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FINAL REPORT OF AN AUDIT
CARRIED OUT
FROM 11 MAY 2017 TO 24 MAY 2017
IN ORDER TO
EVALUATE THE IMPLEMENTATION OF THE ORGANIC PRODUCTION
STANDARDS AND CONTROL MEASURES APPLIED BY A RECOGNISED CONTROL
BODY OPERATING IN SRI LANKA

In response to information provided by the control body, 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 11-24 May 2017 in order to evaluate the application of the organic production standards and control measures applied by a control body (CB) in Sri Lanka. The audit in Sri Lanka was complemented by an office audit at the CB headquarters.

The audit was undertaken as an input to the supervision of the CB by DG for Agriculture and Rural Development. Although elements of a system of controls have been put into place by this CB a number of significant issues have emerged which cast doubt on the overall integrity of the approach taken.

A number of significant failures were noted which undermine the reliability of the system of controls in place. The approach to risk assessment is unsatisfactory as the majority of operators are categorised as high risk by default rather than through a comparative assessment of risk. The risks associated with parallel production and previous non-compliances are not addressed. In addition, inspections observed were superficial. The scope of laboratory analyses was limited and the sampling procedures observed were not satisfactory. The CB failed to launch any meaningful investigations to follow up the significant number of irregularities notified in the Organic Farming Information System (OFIS) leading to a situation where enforcement measures are almost non-existent. Consequently, the control measures applied by the CB cannot be considered as having equivalent effectiveness to those applicable in the European Union.

The report contains recommendations to the CB 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
CA(s)	Competent authority(ies)
CB(s)	Control Body(ies)
CoI(s)	Certificate(s) of Inspection accompanying organic products exported to the EU
COM	European Commission
EC	European Community
EDB	Export Development Board
EU	European Union
GMO(s)	Genetically Modified Organism(s)
HQ	Headquarters (of the CB)
ICS	Internal Control System
MS	Member State(s)
NC	Non-conformity
OFIS	Organic Farming Information System
OS	CB Organic Standard
OSP	Organic Standard Plan
PG(s)	Producer's Group(s) (Group certification for small farms, restricted to operators in developing countries).

1 INTRODUCTION

The audit took place from 11-24 May 2017 in order to evaluate the application of the organic production standards and control measures applied by a control body (CB). The CB was selected for the audit by Directorate-General for Agriculture and Rural Development based on a risk assessment. The audit formed part of DG Health and Food Safety's planned programme.

The audit comprised an office audit at the headquarters (HQ) of the CB and visits to the branch office of the CB and to operators certified by the CB in Sri Lanka. The audit team comprised two auditors from DG Health and Food Safety, one official from Directorate-General for Agriculture and Rural Development and one expert from a European Union (EU) Member State (MS).

An opening meeting was held on 11 May 2017 at the HQ of the CB and an opening meeting was held on 15 May 2017 at the CB branch office in Sri Lanka. At this meeting, the objectives of, and itinerary for, the audit were confirmed by DG Health and Food Safety's team and the control systems were described by the CB.

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

2 OBJECTIVES AND SCOPE

The CB is recognised by the European Commission (COM) 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).

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 COM as competent to carry out controls for the purpose of equivalence.
- to verify that the control measures recognised by the COM 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		
HQ	1.5	Opening Meeting and Office Audit
Branch office in Sri Lanka	3.5	Opening, Closing Meeting and Office Audit
On-Site-Visits		
Visit 1	7	Small – medium sized farms
Visit 2	1	Processor
Visit 3	1	Producer Group
Visit 4	1	Exporter

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 COM 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 Sri Lanka.

5 FINDINGS AND CONCLUSIONS

5.1 ORGANIC PRODUCTION RULES AND CONTROL MEASURES

Legal requirements

According to Article 12(1)(a) of Commission Regulation (EC) No 1235/2008.

