sites were visited:

Visits/meetings	Days	Comments
Control Body		
Central Office	4	Office audit and opening/closing meetings
On-Site-Visits		
Visit 1	1	Plant production operator
Visit 2	1	A producer group (PG)
Visit 3	1	Processing operator

In terms of scope, the audit focused on the organisation and performance of the CB, 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

The audit was carried out under the general provisions of EU legislation and, in particular Article 11(4) of Regulation (EC) No 1235/2008.

Full legal references to EU legal acts in this report are provided in Annex 1 and refer, where applicable, to the last amended version. International standards referred to in this report are provided in Annex 2.

4 BACKGROUND

The CB has been recognised by the Commission for applying, in non-EU countries, equivalent production rules as foreseen in Titles III and IV of Regulation (EC) No 834/2007 and control measures having equivalent effectiveness to that of the EU (Title V of Regulation (EC) No 834/2007). Consequently, the CB is included in the list of recognised CBs established in Annex IV to Regulation (EC) No 1235/2008. The audit focused on the CB's activities in the Dominican Republic.

5 FINDINGS AND CONCLUSIONS

5.1 ORGANIC PRODUCTION RULES AND CONTROL MEASURES

Legal requirements

Articles 10(2), 11(3) and 12(1)(a) and (b) of Commission Regulation (EC) No 1235/2008.

Findings

1. The updated CB EU 834-2007 organic certification requirements (hereinafter referred to as organic production standards) and organic certification manual had been notified to the Commission in the two most recent annual reports (2015 and 2016) in line with Article 12(1)(a) of Regulation (EC) No 1235/2008.
2. The CB stated that they became aware of some weaknesses in their procedures after attending the first CB meeting held in Brussels in November 2017 organised by the Directorate-General for Agriculture and Rural Development. Following this meeting, the CB had amended its procedures and organised training for all inspectors. So a new version of the production standards (version of December 2017) and of the organic certification manual had recently been prepared which has not yet been notified to the Commission along with the required assessment made by the Accreditation Body (AB). The CB stated that the mentioned documents were being assessed by the AB and would shortly be notified to the Commission in the annual report for 2017.
3. The CB has procedures in place to ensure that amendments made to Regulations (EC) No 834/2007 and No 889/2008 are incorporated into the CB's organic production standards

or into the organic certification manual, which includes the CB's organic production rules and applicable control measures.

4. Moreover, the CB has procedures in place to notify any change to previous versions of the CB's organic production standards and procedures to CB staff and operators, which is adequately followed.

Conclusions on organic production rules and control measures

5. The CB regularly notified to the Commission the most recent versions of the CB's organic production standard and control measures assessed by the AB in line with relevant EU requirements.

5.2 SURVEILLANCE AND RE-ASSESSMENT

Legal requirements

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

Findings

6. The CB is accredited to International Organisation for Standardization (ISO) 17065 and is subject to annual surveillance audits by an AB in line with Article 33(3) of Regulation (EC) No 834/2007. The AB carries out regular office audits at the CB's headquarters and witness audits at organic operators in different non-EU countries where the CB operates to observe the performance of the CB's inspectors.
7. The most recent audit at the headquarters of the CB took place in July 2017 and included a witness audit to an operator in another non-EU country.
8. The audit team reviewed the report issued by the AB and noted that it contained three non-conformities, which were not related to the EU certification scheme. In any case, on 30 October 2017 the AB closed all non-conformities as all deficiencies identified in the AB's report had already been addressed by the CB. The AB also noted three observations or opportunities for improvements related to the EU certification scheme, which were also addressed by the CB at the time of the audit.

Conclusions on surveillance and re-assessment

9. The CB undergoes regular on-the-spot evaluation and re-assessment of its activity by an AB and takes appropriate corrective actions.

5.3 NATIONAL AUTHORITIES AND NATIONAL LEGAL REQUIREMENTS

Legal requirements

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

Findings

10. According to the information received from the CB, it had notified its activities to the national authorities in the Dominican Republic and to the other non-EU countries where the CB carries out activities and had been listed by the Commission under the equivalency scheme.

Conclusions on national authorities and national legal requirements

11. According to the information provided by the CB, the CB notified its activity to the relevant national authorities in line with EU requirements.

5.4 STRUCTURE AND ORGANISATION OF THE CONTROL SYSTEM

Legal requirements

Articles 33(1), (2) and (3) and Titles III, IV and V of Council Regulation (EC) No 834/2007.

