EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

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FINAL REPORT OF AN AUDIT

CARRIED OUT

FROM 14 TO 24 NOVEMBER 2017

IN ORDER TO

EVALUATE THE IMPLEMENTATION OF THE ORGANIC PRODUCTION STANDARDS AND CONTROL MEASURES APPLIED BY A RECOGNISED CONTROL BODY OPERATING IN CHINA

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 Directorate-General for Health and Food Safety audit carried out between 14 and 24 November 2017 in order to evaluate the application of the organic standards and control measures applied by a recognised control body in China.

The control body is well organized with qualified staff supported by a well-developed document and computer system. Controls required by the regulations and accreditation standards are generally well implemented and the objectives in terms of the minimum rate of controls and analyses largely achieved.

However, there are some weaknesses in the detection of contamination risks from neighbouring or parallel conventional activities as well as the validation of the means of preventing them. The lack of clear mechanisms in the sanction catalogue to tackle clear breaches of organic production rules related to projects, and more particularly of voluntary infringements, was also noted.

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
CAs	Competent Authorities
CB(s)	Control Body(ies)
CoI	Certificate of Inspection
DG	Directorate General
EU	European Union
HQ	Head Quarter
ICS(s)	Internal Control System(s)
IQS	Internal Quality System
ISO	International Organisation for Standardization
MS	Member State
OFIS	Organic Farming Information System
OMP	Organic Management Plan
OS	Organic Standard
PG(s)	Producer Group(s)
PPP(s)	Plant Protection Product(s)
TC	Transaction Certificate

1 INTRODUCTION

The audit took place from 14 to 24 November 2017 in China and in one Member State (MS) in order to evaluate the application of the organic standards and control measures applied by a recognised control body (CB). The CB was selected for the audit by the Directorate General (DG) 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 visits to operators certified by the CB in China as well to the CB's branch office in China and to the CB's headquarters (HQ) in a MS.

An opening meeting was held on 14 November at the CB office in China. At this meeting, the objectives of, and itinerary for, the audit were confirmed by the audit team and the control system were described by the CB.

The audit on the CB will provide an input to the European Commission's (COM) 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 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 European Commission as competent to carry out controls for the purpose of equivalence.
- to verify that the control measures recognised by the European 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		
Office in China	2	Office audit and opening meeting
CB's Head Office (HQ) in EU	2	Office audit and closing meeting
On-Site-Visits		
Visit 1	1	Producer group (PG) Beekeeping cooperative
Visit 2	1	Feed producer
Visit 3	1	Processor-Exporter
Visit 4	1	Farm with plant production

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 European 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 China.

5 FINDINGS AND CONCLUSIONS

5.1 ORGANIC PRODUCTION RULES AND CONTROL MEASURES

Legal requirements

Article 12(1)(a) and (b) of Commission Regulation (EC) No 1235/2008.

Findings

1. The CB's latest versions of the organic standard (OS), quality manual and operating procedures had been notified to the European Commission in accordance with Article 12(1)(a) of Regulation (EC) No 1235/2008. The last revision of the OS, which included the last amendments of Regulation (EC) No 889/2008, came into force on 1 November 2017. The certified operators were given a transition period, to implement the changes, until 1 January 2018. The accreditation body (AB) was also informed of the publication of the new version of the OS and transition period granted to the certified operators.

2. In order to ensure that amendments made to EU organic regulation are incorporated into the CB´s OS in due time, a new procedure was implemented in 2017 by the CB.

3. The last version of the OS (version 5) is publicly available on the CB website and operators are regularly informed about changes in the OS or it's annexes via electronic newsletters.

Conclusions on organic production rules and control measures

4. The CB complies with its notification obligations to the European Commission of the most recent version of the CB's organic production standard 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

5. The CB is accredited to the International Organisation for Standardization (ISO) 17065:2012 by an European AB. Regular surveillance audits take place, in line with Article 33(3) of Regulation (EC) No 834/2007.