Findings

1. The CB is recognised by the COM in Sri Lanka in accordance with Article 33(3) of Regulation (EC) No 834/2007 and included in Annex IV of Regulation (EC) No 1235/2008.
2. The latest update of the CB's production standards and control measures was notified to the COM in February 2017.
3. The CB production rules and control measures, including all procedures and changes thereto, are notified annually to the accreditation body for the annual surveillance audit. However, it was noted that the CB has not fully incorporated the requirements laid down in Regulation (EU) No 392/2013 as the minimum requirements with regard to additional and unannounced controls are not defined.
4. The CB issues producer group (PG) certification (group certification for small farms restricted to operators in developing countries). The internal inspectors of the Internal Control System (ICS) of the PG cannot be members of the PG.
5. There is a dedicated CB software system in place which enables the scheme coordinator at HQ and local staff in foreign offices to access all the relevant information relating to operators, inspection, sampling and certification activities.

Conclusions on Organic Production Rules and Control Measures

6. The CB fulfils its obligation to notify the COM of any changes that are made to the control measures applied which is in line with Article 12(1)(a) of Regulation (EC) No 1235/2008. However, the CB has not adapted its organic standard to fully reflect control requirements of the evolved EU legislation.

5.2 SURVEILLANCE AND RE-ASSESSMENT

Legal requirements

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

Findings

7. The CB is accredited to the International Organisations for Standardization/International Electro technical Commission 17065 and is subject to annual surveillance audits by an accreditation body.
8. In the pre audit questionnaire, the CB stated that the accreditation report for 2016 was submitted to the COM in February 2017 along with the annual report.
9. The 2016 Assessment report on this CB which was undertaken by the accreditation body was generally favourable. In relation to Sri Lanka, one non-conformity was noted

whereby the reason and justification for a decision to extend a certificate, was not recorded in the client files. There was no documented procedures describing how and what to record.

Conclusions on Surveillance and Re-assessment

10. The CB undergoes regular on-the-spot evaluation/surveillance/multi-annual re-assessment of its activity by an accreditation body which is in accordance with Article 33(3) of Council Regulation (EC) No 834/2007.

5.3 NATIONAL AUTHORITIES AND NATIONAL LEGAL REQUIREMENTS

Legal requirements

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

Findings

11. The Sri Lanka Export Development Board (EDB) is the competent authority to regulate import, export, production and certification of organic agriculture products in Sri Lanka.
12. The EDB are working towards the establishment of a National Organic Control Unit which will function as an independent body to regulate production, certification, imports and exports of organic products in Sri Lanka. At the time of the audit there was no national legislation in place for organic production.

Conclusions on National Authorities and National Legal Requirements

13. The CB has no national level obligations to fulfil relating to organic controls and production.

5.4 STRUCTURE AND ORGANISATION OF THE CONTROL SYSTEM

Legal requirements

Article 33 (1) (2) (3) of Regulation (EC) 834/2007,

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

5.4.1 Organisation and planning of controls

Findings

Recruitment, training and evaluation of inspectors.

14. The recruitment of staff is undertaken according to CB Procedure (09) entitled 'Personnel and Organization'. The CB staff responsible for inspections and

certifications, are full time, payroll employees of the CB and have a university qualification in an appropriate area such as horticulture or agricultural science.

15. Procedure 09 mentioned above, states that once recruited an employee's performance is evaluated once per year, which includes reconfirmation of the code of conduct. During the evaluation, the need for training is identified and agreed upon resulting in a training plan. The evaluation and the training plan are based on evaluation, monitoring, internal and external audits and any other relevant information.

Conflict of Interest

16. For each employee, a Qualification File is maintained by the director with copies of the employment contract, curriculum vitae, signed code of conduct, job description, training certificates/reports, qualifications and notes of evaluation. The Code of Conduct functions as an employment contract for accreditation purposes and is signed in duplicate. Within the Code of Conduct document there is a paragraph describing how conflict of interest is addressed which is considered satisfactory by the audit team.