Codex Guidelines CAC/GL 50-2004 on sampling.

5.4.1 Organisation and planning of controls

Findings

12. The CB has a centralised organisation, which means that all decisions related to planning of controls, certification and sanctions imposed are taken at the headquarters. For this purpose, all inspection reports and supporting documents are submitted by the inspectors directly to headquarters.

13. The CB has well documented and detailed procedures in place. The responsibilities and tasks allocated to each department within the CB headquarters are well described.

Recruitment, training and evaluation of inspectors

14. The CB employs an adequate number of permanent staff and free-lancers to carry out inspection and certification tasks.

15. Newly recruited staff must demonstrate their qualifications for the scope of the inspections. The CB prefers to contract inspectors trained under the International Organic Inspection Association training programme. Before undertaking inspections on their own, newcomers must accompany a senior inspector on at least one inspection and then be accompanied during other inspection. To maintain competence, inspectors must attend all prescribed training and must be annually evaluated. Inspectors field evaluation may occur less than annually but at least every three years.

16. The audit team reviewed records of these activities and also of the annual training for inspectors held in the CB office which confirmed that training organised related to the organic production rules applied by the CB.
17. The performance of all inspectors must be evaluated by the CB certification reviewers, who take into account the inspection reports and the evaluation submitted by the operators inspected. Inspectors are also evaluated on the field by CB field evaluators. A witness evaluation form is submitted to the inspection co-ordinator to be included in the inspector's annual evaluation. In the certification process, the inspection reports submitted by the inspectors are also checked by reviewers, who verify that the report has been issued in accordance with CB procedures. The documents attached to the report are also reviewed to ensure consistency with the contents of the report. This review process is part of the CB supervision of the performance of inspectors.
18. Specific training on organic production is provided through regular online training activities organised by the CB headquarters.
19. The CB has a rotation policy in place requiring that operators should not be inspected by the same inspector for more than five consecutive years.

Conflict of interest

20. All staff members must annually complete a conflict of interest disclosure describing the commitment to objectivity and by which person disclose any perceived conflicts that could directly affect the objectivity of an operation certification. The CB reviews all declarations in order to identify any risk to impartiality.
21. The audit team reviewed files of inspectors and confirmed that staff records on training, absence of conflict of interest and evaluation of competence were collected and kept up-to-date.

Risk assessment and planning of controls

22. Inspectors are assigned by the inspectors coordinators based on scope of the inspection, qualification of the inspector, proximity to operator, availability, cost and assessing any potential conflict of interest. The annual inspections are not planned at the beginning of the year for the entire year, because the CB does not know when the operators are going to ask for renewal of certification. Additional inspections and sampling are planned at the beginning of the year.
23. According to the CB organic certification manual, all operators must be inspected annually and additional unannounced visits must be carried out on a risk basis. In order to organise the planning and nature of the inspections, the CB evaluates the Organic System Plan (OSP) submitted by operators. The information submitted must include a description of the unit and of the activities carried out (e.g. type of crops to be grown, off-farm inputs used, storage, processing and packaging) as well of the precautionary measures to be taken to avoid or reduce the risk of contamination of organic products (e.g. existence of non-organic neighbours and separation areas established). The CB certification reviewers must evaluate the OSPs and if needed, seek clarification from operators.
24. The CB categorises organic operators into risk categories, in principle, based on the general evaluation of the risk of non-compliance with organic production rules, taking

into account results of previous controls, the quantity of products concerned and the risk for exchange of products. In addition, all PGs producing bananas are considered high risk operators.