6. The CB's office in China was classified as a "critical site" by the AB due to its responsibilities (certification's contract review, qualification of personnel, the planning and implementation of the control plan and issuance of certificates). The most recent AB's surveillance audit took place in May and June 2017 at the CB headquarters and in July 2017 at the CB office in China. These audits included office audits and witness audits of the CB inspectors in China. No non-compliances were detected by the AB.

7. The critical sites of the CB are subject to internal audits by the CB HQ at least every five years (previous internal audit in China performed in November 2015). One critical non-compliance (lack of information to assess the product flows in a big multi sites operator and to assess the livestock density and organic manure spreading plan) and four non-critical non-compliances were found (as well as 3 sensitive points). An action plan was developed to address the eight findings. One of the non-critical non-compliances was not yet closed at the time of the audit.

8. The office in China is also subject to continuous supervision by CB HQ. The annual reports of the activities of the Chinese site as well as performance indicators are reviewed by the CB headquarter during the annual management review in the CB's HQ.

Conclusions on surveillance and re-assessment

9. The CB complies with the requirements of Article 33(3) of Council Regulation (EC) No 834/2007 related to on-the-spot evaluation, surveillance and multiannual re-assessment of their activities by an AB.

5.3 National Authorities and National Legal Requirements

Legal requirements

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

Findings

10. The CB informed the CAs in China of its activities in line with Article 11(3)(d) of Commission Regulation (EC) No 1235/2008. The CB office in China is also accredited to ISO 17065:2012 by the National Accreditation Services and approved by the CA for the certification of Chinese organic certification standard (GB/T 19630-2011) since 2008. The CB Branch office is subject to regular supervisions by the CA in China.

Conclusions on national authorities and national requirements

11. The CB complies with Article 11(3)(d) of Commission Regulation (EC) No 1235/2008, related to the notification of its activity to the relevant authorities in China.

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 HQ located in a MS is responsible for the definition of the CB's policy, update of the OS and the development of the manual of procedures as well as computer systems supporting the certification process. The CB HQ provides technical and management support to all the CB Branch offices.

13. The distribution of tasks and responsibilities between the HQ and the CB branch office are clearly defined and documented. The CB HQ is a shareholder of the local branches and has sufficient legal authority to ensure that the CB's quality policy and manual of procedures are implemented by the branch office.

14. Organisation charts, job descriptions and a list of personnel with designated tasks are available at CB Branch offices and HQ levels and were up to date. The methodology to define and organise the control plans and to qualify and supervise the personnel are defined by the CB HQ but implemented by the CB Branch offices (subject to supervision by the HQ). A centrally operated computer system facilitates communication between the different CB branch offices and the HQ in the certification process and supervision of the personnel trainings and performance.

Recruitment, training and evaluation of inspectors

15. The Chinese CB employs an adequate number of personnel to carry out administration, inspection and certification tasks. Most of the inspectors are employed by the CB, the rest are freelancers.

16. Procedures are in place for the recruitment and training of the personnel. Inspectors should have at least a bachelor's degree (in relation to agriculture, food technology, quality management) or equivalent professional experience. New employees, including freelancers, are trained by the branch office on the latest version of the OS, internal procedures and methodology of the CB. These trainings are supported by detailed training materials and the use of an E-LEARNING platform developed by the CB HQ.

17. The audit team was presented evidences that inspectors have undergo theoretical and practical training before they were allowed to carry out inspection on their own and that regular trainings are provided for the products categories they are qualified. The CB divided the activities in: beekeeping, crops, handling, livestock, producers' group (PG) or wild collection. The category "Handling", includes the preparation and processing of food or feed and trading/export.

18. CBs' staffs are provided with ongoing training combined with performance monitoring (through feedback from clients, review of inspection reports, level of activity and for inspectors, periodic observation on site). Annual meetings are also organised to update and calibrate the inspector's skills. Files reviewed by the audit team confirmed that staff complied with the training and qualification requirements.