Risk Assessment, Planning of Controls and timing of inspections

17. The CB office in Sri Lanka is a 'critical location' according to the principles defined under point 2.2 of the International Accreditation Forum (IAF) guide GD 3:2003 and thus carries out risk assessment of operators, planning of inspections, certification of operators and the issuing of certificates on-site.
18. The CB issues certificates to an umbrella group, which is described as a "Project". Such certificates cover numerous processors, big farms as well as several PGs made up of small farms, all of which are identified in an annex to the certificate. In the event of non-compliant farms or processors being delisted, the annex is amended. The CB's use of the term Project in this scenario is considered as an operator within the meaning of EU legislation on organics.
19. The planning of annual inspections and additional random inspections is described in Article 65.4 of the OS and in PLAN.WO1 and PLAN.ORG.WO1 in the Organic Program Manual. The HQ of the CB defines the methodology for undertaking a risk assessment for organic operators. Each critical location performs the risk assessment for their own operators and the results are inputted in the CB dedicated software system which is accessible to all relevant CB staff.
20. The CB's risk assessment policy document ORGRIAS.D01(04) is a checklist of the relevant topics to be considered when undertaking a risk assessment. It consists of a series of 18 questions. Questions that are included in this document require a Yes / No response. A single 'Yes' response automatically ranks the operator as being high risk. The audit team noted that the majority of the Projects are classified as high risk. All high risk Projects are subject to annual sampling and this was confirmed during the farm inspection.

21. The audit team reviewed a number of files and observed that the risk assessment was established for each Project group. The risk assessment questionnaire covers all the actors within the Project group, and the responses to this questionnaire is used to establish the risk categorisation of operators. This is used as the basis for selecting the individual production or processing units for additional controls. At the time of the audit, the CB was responsible for controlling 193 Projects relating to organic production. Of these, 134 were categorised as high risk, no medium risk category Projects existed and 59 Projects were categorised as low risk.
22. Although the certification is held by the Project, all processors and every individual farm are subject to individual inspections by the CB.
23. For the purpose of this audit, one Project was chosen. It was noted that for the purpose of the ICS, this CB placed all producer groups into an association.
24. The audit team noted that the risk assessment policy document did not include any reference to parallel production although Article 65.4 of the Organic Standard (OS) did include this. In addition, the application form filled in by the operator does not request any information on parallel production and does not require any description of the farm holding. Previous non-compliances, such as pesticide detections or number of rejection of request for Certificate of Inspection (CoI), are not reliably taken into account for subsequent risk analysis (see paragraph 45 and 73). The application form requires information on genetically modified organisms (GMOs).
25. A review of inspection reports indicated that although the application form provided by the operator requested information on GMOs, in practice this question was rarely addressed by inspectors. The inspection reports referred to the specific date of the inspection however it did not specify the time spent for each inspection.
26. In relation to the numbers of annual inspections and additional inspections undertaken, the audit team noted, that the figures submitted in the annual report to the Commission, indicates that not all processors were subject to an annual inspection. In relation to the additional inspections undertaken at processors, the minimum requirement of ten percent was achieved. The CB confirmed that the figures in the annual report contained errors and all processors were subject to an annual control.
27. In the Sri Lankan office the definition of unannounced inspection was providing 48 hours notice. The CB explained that the term 'follow-up' inspections had been incorrectly used in its IT system in place of annual surveillance inspections. This matter had been rectified shortly before the commencement of this audit.

New operators and new operators previously certified by other CBs.

28. To become a client of this CB, all new operators are required to fill in an application form providing details of their farm holding, the products being produced and their agreement to be controlled by this CB.

29. There is a procedure described in the CB Programme Manual Organic Production, CONTR.ORG.WO1 which describes the requirements when an already certified client wants to change to this CB. Information regarding current certification status, including any outstanding notices of non-compliances must be obtained from the previous CB.
30. In Sri Lanka, the audit team were informed that there was only one instance of an operator transferring from another CB to this CB and there was no occurrence of any operator leaving this CB.

Conclusions on Structure and Organisation of the Control System

31. The CB conducts a risk assessment in which the majority of operators are categorised as high risk by default rather than through a comparative calculation of risk. In addition, the risk associated with parallel production and previous non-compliances is not addressed. The implementation of control measures does not ensure that the organic standard is effectively achieved in that the CB always gives prior notice in case of unannounced inspections.
32. In addition, the Annual Report submitted to the Commission was inaccurate in to some details which is not in line with Article 11(3) of Regulation (EC) No 1235/2008.
33. Appropriate staff resources are allocated for the controls of operators and adequate measures to ensure absence of conflict of interest are in place and applied.