25. These risk criteria had recently been established and were not followed to select operators for additional visits or sampling in 2017. Moreover, the planning for additional visits and sampling for 2018 was not adequately based on the above-mentioned risk criteria. The audit team noted that the largest operators were not selected for additional visits and PGs producing bananas, which are considered high risk by the CB, were also not selected. The audit team noted, that some of the additional inspections which have to be planned by the CB based on a risk assessment of its certified operators were, in practice, carried out as follow-up visits of previous non-compliances in the process of certification.
26. According to the overview provided by the CB, the CB did not carry out annual visits to 100% of the certified operators which is not in line with Chapter 6 of the CB organic certification manual. The CB explained that the renewal application is submitted around every 12 months, the CB may extend the deadlines up to six months due to different circumstances (hurricanes, deadline extensions, etc.). In addition, the number of additional inspections carried out in 2017 did not reach the minimum number of 10% required by Chapter 6 of the CB organic certification manual. Nevertheless, for 2018 the number of planned additional visits will cover at least 10% of certified operators. In the Dominican Republic around 34% of the operators were not visited in 2017. As regards the activities of the CB worldwide, around 25% of the operators certified under the EU scheme were not visited in 2017.
27. In the case of PGs, all members in the group must be inspected annually by the Internal Control System (ICS) inspectors to verify their compliance with the PG internal organic provisions. If no major irregularities are found, they are placed on the list of approved members allowed to supply organic products to PGs for that year. A PG must submit the lists of approved members to the CB when applying for its certification as an organic operator. The list of rejected members is presented to the CB at the time of the inspection.
28. According to the CB procedures for PGs, all new members in the PG must be subject to external inspections by the CB. This is taken into account by the CB when planning the inspection to PGs. In the special instructions issued to inspectors, the number of members to be subject to external inspections depends on the risk category of the PG (20% for high risk, 15% for medium, 10% low). All the PGs producing bananas are considered by the CB as high risk operators. However, in a PG visited producing bananas, the audit team noted that the number of inspections carried out at PG members in the previous inspection were lower than the number required in the CB procedures (14% of the members were inspected instead of 20% as is required by the CB procedures). In 2018, the CB instructed the inspector to visit 24 members which is not correct as the CB was aware that, in August 2017, 31 new members had been notified by the PG. In addition, the real number of members at the date of inspection was 118, of which around 80 were new members. The CB was not aware of the circumstances prior to planning the inspection as the PG failed to keep the CB adequately informed of the list of its members so the CB did not have the necessary information to evaluate the number of members to be inspected.

New operators previously certified by other CBs

29. The CB has a procedure in place for the certification of operators who change CB. The audit team reviewed a number of files and noted that the procedure was adequately followed by the CB. When new operators apply to this CB they are required to declare whether they are or were previously under control of another CB. In this case, the CB must contact the previous CB and request information on the current status of the operator and on any pending non-compliances which would need following up. The audit team was shown examples of this exchange of communication and noted that the CB followed the procedures in place.

Conclusions on organisation and planning of controls

30. The CB allocates appropriate staff resources to controls of operators and applies adequate measures to ensure the absence of conflict of interest. Procedures regarding recruitment, evaluation and training of staff are appropriately implemented.
31. However, the effectiveness of the control system is reduced as it cannot be ensured that all operators are visited annually and that at least 10% of them are subject to additional visits. In addition, the system does not ensure that operators with the highest risk profile are targeted for additional controls and sampling. The lack of information provided by PGs to the CB related to the number of members may result in a smaller number of members being inspected by the CB at PGs during the annual inspection than is required by the CB procedures.

5.4.2 Off-farm input verification system

Findings

32. The CB keeps and updates lists of off-farm inputs authorised for use in organic production, which are included in the Annexes of the CB's organic production standards. The CB must approve the use of off-farm input. Only inputs listed in the Annexes of the CB's organic production standards may be used. Operators must declare the intention of use of plant protection products (PPPs) and fertilizers even if such substances are included in the CB organic standards annexes and the CB must explicitly authorise their use in advance.
33. The CB certification reviewers must verify the status of each input under the EU regulation on organic production and document the justification for approval of each input in the operator Input Tracking Form that is used by the CB reviewers to track the approval of inputs for each OSP submitted by the operators.
34. The CB has a procedure to regularly check the use of inputs. All inputs must be reviewed and approved in-house by the CB. Reviewers conduct an in-house input review for products not previously approved, including manure and compost and must complete the EU-Internal Input Review Checklist to ensure that only input authorised in the EU standards are used by operators.
35. During their inspections, the CB adequately checks that no unauthorised off-farm inputs are used by operators, including the checking of storage premises.

Conclusions on off-farm input verification system

36. The CB applies its production rules on off-farm input products and adequately verifies the use of approved products during controls.