Conflict of interest

19. All staff, either internal or external, commit to act in an impartial manner, and to reveal any existing or potential risk to impartiality. Inspectors have to submit an annual declaration of any risk of conflict of interest identified and the list of operators concerned. Any risk identified after the assignment of inspection has to be notified to the impartiality committee. The list of staff member and potential risks are evaluated by the CB line manager or another superior staff of the CB who is responsible for the management of issues related to conflict of interest.

20. A report on the management of the risk of partiality is presented annually to the impartiality committee for evaluation. The conclusions of the impartiality committee are presented to the top management of the CB.

21. In China, the CB follows the requirement of the Chinese organic standard requiring the rotation of inspectors (performance of maximum three consecutive inspections to the same operator).

22. The audit team reviewed individual files and confirmed that records relating to trainings, absence of conflict of interest and evaluations of competence were complete and up-to-date.

Risk assessment and planning of controls

23. At the beginning of each year, operators in China are requested to submit to the CB their organic management plan (OMP) and related annexes such as list of inputs, maps of plots

or processing and storage facilities, recipes, labels. Every February, the CB carries out a risk based analysis of the certified operators including a risk assessment of the products produced or traded.

24. For the risk assessment of products, the specific risks in China, previous alerts recorded for the same product exported to the EU and/or United States as well as ongoing crises leads to reinforced checks by the CB. Contaminations detected in the Chinese OS control plan are not considered in the risk analysis.

25. For China, the CB has evaluated 75 products, 15 were considered high risk and 26 medium risk. Products categorised as high risk are incorporated into the CB's sampling plan. The sampling plan also defines the steps in the production process and the period of the year in which the sampling is to take place.

26. The risk profile of operators is determined based on a set of criteria such as the level of risk of the products considered or the production quantities, the presence of parallel production, the detection of major non-compliances (or positive analyses results), the efficiency of the OMP and/or the level of cooperation.

27. Depending on the results of the assessment, a level of risk is assigned to the operator and the control plan is adapted (i.e. additional audits, samples or documentary reviews).

28. For 2017, the risk assessment of operators certified at the beginning of the year resulted in the categorisation as high risk for 10.2 % of the operators. This led to the planning of additional inspections. Operators were also selected, based on the risk level, to be subject to unannounced inspections. In 2017, 28 % of the total number of inspections (annual and additional) was planned as unannounced.

29. When an inspection is planned, the assigned inspector receives all the necessary information via the computer system developed by the CB. The transmitted client file includes at least the previous inspection report and follow-up, the latest version of the OMP and its annexes (i.e. list of inputs, maps, recipes, labels). Instructions for carrying out the control are also included (type of inspection (announced or not), minimum duration, target period for the inspection and sampling, type and number of samples to be taken).

30. The audit team reviewed a number of inspection files and noted that most of the control plan was implemented as planned. However, some inspections and sampling were not always carried out at the most appropriate time determined by the risk assessment. There were delays of a number of weeks up to months or the recurrent inspection of one crop producer during winter time. No monitoring of these deviations or performance indicators is implemented by the CB to verify the pertinence of the real inspection periods.

31. A specific risk assessment is also conducted for PGs to define the number of inspections by the CB to confirm the efficiency of the internal control system (ICS) of the group. The CB defines two categories of PGs in his procedures. The first category complies with the requirements of the EU Guidelines for group certification[1] which requires the application of an efficient ICS including at least one annual internal inspection to each individual member by qualified internal inspectors. The second category is more a management by "project" in which the CB provides certification to a group of operator bound by a

[1] Included in the Guidelines on imports of organic products into the European Union

contractual agreements and arrangements such as the existence of an internal quality system (IQS) applied by its members.

32. For PGs with an ICS, the CB's annual inspection includes inspections of a sample of individual members of the group to evaluate the effectiveness of the ICS. The ICS is considered as effective if less than 10 % of members inspected are found with major non-compliances and non-effective if more than 20 % of members inspected are found to have major non-compliances. If between 10% and 20 % are found with major non-compliances, additional investigation and corrective action are required of the PG.