5.4.2 Off-farm input verification system

Findings

34. Article 12 of the OS state that fertilisers and plant protection products are to be used in accordance with the relevant EU regulations. In addition, the work instruction in place INSP.ORG.WO1, requires the CB inspectors to verify the use of off-farm inputs during on-site inspections. The audit team noted that the calculation of nitrate applied did not always include the contribution from the farmer's own livestock. When a farm received a given amount of plant protection products for spraying, there were no records to establish which products were used and when and where they were applied. No evidence-based or documentary checks were carried out by CB inspectors on the origin of inputs distributed to farmers by the association or the trading company (Project and certificate holder). The CB had not previously noted any of these non-compliances which is contrary to the instructions provided in INSP.ORG.WO1.

Conclusions on Off-Farm Input Verification System

35. The verification of the off-farm inputs is not undertaken in a systematic way by the CB inspectors.

5.4.3 Handling of derogations and exemptions

Findings

36. Derogations relating to the CB retroactively recognising the conversion period of land are addressed in Article 36.2 of the OS which specifically refers to the requirements of Article 36.2 of Regulation (EU) No 889/2008. The CB has added other conditions which include independent third party declarations regarding the activities on the land, physical inspection and soil sampling and testing.
37. Derogations relating to use of conventional and untreated seed or vegetable propagating material not obtained by the organic product method is addressed in Article 45 of the OS.
38. Certifiers and auditors had relatively little hands on experience on granting derogations. No systematic check is carried out in relation to retrospective conversion of land as the CB relies on the declarations received by the ICS from third parties such as local authorities. The in conversion fields, and the destination of the products in conversion were not assessed by the CB inspectors. The 'Farm book' which is provided by the association to all farmers in the PG and records all inspections and training does not include any information on the conversion period. In addition, inspectors did not check the ICS IT system as to whether it includes these details. No retroactive conversion was recorded by the CB, although it is mentioned in the checklist and registered in the farmer association's records. Neither was it communicated to the Commission.
39. The audit team checked one operator for derogations. The use of the specific search facilities in the software system showed that no derogations applied to this operator. However, when the application form for this operator was reviewed, the applicant had clearly stated that no propagating material was available in Sri Lanka and conventional propagating material had to be used. This declaration had not been handled as a derogation.
40. Although this CB has its own database available to its clients to allow them to search if some seed producers had the required seeds available, the list is rather limited. There was a relatively small number of possibilities in the number of producers and range of products. The CB requests the operator to demonstrate in the derogation application form that they have searched a number of suppliers and failed to obtain what they required.
41. In relation to GMOs, a declaration by the applicant is initially required in the application form, however, verification of such declarations as referred to in Article 69 of Regulation (EC) No 889/2008 was not undertaken during subsequent inspections.

Conclusions on handling of derogations and exemptions

42. Although the CB has addressed the issue of derogations in its OS and has procedures in place, the CB does not implement these in a reliable manner. The credibility and reliability of the OS is undermined by this failure of implementation.

5.4.4 Sampling

Findings

43. In Annex XV 4e of the OS there is a work instruction for CB inspectors which states *'the inspector takes for example four samples of four individual farmers separately and mixes them together. The mixture is equally divided into three samples: a sample for the laboratory and one for the licensee a counter sample stays with CB. The laboratory will screen the sample for residues. The detection level is still sufficient on the individual farmer (0,01 mg/kg). If residue is detected, the separate samples can be analysed to narrow the detection'*.
44. Within the CB's procedures, there is an eight page sampling guideline which is based on the Commission Directive 2002/63/EC establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin. In addition this guideline provides instructions on field sampling and soil sampling.
45. The CB did not have an annual sampling plan in place which is based on an appropriate risk assessment (see paragraphs 20 and 31). There was no strategic approach to planning this 5% sampling criteria. The audit team was informed by the CB that previous results from non-compliant samples were not factored into any sampling practices for the following year. The audit team observed the CB inspectors undertaking sampling on suspicion.
46. According to the pre audit questionnaire, 254 samples were taken in Sri Lanka in 2016. The CB stated that they always ensure that the minimum requirement of 5% of the total number of operators is subject to sampling for the testing of residues of plant protection products.
47. All inspectors are permitted to sample during inspection visits. The CB has contracts with two accredited laboratories in the EU and CB inspectors can decide which laboratory the samples should be sent to.
48. The scope of detection methods used for plant protection products for the two laboratories were requested by the audit team, however, only one such document was available at the time of the office audit at the HQ.
49. Although the scope of analysis for plant protection products undertaken by the laboratory was relatively wide, the audit team noted that at least three plant protection