5.4.3 Handling of derogations and exemptions

Findings

37. Derogations and exceptional production rules are provided for in the CB's organic production standards and in the organic certification manual. The audit team was informed that in principle only three types of derogations are foreseen in CB procedures: the retroactive recognition of the conversion period, the use of untreated non-organic seeds and exceeding the 6 kg copper limited in a given year provided that the average quantity actually used over a 5-year period (current year and four preceding years) does not exceed 6 kg.
38. The audit team asked for a list of derogations granted in 2017. The CB provided a list of farmers that had been granted the retroactive recognition of the conversion period. The CB has a new form filled in by the reviewer to register the derogations granted to each operator, but there is no a procedure to grant a derogation which describes what conditions have to be fulfilled by operators. In practice the derogation is granted during the process of application based on a declaration by the operator stating that only substances authorised for organic production have been used during the past three years.
39. The audit team reviewed a number of files related to derogations for the retroactive recognition of the conversion period. In some cases, the CB granted the retroactive recognition of the conversion period to operators producing conventional banana based on a declaration by the operator stating that only substances authorised for organic production had used during the past three years. The CB did not conduct any other investigation to confirm the operator's statement.
40. In addition, during the visit to a PG, the audit team confirmed that new farmers were added to the list of approved PG members without undergoing any conversion period. The ICS had recognised previous periods as part of the conversion period, without evidence that no unauthorised products have been applied in the parcels during the three previous years. The CB included these new farmers in the certificate without requiring supporting documents and without carrying out inspections. This is not in line with point 2.1 of the CB organic production standards, Article 17 of Regulation (EC) No 834/2007 and Article 36 of Regulation (EC) No 889/2008 where it is established that satisfactory proof has to be furnished to the CB by the relevant operator. The CB stated that a detailed procedure would be drafted establishing the conditions for granting derogation for the retroactive recognition of the conversion period.

Conclusions on handling of derogations and exemptions

41. The CB procedure for granting derogations does not ensure that the CB has satisfactory proof allowing it to verify that all necessary conditions set out in the CB organic production standards were met by operators.

5.4.4 *Sampling*

Findings

42. The CB has an annual sampling programme in place to detect, in principle, the use of non-authorized PPPs. Samples are taken to comply with the minimum requirements of EU organic rules, in case of suspicion or in follow-up visits. In addition, samples may be taken for detection of genetically modified organisms and fertilizers in cases of suspicion. The CB has a sampling protocol in place. This includes guidance to the inspectors on how to take a sample, the equipment to be used and the listed laboratories to which samples must be submitted. During one of the site-visits, the CB demonstrated how sampling was performed. The audit team noted that the inspector followed the sampling protocol.
43. The CB's sampling protocol provides for the use of cooling boxes or other equipment to ensure the preservation of the samples, at least in cases of perishable samples taken for the detection of PPPs which is in line with chapter 2.3.5.3 "Packaging and transmission of laboratory samples" of the Codex guidelines for sampling.
44. The number of samples taken in 2017 largely exceeded 5% of the total number of operators in the Dominican Republic. The CB explained that sampling is targeted taking into account the risk category of operators as established in the CB organic certification manual. However, in 2017 the selection of operators for sampling was not based on the risk assessment established by the CB. Moreover, the audit team noted that in 2018 the operators were selected randomly for sampling contrary to the CB requirements of the CB organic certification manual.
45. In 2017 six positive results were identified on sampling by the CB, all of which showed the presence of non-authorized PPPs.
46. The CB has a procedure in place to ensure that laboratories entrusted with the analysis of samples are accredited to ISO/17025 and that methods used are validated and the scope of analytes to be tested for is adequate. At the time of the audit, there was one laboratory used by the CB to carry out analysis for pesticides in the Dominican Republic. However, the CB only requests the laboratory to test for substances (PPP) by using multi-residue methods and does not request testing for non-authorized substances which can only be detected by using single residue methods. In one case reviewed by the audit team, the CB had instructed the inspector to take samples at an operator where unauthorized substances were found during the previous inspection. One of the substances was Fosetyl-Aluminium, a product widely used in banana as a post-harvest treatment that can only be detected by using single-residue methods. However, the CB requested the laboratory to perform only the multi-residue methods.
47. The CB follows a detailed procedure for the interpretation of laboratory results. If the levels of a non-authorized PPP exceed Maximum Residue Level (MRL) set by the EU legislation or above 0.015ppm (calculated using 50% correction factor for analytical uncertainty) if there is no MRL, the product lot is not considered as organic, and the CB will conduct an investigation to determine the cause of the contamination. In addition, the product batch may be temporarily suspended during the investigation when: a) a non-authorized PPP for which there is no MRL set by EU legislation is detected between 0.01 and 0.015; b) there are three or more detections of the same non-authorized PPP in

different batches of the same product, regardless of concentration: or c) multiple non-authorized PPPs were detected above 0.01 but below the EU MRL for the same products.