33. The audit team found that the minimum number of farms of the PG to be inspected, recommended by the guidelines, was respected. The CB also take into account the ratio between the turnover of the operator and the average certification costs to identify large farmers who must be subject to individual annual visits by the CB. New PG applicants are also subject to systematic inspections by the ICS and CB before joining the list of certified members. The audit team noted that, the planning of CBs' inspections does not take into account the dates of performance of the internal inspection so as to allow an adequate evaluation of the performance of the ICS.

34. For the group of operators with a common IQS, no annual internal inspections take place but all members are subject to annual inspections by the CB as if they were individual "operators". At the end of the certification process operators are listed in the annex of a single "group" certificate.

New operators previously certified by other CBs

35. The CB has a procedure in place for the operators wishing to change CB. The CB requests the last inspection report and certificate issued by the previous CB to take into account the findings of the previous inspection report and organise the follow-up and evaluation of the resolution of previous non-compliances. The audit team confirmed that the procedure was adequately followed by the CB.

36. A draft procedure for the management of operators dealing with more than one certification body (dual certification) was also presented to the audit team. The procedure take into account the specificities and risks related to operators requesting dual certification for the same products and/or site and defines the different scenarios and associated reinforced checks (i.e. mass balance and traceability exercises or verification of other CB documentation). This procedure also envisages the exchange of information relating to the issue of transaction certificates (TC) for products certified by both CBs on the same site. This was considered as a strength by the audit team.

Conclusions on organisation and planning of controls

37. The organisation of the CB between the HQ and the local office in China is correctly established and supported by a detailed quality manual and supportive computer systems. Appropriate staff resources and skills are allocated to the performance of controls and supervision of operators. Adequate measures to ensure the absence of any conflict of interest and transfer of certified operators between CBs are also implemented.

38. The CB applies a detailed and complex risk assessment system to design the annual control plan and to reinforce checks on high risk products and operators. The minimum

numbers of additional visits and unannounced inspections are respected and generally exceeded.

39. However, inspections and sampling are not always done at the designated or relevant times and these discrepancies are not tracked and evaluated to assess the impact on operator controls.

5.4.2 Off-farm input verification system

Findings

40. The CB has a mechanism to validate inputs considered suitable to be used in organic agriculture in accordance with Regulation (EC) No 834/2007 and (EC) No 889/2008. The lists of approved inputs are published in the annexes of the CB's OS. The CB has recently implemented a new procedure to facilitate the follow-up of amendments made to the EU Regulations in order to keep the CB´s lists updated.

41. At the initial application, each operator has to provide the list of inputs used within his OMP subject to the assessment by the CB and must inform about changes during the annual update. The information is provided to the inspector through the computer system used by the CB and verified during the inspection. In case of use of off-farm inputs not included in the OMP, the inspector checks if such input respects the OS requirements.

42. A local interpretation rule of the definition "Factory Farming" was established in China to evaluate the origin of animal manure purchased at farm level (based on the type of rearing and spreading capacities). This facilitates the harmonisation of the evaluation of inputs.

43. During inspections, CB Inspectors check that off-farm inputs used correspond to those notified by the operator when updating his OMP and are in line with CB OS annexes.

Conclusions on off-farm input verification system

44. The CB has adequate procedures to approve and publish lists of approved off-farm input products and to ensure verification of use of off-farm input during inspections.

45. The implementation of the new procedure for monitoring changes in European regulations should avoid discrepancies in the OS.

5.4.3 Handling of derogations and exemptions

Findings

46. A list of granted derogations and exceptional production rules is published by the CB with the derogation criteria and conditions to be met. All requests for derogations introduced by operators are recorded in a dedicated table where, on a day by day basis, the Chinese office records the name of the operator requesting the derogation, the date and type of derogation requested and whether it was granted or not.