products which had been associated with notifications in the EU rapid alert system for food and feed (RASFF) concerning the presence of certain un authorised substances from Sri Lanka, were not included. The personnel at the CB headquarters confirmed that the CB does not engage with the laboratory to define the most appropriate scope of plant protection products to be tested as they rely on the laboratories expertise. Nevertheless, such information should be factored into subsequent risk assessments.

50. The audit team noted that the analytical request form of the laboratory only required the CB inspector to tick the category of product (for example fruit and vegetables) and the CB relied on the laboratory to choose the scope of analysis. This carries the risk that the laboratory excludes the testing for pesticides that may not normally be used for fruit and vegetable production or illegal pesticides.
51. The audit team witnessed a sampling exercise undertaken by the CB inspectors. It was noted that the instructions were generally followed. However, the sampling form filled in by the CB inspector during the aggregation exercise to generate the laboratory sample did not include the identification of the field.¹
52. In relation to the sampling, there were a number of issues. The sample size was not always appropriate and the audit team noted that laboratory reports stated that sample size was too small and results may be affected. In addition, the preservation and transportation of the samples was not satisfactory. The audit team noted that the samples of leaves began to decay in the plastic bags in which they were stored for approximately two days. Although 'cool boxes' were used they were not equipped to ensure the preservation of the samples of fresh leaves. In addition, the samples were dispatched to the laboratory (mainly in the EU) without any cold preservation.

Conclusions on Sampling

53. Although the requirement to sample 5% of operators is achieved, it is not based on an appropriate risk based sampling plan as required by Article 65.2 of the OS.
54. The CB does not utilise information from notifications to improve their risk assessment.
55. The scope of analysis, approach to sampling and transportation of laboratory samples, risks undermining the reliability of laboratory results.

¹ In their response to the draft report the CB noted the following: 'During the EU COM audit, several fields were sampled. Out of them 2 were separately aggregated for analysis based on the risk identified on site visit. Therefore, the 2 were analyzed separately using one sample submission from, rest of the samples belonging to other fields were aggregated into one sample and analyzed. In the sample submission form only one field was mentioned was a human mistake. This can be however corrected via crosscheck the information in the inspection checklist. To verify whether it is an isolated case or not all sample submission forms for 2016 and 2017 were reviewed. This found to be a rare and isolated case. To prevent re-occurrence of this mistake in future, a harmonization session for inspectors was planned in December 2017. Procedures and documentation on sampling is included to the harmonization session.'

5.5 LIST OF ORGANIC OPERATORS

Legal Requirements

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

Findings

56. The CB has a search tool on its website, which requires each individual to register to obtain a password. Once registered, information on specified operators and products and the corresponding certification status is available. There is no direct user friendly approach to obtaining a list of organic operators for any specific country. This is not in line Article (11)(3) of Commission Regulation (EC) No 1235/2008.

Conclusions on List of Organic Operators

57. The CB's website has a search facility which provides access to information on operators and products and their certification status, however, there is no access to a single list of organic operators subject to the CB's control system.

5.6 CONTROLS ON ORGANIC PRODUCTION

Legal Requirements

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

Article 23 of Regulation (EC) no 834/2007.

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

Article 27(13) of Regulation (EC) No 834/2007

Findings

5.6.1 Controls of operators

58. The audit team observed CB inspectors from the CB performing documentary based checks relating to the Organic Standard Plan (OSP) for processing and the ICS for the farms visited.

59. The OSP used by this CB referred to organic standards for the EU, USA and Japan. There was one OSP in place for all units in the 'Project', e.g. processor, traders, farmers and producer groups. The OSP was initially completed in July 2003 and was last updated on 8th May 2017. Each 'Project' is required to update this OSP prior to the annual inspection.