48. This interpretation of laboratory results is not in line with EU rules which prescribe that the use of non-authorized substances is not permitted in organic production. Therefore, the CB does not take action whenever the presence of an unauthorized substance is notified by an accredited laboratory to ascertain the use of such substance by the operator concerned.
49. The audit team reviewed several operator files related to the detection of PPPs in organic products. The actions taken by the CB were not appropriate in any of the cases reviewed. Most of the files were often incomplete as the communication date for the laboratory to the CB was not documented and the sampling forms were missing. In some cases, it took more than eight months from the date the sample was taken until the operator was notified by the CB of the laboratory result. Moreover, the CB did not impose any temporary suspension while investigation was ongoing. In these cases, operators were requested to provide explanations long after the case had been filed and the certification renewed.

Conclusions on sampling

50. The CB takes a number of samples which exceeds the percentages established in the CB organic certification manual.
51. However, the effectiveness of the sampling system is undermined as the selection of operators for sampling was not based on adequate risk assessment. Moreover, the interpretation of analytical results does not allow the CB to take appropriate measures in case of detection of PPPs and the limited scope and testing methods used for organic samples does not ensure that all potentially non-authorized substances commonly used in organic production are detected.

5.5 LIST OF ORGANIC OPERATORS

Legal Requirements

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

Findings

52. The CB keeps a list of organic operators subject to its controls. The list is published on the CB's website in line with Article 11(3)(e) of Regulation (EC) No 1235/2008. The list contains the names of the operators and the country, in which they operate, as well as the date of validity of the certificates issued by the CB, the current status of the certificates (valid/expired/suspended) and the product categories certified. The list is monthly updated.

Conclusions on lists of organic operators

53. The CB publishes, on its website, a list of organic operators subject to the CB's control system which contain all relevant information required by EU regulation.

5.6 CONTROLS ON ORGANIC PRODUCTION

Legal Requirements

Articles 23, 24, 25, 27(13), 33(1) and (3) of Council Regulation (EC) No 834/2007.

Titles III, IV and V of Council Regulation (EC) No 834/2007.

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

Findings

5.6.1 Controls of operators

54. The CB has a procedure in place with detailed work instructions which provides guidance to inspectors on the performance of controls. The organic certification manual and the inspection manual cover all stages of the inspection process, from the preparation of an inspection to reporting. Specific checklists and report templates are provided to CB inspectors for different types of operators (processors, traders, operators and PGs) which cover all relevant requirements of the CB's standards. The CB, for each inspection, also provides inspectors with special instructions to guide the inspectors to focus on certain aspects according to the specificities of the relevant operators.
55. All CB inspectors met by the audit team followed the CB's manual of procedures. For inspections, an opening meeting is held where the CB's inspector confirms the scope and presents the schedule and the methodology of the inspection as well as the follow-up of the implementation of corrective actions taken by operators to address non-compliances found during the previous inspection. A final meeting is held where the CB's inspector makes a summary of all irregularities found. The report is provided to the operator who must sign it.
56. At the operators visited, the inspection was in general effectively conducted. The inspector attaches to the inspection report scanned copies of all records verified during the inspection.
57. The audit team observed a good level of performance by the CB's inspectors, who demonstrated good knowledge and skills to carry out effective inspections. All relevant requirements were checked and no significant aspects were overlooked during the inspections.
58. However, the audit team noted some shortcomings in the performance of one inspector. At a producer, the inspector did not walk the entire perimeter of the plot as required by the inspection manual. There was contradictory information regarding the conventional neighbouring plots in the map provided by the operator during the inspection and the one submitted to the CB. This was not verified as the inspector did not walk the entire perimeter. In addition, the inspector had not verified the harvest estimation during the inspection. As regards the verification of records, the CB does not require operators to keep records of the fumigation equipment when applications of PPPs are applied by subcontracted companies.

59. During a CB inspection at a PG witnessed by the audit team, it was noted that the CB inspector reviewed a representative number of inspection reports prepared by the ICS to confirm that all individual members were inspected. The inspector evaluated the quality of the inspection reports and all information attached such as information on maps, records of fertilizers and PPPs applied, etc. Individual members of the PG were selected for external inspections by the CB based on risk. All new PG members have to be inspected as well. The inspector was very knowledgeable and experienced and detected many failures in the performance of the ICS, such as the inconsistency in the records of application of PPPs, incomplete information on plots, lack of evidence for decisions to shorten conversion period, lack of notification to the CB of members joining and quitting the group, etc. However, the CB had failed to detect any of these shortcomings in their inspections in the past two years, where no non-compliances had been raised in the inspection reports.
60. PG inspections are not necessarily planned to take place after the ICS inspections. The fact that external inspections take place at any moment of time means that the CB cannot compare the outcome of its inspections against the outcome of internal inspections, as the conditions under which inspections take place at the same farmer may be different. Moreover, the CB does not systematically witness the performance of internal inspectors. With this system the CB does not have control measures to ensure adequate evaluation of effectiveness of the ICS. In addition, the CB did not have a description of the process to evaluate the effectiveness of the ICS implemented by PGs.