47. Since the 1 January 2017, the Chinese office granted 11 derogations for "mutilation of animals" such as dehorning, 13 for retroactive recognition of the conversion period of

plots of land and 67 for the use of non-organic vegetative propagating material and seeds for cultivation.

48. The audit team reviewed some files where derogations had been granted or refused and noted that the CB adequately followed its procedures (i.e. for the mutilation, confirmation by a veterinary that the operations were necessary and the reason where available).

49. For the retroactive recognition, declaration by an independent third party where requested and recorded (i.e.: absence of any application of an unauthorized product, non-cultivated or abandoned land or traditionally farmed for at least 3 years). The CB also combined it with field visits by CB's inspectors and, in case of suspicion, performance of a soil or weeds analyses to detect residues of pesticides or chemical fertilisers.

50. For non-organic vegetative propagating material and seeds, statements about absence of Genetically Modified Organism (GMO) and non-treatment of the seeds must be provided by at least 2 suppliers for each variety. The CB reserves the right to contact them to verify the information.

Conclusions on handling of derogations and exemptions

51. The CB properly granted derogations and verified the implementation at operators in accordance with its procedures.

5.4.4 Sampling

Findings

52. The CB has an annual sampling programme in place. During the risk assessment, high risk products and operators are selected and the type of analyses and period to sample fixed. Inspectors also have the instruction to take samples during the inspection in cases of suspicion.

53. A detailed sampling instruction is provided to inspectors describing the methodology, equipment and reporting of the sampling. Although the instruction refers to the EU regulation related to sampling, the audit team found some omissions from the EU regulation (i.e. no minimum weight or volume for the incremental samples, possibility to generate the three laboratory sample by direct distribution of the incremental samples in the 3 laboratory samples' bags without prior mixing or laboratory sample composed of the aggregation of incremental samples from different batches). Nevertheless, in the sampling witnessed by the audit team and sampling records presented no major deviations were observed.

54. The audit team reviewed the 2016 and 2017 sampling programmes and noted that the total number of samples exceeded the minimum requirement set as at least equal to 5 % of the operators certified. In 2016, 468 samples were planned and 582 performed (additional sampling performed during investigations following suspicion or notifications and on new high risk clients or products). For 2017, the risk assessment led to the designation of 46% of operators for compulsory sampling at least once per year.

55. At the time of the audit, 364 samples were already taken by the CB. A dedicated instruction describes the management of the samples and the analyses results.

56. Of the 334 analyses results already received 30 presented non-compliances (three due to presence of genetically modified organisms, 26 with residues of pesticides and one case with both). All non-compliances were subject to investigations including the performance of seven counter-analysis (four positive confirmation). For the cases closed, the conclusions were added in the client's file to allow follow up by inspectors.

57. In order to assist decision-making in the case of positive results, the CB has defined action levels for which precautionary measures (suspension of issuance of transaction certificate (TC) or certificate of inspection (CoI)) must be applied to the products, parcels or certificates concerned during the conduct of the investigation (i.e. GMO more than 0.1% or recurrent pesticides contaminations not explained during audit, or with levels above 20 ppb). These action levels are related to the sampling situations, kind of substance detected and product concerned.

58. When a positive result is received, the investigations and impact on the certification decision are coordinated between the analysis officer and the certification officer. The operator concerned is informed of the analytical result and requested to investigate the origin of the contamination. As soon as the operator is notified by letter, products from the parcel, lot or operator concerned are blocked if above the action levels (no issuance of TC or CoI). The audit team noted that for the 34 positive results recorded in 2017 (30 routine and 4 counter-analysis), although seven results were notified within the week of reception (and the related products blocked), the other cases were subject to slower reactions by the CB (four cases where information and blocking occured within a two week period and seven within 1 month after reception of the analytical result).