60. The audit team noted that the information in the OSP was vague and the CB inspector did not use the information provided to effectively check relevant issues. The OSP

correctly indicated that there was no multi ingredient product produced by the operator visited.

61. However, the inspectors selected a one crop product (tea) in the operator referred to under paragraph 60 for the assessment of the 95% organic ingredient requirement. This verification exercise is not plausible as this requirement can only be checked in multi ingredient products, i.e. that contain more than one ingredient as required in Article 23(4) of Regulation (EC) No 834/2007.
62. The verification of the origin of the incoming products and their organic status was only checked by the internal traceability of the operator but the CB inspector did not request to see the relevant records.

5.6.2 Internal Control Systems

63. The audit team observed CB inspectors reviewing one ICS of one Project. All the sites visited belonged to the same Project. A total of seven farms were visited, ranging in size from half an acre to forty eight acres. The CB inspector stated that no parallel production existed in any of these farms.
64. In each farm, the CB inspector reviewed the 'Farm Workbook'. The previous two ICS inspection reports were also reviewed by the CB inspector. The frequency of inspection of those farms visited, were considered appropriate by the audit team. The 'Farm Workbook' is given to the farmer after the farm has achieved organic status. There are no records of the in-conversion period noted in the 'Farm Workbook'.
65. All details relating to the preparation, distribution and use of liquid fertilisers, compost, farm manure is registered in this document. It also records every visit of the ICS inspectors and CB inspectors. Training that the farmer had undertaken were also recorded. At the back of the document there was a copy of Regulation (EC) No 889/2008 in the local language. Both at the Association (ICS) and farm level there is no documentary evidence available, such as delivery notes for these farm inputs (see paragraph 34). This had been correctly noted and recorded as a non-compliance by the CB inspector observed.
66. The CB inspectors had a spreadsheet, listing all farmers in each of the farmer groups selected for inspection on this occasion. No individual reports were prepared by the CB inspectors for each farm visit. The CB inspectors reported their findings of all farms visited on the single spreadsheet. It should be noted that each farm visit undertaken by the ICS inspectors resulted in a written report.
67. The CB inspections observed involved inspectors walking through all the land in the smaller farms. In the medium sized farm visited the two inspectors split up to undertake the visual inspection. Although the physical inspections of the farms were in general, satisfactory, the interaction by the CB inspectors with the ICS inspectors was not always sufficiently thorough. As an example the CB inspectors did not verify the responses by the ICS inspectors or the farmers as no requests were made for documentary evidence.

68. The CB inspector has to cross-check the findings of the ICS with his own findings through a form of system audit. In case the findings of the CB inspector and the findings of the ICS differs, the effectiveness of the ICS is put into doubt. If the findings of these two parties systematically differ, the ICS must be sanctioned (major non-compliance) and as long as the ICS does not do the necessary actions to rectify the situation, the CB inspector will be required to inspect 100% of the individual farmers. However, to date no group sanction has ever been applied by the CB (see paragraph 80).

5.6.3 Labelling

69. During the visit to the tea processor, the audit team was informed that all input was certified organic. However, the audit team noted that a number of bulk bags in the processing unit were labelled as 'organic/in-conversion product'. This issue was not detected by the CB inspector.

5.6.4 Traceability

70. A traceability exercise was performed by the auditors which checked all relevant documents for the internal traceability and delivery documents for export. The weakness observed related to the inspector not paying attention to the delivery document to verify the origin and status of the products delivered by the supplier. In addition a mass balance exercise was observed, however, it only focussed on one day's production rather than the production over a reasonable period of time.

Conclusions on Controls of Organic Production

71. The assurance that organic products exported from Sri Lanka to the EU have been produced in accordance with CB production rules is weakened by the lack of understanding of basic organic rules in addition to superficial verification and incomplete records.²

5.7 EXPORT CERTIFICATION SYSTEM

Legal Requirements

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

Findings

72. The Sri Lanka office is a 'critical location' and is responsible for issuing CoIs to Sri Lankan operators. The client applies through the client portal of the CB software system for permission to export. The application has to be accompanied by a commercial invoice, a bill of lading and a declaration of compliance confirming the organic status of

² In response to the draft report the CB noted that a harmonization session for inspectors was planned on December 2017.

the products. The CB administrative staffs are alerted to such applications and they undertake the initial screening of the documentation.