5.6.2 Labelling

61. The CB inspections at operators include the verification of labelling. Before export to the EU, the operator must submit the labels for approval by the CB. The audit team noted at one operator visited, that the CB code used on the label of the final product was that of the CB who controlled the exporter of the product and not the code of the CB who controlled the last production or preparation activity. This is not in line with Article 24 of Regulation (EC) No 834/2007.

5.6.3 Traceability

62. Traceability checks must be systematically carried out in accordance with the CB organic standards. During the inspections witnessed, the audit team noted that all CB inspectors performed traceability exercises covering all stages of production, from purchase to the sale of the organic products. The exercises included calculations of quantities used and stored, taking into account internal records kept by the operators as well as copies of invoices and documentary evidence proving the organic origin of the supplies.

Conclusions on controls on organic production

63. The CB controls on organic production are generally effective and included adequate traceability checks.
64. However, the effectiveness of these controls is reduced by the fact that the procedures in place do not allow the adequate evaluation of the effectiveness of the ICS at PGs and by the lack of comprehensive verification of some requirements (such as harvest estimation, neighboring cultivations and labelling).

5.7 EXPORT CERTIFICATION SYSTEM

Legal Requirements

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

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

Findings

65. At the time of the audit the CB was not issuing Certificates of Inspections (CoI) as it did not have under its control any exporter in the Dominican Republic. In any case, the CB requires that domestic transactions are covered by a certificate issued by the CB or by another CB included in Annex IV to Regulation (EC) No 1235/2008. The issuance of CoIs is based on domestic transaction certificates which are issued by CBs for all transactions taking place in the Dominican Republic. The audit team reviewed the issuance of transaction certificates for products exported from the Dominican Republic and noted that they were issued based on documents supporting the organic status of the products.
66. The audit team reviewed a number of files related to export from other non- EU countries and noted that the model of CoI used by the CB is compliant with the model in EU legislation and that the procedure to issue them is adequate. The audit team was shown examples of how CoIs were issued by a regional office in a non-EU country where the CB operates and has certified exporters. The audit team concluded that the CB issued CoIs in line with Regulation (EC) No 1235/2008. However, the CB does not have procedures to carry out risk based physical checks on consignments intended for export to the EU which is not in line with Article 13.4 of Regulation (EC) No 1235/2008.
67. In the case of banana producers, operators request CoIs covering weekly production. CoIs are not issued for quantities which exceed the quantities that were estimated by the CB during inspections. In the case of PGs, the CB receives a list of members of the PG which were approved during annual inspections by the ICS of the PG. The list includes the maximum quantities that each individual member may produce weekly. However, this estimation is a general estimation of the harvesting yields in the region, and not adjusted to individual producers. A weak point of inspections is that there is no systematic verification of harvest estimation by either the CB or by the ICS (see paragraphs 58 and 64).

Conclusions on export certification system

68. The CB has a system in place that, in general, ensures the issuance of CoIs for organic products for EU export are based on documents supporting the organic status of the products. However, the procedure in place does not ensure that physical checks based on a risk assessment are carried out on consignments intended for export to the EU.

5.8 IRREGULARITIES AND FOLLOW-UP OF EU NOTIFICATIONS

Legal Requirements

Articles 30 and 33(3) and (1) of Council Regulation (EC) No 834/2007.

Title V and Annex IV of Commission Regulation (EC) No 1235/2008.