59. For the 29 cases out of the 34 which have been closed at the time of the audit, the duration of the investigation was also very variable (four took less than 1 month, twelve needed two months and four more than three month). Decisions led to three suspensions of certificates, 10 downgrading of the lot and/or return in conversion of the field and the others confirmed the organic status (often with request of implementation of systematic sampling by a third party for the subsequent consignments presented for issuance of CoI).

60. These intervals were also observed in the 2016 analyses (i.e. one case of non-compliance detected following the reception of analyses results in June was only notified to the processor in August and the investigation closed end October).

61. For the high risk products and operators, the CB requests third party sampling and analyses to be performed (in an ISO 17025 accredited laboratory with defined limits of quantification (i.e.: < 0.01 ppm)) and the results to be provided before the issuance of a CoI.

62. The CB has a procedure in place to ensure that laboratories entrusted with the analysis of samples are accredited to ISO 17025. At the time of the audit, all laboratories used were accredited. The HQ of the CB edits the list of approved laboratories and general recommendations on the requirements for samples.

Conclusions on sampling

63. The annual number of samples taken by the CB generally exceeds the minimum number required. The samples are taken following a detailed sampling procedure and analyses performed in adequately accredited laboratories.

64. Although all positive results are subject to investigations and eventual sanctions and follow-up as described in the procedure, in the case of detection of non-compliances, the CB takes excessive time for the notification and implementation of actions to prevent the setting in circulation of the non-compliant products. These delays prevent to guarantee that only compliant products are commercialised.

5.5 LIST OF ORGANIC OPERATORS

Legal Requirements

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

Findings

65. The CB publishes the list of organic operators subject to its controls on its website, this is in line with Article 11(3)(e) of Regulation (EC) No 1235/2008. The list contains the names and link to the certificates of the operators and is regularly updated.

66. The certification status is given with the eventual notification of products subject to temporary suspension. The copies of the certificates accessible online give the details on the list of products certified and periods of validity by production/handling site.

Conclusions on list of organic operators

67. The CB complies with the requirements of Article 11(3)(e) of Commission Regulation (EC) No 1235/2008 related to the web publication of the list of organic operator's subject to the CB´s control system.

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.

Codex Alimentarius Guidelines CAC/GL 32-1999, in particular Annex III.

Findings

5.6.1 Controls of operators

68. The audit team witnessed the performance of inspections at different types of operators:
    - A farm with crop production (mainly vegetables);
    - A cooperative of beekeepers: inspection of 2 farms (1 organic and 1 in conversion) and of the cooperative's collection centre and administration (ICS);
    - A producer of animal feed (with parallel production);
    - A processor and trader of vegetables (with parallel production).

69. The CB procedures and instructions cover all stages of the inspection process, from the preparation of the inspection to its reporting. Specific checklists and report templates are used for each type of farms, PGs (ICS or IQS), processors (food, feed or yeast production) or exporters/traders to cover the OS requirements. It also includes specific forms to report the mass balance and traceability exercises performed by the inspectors.

70. The CB inspectors met by the audit team were knowledgeable and familiar with CB's procedures and IT tool and used the latest version of the CB's OS. They had received the relevant documents and data related to the inspected operators to adequately prepare the inspections (i.e.: OMP, previous year's audit reports, corrective action plan and certification decisions, certificates, products description and products and operator risk assessmen).

71. The inspectors correctly implemented the inspection procedures to conduct the visit of the operators. The audit team witnessed the assessment of the production sites and sampling.

72. The inspections were in general correctly conducted by inspectors who covered all the points included in the scope of these inspections. Nevertheless, the audit team observed some weaknesses (described in paragraphs 73 to 75).

73. The information collected in the OMP is not always correctly evaluated (at the CB's office):

    - The declaration of preventive destruction of male brood (to prevent bee mites) in the application form of the beekeepers' cooperative was not detected as non-compliant.

    - For the vegetable processing plant, errors or inconsistencies noted by the inspector in the flowchart, or the absence of a procedure for the management of labels for products certified for the EU OS.

    - Maps of the location of the plots of lands or beehives were inaccurate, preventing a precise location and an appropriate identification of the surrounding activities.