73. In the event that an application is not accepted for any reason, the client receives a return email stating the application has been rejected. The CB software system does not retain any record of the operator's rejected applications (information useful to be factored into the subsequent risk assessment for that year).
74. It is up to the operator to apply again if they wish to pursue the CoI for that particular consignment.

Conclusions on Export Certification System

75. The CB issues CoIs for organic products for export to the EU in compliance with Article 13 of Commission Regulation (EC) No 1235/2008.

5.8 IRREGULARITIES AND FOLLOW-UP OF EU NOTIFICATIONS

Legal Requirements

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

Article 30 of Regulation (EC) No 834/2007.

Findings

76. The CB procedure WO1(26) deals with all aspects for handling non-compliances. It states that a non-compliance with any item of the regulation results in a non-conformity (NC). NCs are evaluated by the certifier and once formally approved, the client is informed. The follow-up of any NC within a specified time period is the responsibility of the client. The CB closes the NC if there is objective evidence that addresses the issue. When corrective actions are not implemented by operators, certification cannot be granted. The above mentioned procedure also describes in detail the steps to be taken to upgrade the status of non-compliances when the appropriate action is not taken by the operators.
77. The procedures/checklists refer to major and minor non-compliances, and give instructions of the enforcement measures to be implemented in the case of severe non-compliances.
78. Although the annual report to the Commission (covering the year 2016) from the CB records several (37) major non-compliances of the OS, there were no decertification of products or operators reported. This was discussed with the CB at the HQ office audit and it was explained that operators frequently withdrew non-compliant consignments before the CB takes a decision on decertification of the product. The CB does not report such events in the annual report. Information was provided by the CB where it was

illustrated that operators' certificates were suspended during investigation. However, there was no evidence of operators being decertified.

79. In relation to the management of complaints in the ICS, the CB inspector reviewed some examples during his visit. The detection of unauthorised product was handled by the company as a means to address the complaints by the clients. The audit team noted that there was no systematic approach to handling such complaints to enable the root cause to be investigated and this was not taken into consideration by the CB inspector. In addition there was no corrective action implemented to alleviate the origin of the problem.
80. The withdrawal of certification at PG level is not possible as certification is issued at the higher Project level (see paragraph 18). This results in a situation where certificates are rarely withdrawn or suspended.
81. The ICS applies sanctions to individual group members concerned by a NC. The CB has incorporated the general EU Guidelines on organic producer group certification schemes which foresees sanctions being applied to the group as a whole, including, in case of serious deficiencies, the withdrawal of the certification of the group. However, at the time of the audit, no group sanctions have been applied by the CB. In addition, there is no detailed procedure/qualitative assessment, nor a documented sanctions policy vis-à-vis groups, to establish in which circumstances a non-conformity or a number of non-conformities can be considered serious enough to undermine the effectiveness and reliability of the ICS, which in turn would result in a group sanction.
82. There were 12 OFIS notifications received in 2016. One case reviewed by the audit team illustrated the key elements of how the CB approached EU notifications of irregularities. The laboratory reports from the reporting MS had detected unauthorised substances in November 2016 in the fruit which was preserved in glass jars. The CB quarantined the product in question and initiated an investigation, which included testing of leaves of the remaining plants as well as retesting additional fruit product from the same consignment. The laboratory analysis reports which the CB received from their cooperating laboratories did not detect any unauthorised substances. However, an agreement to return the consignment to Sri Lanka was taken and no sanction was implemented and no further follow up was undertaken.
83. The findings from this and other OFIS investigations are not factored into the following years' risk assessments.

Conclusions on Irregularities and Follow-Up of EU notifications

84. Although non-compliances exist there is no evidence that any enforcement measures are applied.
85. The follow-up of EU notifications by the CB are generally incomplete. These are not targeted at correcting the control system operated by the CB and reducing the number of

OFIS cases. Frequently, the solution involves withdrawing the consignment which satisfies the notifying MSs and this results in the file being closed.

6 OVERALL CONCLUSIONS

The audit was undertaken as an input to the supervision of the CB by DG AGRI. Although elements of a system of controls have been put into place by this CB, a number of significant issues have emerged which cast doubt on the overall integrity of the approach taken.