Findings

Handling of irregularities by the CB

69. The CB organic standards requires that where an operator considers or suspects that a product is not in compliance with organic production rules, the operator must initiate procedures either to withdraw from this product any reference to the organic production method or separate and identify the product. The operator may only put it into processing or packaging or on the market without indication referring to the organic production method. In case of such doubt, the operator shall immediately inform the CB. The CB may prohibit the operator from marketing the product with indications referring to the organic production method, until it is satisfied, by the information received from the operator or from other sources, that any doubt has been eliminated. However, in two cases reviewed by the audit team the operator did not inform the CB that products exported to the EU may not be in compliance with organic production rules. The CB did not take any action against the operators which did not fulfil his obligation.
70. The CB organic standards also requires that where the CB has a substantiated suspicion that an operator intends to market a product that was not produced in compliance with organic production rules, the CB may temporarily suspend the operator from placing the product on the market for a period. During this time the CB must investigate the operator through a desk audit, unannounced control visit, residue sampling, and/or review of information available from the operator as applicable. The CB must temporarily suspend the operator from marketing the product as organic for 90 days or until the investigation is complete, whichever occurs first.
71. The CB has a policy in place to handle irregularities found at operators. Enforcement measures are taken on an ad-hoc basis, depending on the nature and severity of the non-compliance. These can range from minor issues that require correction, but do not preclude certification, to major non-compliances that lead to the cancellation of certification. The audit team reviewed some files where operators were suspended, however, it was noted that it took several months to notify the operators of the suspension.
72. In addition, specific sanctions are described for three particular cases (presence of unauthorised substances in analytical results, use of unauthorised substances and absence of records). As regards the presence of PPPs, the CB applies a temporary suspension while the investigation (to identify the reason of the presence of the PPP) takes place. If the use by a grower of an unauthorised substance is proved, the land where the substance was used has to undergo a conversion period of 2/3 years depending on the type of crop.
73. However, in the cases reviewed by the audit team related to laboratory analysis results of samples taken by the CB indicating the presence of non-authorised PPPs, the CB did not

temporarily suspend the operator from marketing the products until the investigation was complete. The audit team noted that such investigations do not take place in several cases as the CB applies a method for interpreting the laboratory results which overall leads to decreasing the presence by applying a 50% uncertainty (see paragraph 48). This is not acceptable as the accredited laboratory reports the presence of an unauthorised substance in a reliable manner. Moreover, the CB informed the operators concerned several months later and the certification was renewed.

74. The audit team reviewed other cases not linked to the presence of non-authorised PPPs and noted that the CB took adequate action to address the irregularities.

Follow-up of EU notifications

75. The CB informed the audit team that in the past they did not have a procedure to deal with Organic Farming Information System (OFIS) notifications. This was also an issue raised in the most recent audit carried out by the AB.
76. The CB has very recently modified the organic certification manual to include a procedure to respond to OFIS notifications within the 30 days deadline established in EU Regulations.
77. The audit team reviewed the files concerning the four OFIS notifications related to consignments which had tested positive in the EU for the presence of unauthorized substances. The CB did not respond in due time to the Commission in three cases. In the last case the CB responded within the 30 days prescribed as the CB had already implemented the above-mentioned new procedure for OFIS notifications.
78. In any case, the action taken by the CB in response to notifications related to the presence of non-authorised PPPs could not be considered satisfactory for the reasons already described in paragraphs 47, 48, 49, 71 and 73.
79. Due to these deficiencies it took more than one year to decertify a producer involved in three of the four OFIS notifications. The failure of the CB to take appropriate action in the first OFIS case could be the reason that the operator continued to market non-compliant products which were notified through the OFIS cases twice more during the year.

Conclusions on handling of irregularities by the CB and follow-up of EU notifications

80. Overall, the CB effectively applies its procedures to handle infringements and irregularities identified at operators other than those related to the presence of non-authorised PPPs.
81. However, the effectiveness of the control system is reduced by the fact that the CB does not take appropriate action in all cases where the analytical results show any presence of non-authorised PPPs, including the OFIS notifications, which were not properly followed up.

6 OVERALL CONCLUSIONS

The CB has a documented control system in place that covers operators certified by the CB. CB inspectors are subject to regular training and evaluation. CB inspections are generally

effective and include traceability checks and the system for export is in general in line with EU rules.

However, the CB's control and sampling plans are not based on an adequate risk assessment of its certified operators. The CB does not carry out annual visits at all its operators and does not carry out additional visits to at least 10% of operators. This reduces the effectiveness of the control system in place as it cannot guarantee that all operators comply with organic production standards, in particular high risk operators, who are not necessarily subject to sampling and additional visits.

In addition, the CB does not take any action in most cases where the analytical results show the presence of unauthorised PPPs. As a consequence, products are marketed as organic without the CB taking any action to investigate the use of the substances by operators. Moreover, the CB does not have a procedure for granting derogations on the retroactive recognition of the conversion period to ensure that such derogations are only granted when the CB has satisfactory proof that all conditions are met by operators.

7 CLOSING MEETING

A closing meeting was held on 1 February with representatives of the CB. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit.

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

8 RECOMMENDATIONS

No.	Recommendation
1.	<p>Ensure that all operators are annually visited and that additional inspections are carried out at least 10% of the operators as established in Chapter 6 of the CB organic certification manual.</p> <p><i>Recommendation is based on conclusion No 31</i></p> <p><i>Associated finding: No 26</i></p>
2.	<p>Ensure that risk assessment applied by the CB serves as an adequate basis to determine the nature and frequency of controls and that for additional visits, operators are selected on a risk basis in line with Chapter 6 of the CB organic certification manual.</p> <p><i>Recommendation is based on conclusions No 31</i></p> <p><i>Associated finding: No 25</i></p>
3.	<p>Ensure that the CB controls carried out on PGs include inspections of a minimum number of PG members in line with the CB grower group inspection policy chapter of the organic certification review procedures.</p> <p><i>Recommendation is based in conclusion No 31</i></p> <p><i>Associated finding: No 28</i></p>
4.	<p>Ensure that derogations and exceptional production rules are granted based in procedures and line with point 2.1 of the CB organic production standards, Article 17 of Regulation (EC) No 834/2007 and Article 36 of Regulation (EC) No 889/2008.</p> <p><i>Recommendation is based on conclusion No 41</i></p> <p><i>Associated findings: No 38, 39, 40 and 59</i></p>
5.	<p>Ensure that the selection of operators for sampling is based on the general evaluation of risk of non-compliance whit the organic rules as established in Chapter 9 of the CB organic certification manual and Article 65(2) of Regulation (EC) No 834/2007.</p> <p><i>Recommendation is based on conclusion No 51</i></p> <p><i>Associated findings: No 44 and 45</i></p>
6.	<p>Ensure that the interpretation of analytical results serves as a good basis to take actions in case of non-compliance in line with point 8.1.3 of the organic standards.</p> <p><i>Recommendation is based on conclusion No 51</i></p> <p><i>Associated findings: No 47 and 48</i></p>

7.	<p>Ensure that the CB has a procedure in place for checking whether the analytical scope of the laboratory used for testing is adequate to detect the use of products not authorised in organic production, in particular, ensure that the scope of the testing is fit for purpose and include substances that can only be detected by single methods.</p> <p><i>Recommendation is based on conclusion No 51</i></p> <p><i>Associated finding: No 46</i></p>
8.	<p>Ensure that inspections at operators are effective. In particular, ensure that all requirements of organic production are checked and that the assessment by the CB of controls carried out by PGs is adequate in order to guarantee the effectiveness of such controls and in particular that the timing and nature of the CB inspections to PGs serve as a good tool to evaluate the effectiveness of the ICS.</p> <p><i>Recommendation is based on conclusion No 64</i></p> <p><i>Associated findings: No 58, 59, 60 and 67</i></p>
9.	<p>Ensure that inspectors verify the labelling of packaged products, to confirm the fulfilment of the requirement of Article 24(1)(a) of Regulation (EC) No 889/2008, which requires that the code of the CB to whom the operator who carried out the most recent processing or preparation operation on the product shall also appear on the labelling.</p> <p><i>Recommendation is based on conclusion No 64</i></p> <p><i>Associated finding: No 61</i></p>
10.	<p>Ensure that physical checks based on risk assessment are carried out on exported consignments as is required in Article 13.4 of Regulation (EC) No 1235/2008.</p> <p><i>Recommendation is based on conclusion No 68</i></p> <p><i>Associated finding: No 66</i></p>
11.	<p>Ensure that measures in case of suspicion of infringements and irregularities are taken and are adequate to prevent the fraudulent use of the organic indications in line with point 8 of the CB organic standards. In particular, ensure that adequate actions are taken in all cases when analytical results show the presence of a substance not authorised PPPs in organic production.</p> <p><i>Recommendation is based on conclusion No 81</i></p> <p><i>Associated findings: No 69 and 73</i></p>
12.	<p>Ensure that, when notifications are received via OFIS, the CB implements the procedures in place to proper follow-up them in a timely manner and that the results of the investigations and the action taken are adequate to address the non-compliances in line with the CB organic certification manual.</p> <p><i>Recommendation is based on conclusions No 81</i></p>

	<i>Associated findings: No 77, 78 and 79</i>
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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=2018-6392

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 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
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

ANNEX 2: STANDARDS QUOTED IN THIS REPORT

Reference	Title	Publication
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/