A number of significant failures were noted which undermine the reliability of the system of controls in place. The approach to risk assessment is unsatisfactory as the majority of operators are categorised as high risk by default rather than through a comparative assessment of risk. The risks associated with parallel production and previous non-compliances are not addressed. In addition, inspections observed were superficial. The scope of laboratory analyses was limited and the sampling procedures observed were not satisfactory. The CB failed to launch any meaningful investigations to follow up the significant number of irregularities notified in the Organic Farming Information System (OFIS) leading to a situation where enforcement measures are almost non-existent. Consequently, the control measures applied by the CB cannot be considered as having equivalent effectiveness to those applicable in the EU.

7 CLOSING MEETING

A closing meeting was held in Sri Lanka on 24 May 2017 with representatives of the CB. At this meeting, the DG Health and Food Safety 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

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

No.	Recommendation
1.	<p>Ensure that the new control requirements introduced by Regulation (EC) No 392/2013 are incorporated into the CB's control measures.</p> <p><i>Recommendation is based on conclusion No 6</i></p> <p><i>Associated finding No 3</i></p>
2.	<p>Ensure, for the planning of annual, additional and unannounced controls and sampling, in line with Article 65 of the OS, that all relevant risk criteria are considered, in particular, the risk related to parallel production and previous non-compliances. Moreover, ensure that control measures are applied effectively in order to achieve the organic standard, and in particular that no prior notice is given in case of unannounced inspections.</p> <p><i>Recommendation is based on conclusions Nos 31, 53, and 54.</i></p> <p><i>Associated findings Nos 20, 21, 24, 27, 45, 49, 73 and 83.</i></p>
3.	<p>Ensure the Annual Report submitted annually to the Commission includes accurate information on the activities carried out by the CB, as required by Article 11(3) of the regulation (EC) No 1235/2008.</p> <p><i>Recommendation is based on conclusions No 32</i></p> <p><i>Associated findings No 26, 78</i></p>
4.	<p>Ensure that control measures are established in order to correctly implement the OS and in particular to instruct CB inspectors to systematically and effectively verify off-farm inputs for organic production during control visits.</p> <p><i>Recommendation is based on conclusion No 35.</i></p> <p><i>Associated finding No 34.</i></p>
5.	<p>Ensure that derogations and exemptions are granted in line with Article 36.2 of the OS and to ensure that implementation is verified by CB.</p> <p><i>Recommendation is based on conclusion No 42</i></p> <p><i>Associated finding No 38 and No 39</i></p>

No.	Recommendation
6.	<p>Ensure that the requirements of Annex XV of the OS and the sampling guideline are implemented in particular the approach to sampling and transportation of laboratory samples and that the scope of analysis is appropriate.</p> <p><i>Recommendation is based on conclusions No 55</i></p> <p><i>Associated finding No 49, 50, 51, 52</i></p>
7.	<p>The CB should ensure that an updated list of operators subject to the control system is published on the CB's website and is publicly available as required by Article 11(3)(e) of Commission Regulation (EC) No 1235/2008.</p> <p><i>Recommendation is based on conclusion No 57</i></p> <p><i>Associated finding No 56</i></p>
8.	<p>Ensure that controls of operators are effective and that the requirements of the OS are thoroughly and logically checked and that relevant records are complete to enable the operator to identify and the CB to verify the compliance with the rules in line with Article 66.</p> <p><i>Recommendation is based on conclusions No 71</i></p> <p><i>Associated finding Nos 60, 61, 62, 67, 69, 70</i></p>
9.	<p>Ensure that the follow-up of EU notifications are taken to completion and in particular that appropriate corrections are implemented aiming at improving the system of controls and reducing the number of OFIS notification in the future.</p> <p><i>Recommendation is based on conclusions No 84 and No 85.</i></p> <p><i>Associated finding Nos 78, 79, 80, 81, 82.</i></p>

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=2017-6082

ANNEX 1 – LEGAL REFERENCES

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

ANNEX 2: STANDARDS QUOTED IN THIS REPORT

Reference	Title	Publication
ISO/IEC 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/