74. The inspectors did not visit all the production and storage facilities of the operator to check for the presence of unauthorized products or activities not notified in the OMP:

    - For the beekeepers, the inspector only focused on the stock of inputs designated by the beekeepers and did not inspect the other places or storage spaces on the farm (i.e. no checks in the cabinet and freezer present in storage room of beekeeper inputs);

    - In the processing plant, the inspector did not request to visit the storage room of the stock of cleaning, disinfection and pesticides products.

    - In the feed establishment, the inspector was guided by the operator within the storage and production buildings to visit only the storage facilities and production equipment designated as used in organic production, but didn't challenge or verify the activities described in the flow-chart and mapping provided in the OMP.

75. Although the inspectors verify the existence of means to prevent cross-contamination in the case of parallel production (organic and conventional), the demonstration of their effectiveness is not correctly evaluated:

- For the containers used for the collection and distribution of honey, the inspector only asked if cleaning was carried out, but no records were requested for the performance of the cleaning or chemicals used;

- At the feed producer, the CB inspector accepted the cleaning procedure for the production line used for parallel production, based on a visual check of colour changes after the passing a rinsing load of 300 kg of calcium carbonate. This does not meet the good practice standards necessary for prevention of cross-contamination in feed mills, which requires the identification of the risky products (whose presence is to be prevented in the organic production), definition of the acceptable contamination limits and determination of the rate of cross-contamination of the production lines. This in order to objectively calculate the number and volume of the rinsing batches. There was also no question about the re-use of calcium carbonate used as a rinse agent;

- The feed raw materials were also stored in common warehouses along with the conventional products without physical separation or adequate protection against dust contamination from handling activities in the same spaces. This was not noted by the inspector;

- At the vegetable processor, although the inspector noted the insufficient separation in storage between organic and conventional products in the raw materials fridge (bulk products in plastic baskets), he only recommended a greater distance between stacks of baskets but never mentioned their covering to prevent airborne contamination due to ventilation in the fridge.

5.6.2 Labelling

76. The CB correctly approves at office level the labels which operators intend to apply on the organic products. Inspectors verify labels used during the inspections to confirm that they are used and correctly applied. The audit team confirmed that the CB adequately followed its procedure and inspectors were able to detect inadequate labelling of products in stock. The lack of controls at reception by operators of the organic status of purchased products was also correctly detected and reported by the inspector in one establishment.

5.6.3 Traceability

77. Traceability systems in place were checked in accordance with the CB organic standards. During the inspections witnessed, the audit team noted that CB inspectors properly perform traceability exercises and mass balance verifications. CB's procedure prescribes at least one mass balance exercise to be performed each year per activity such as production, processing or distribution on the most risky products. This in combination with at least one traceability exercise every two years (downward or upward) on most risky products. Additional verification of origin could also be done on inputs. Inspectors also did random checks of invoices and/or other accompanying documents to assess the truth of the records provided.

Conclusions on controls on organic production

78. Overall, the CB has good tools and qualified personnel to implement the controls of the different categories of organic operators.

79. Nevertheless, the effectiveness of the controls is undermined by the deficiencies in the verification of the information included in the OMPs and of the activities and products present within the certified establishments.

80. Inspections of the correct identification of risks of cross contamination (by substances or unauthorized products) by the operators and of the preventive and cleaning measures (including records and monitoring of their effectiveness) are not always correctly performed to guarantee the preservation of the integrity of organic products.

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

81. The CB has a procedure in place for the issuance of CoIs. At least three days before export, the operator in charge of the last production or preparation step submits the CoI request form with accompanying documents such as commercial invoice, transport documents and TC from the suppliers of raw materials if the supplier is certified by a different CB. For high risk products or consignments from operators subject to reinforced checks, analyses reports should also be provided (sampled by a third party and analysed in accredited laboratory).

82. Based on the review of the documents submitted, the CB performs a risk assessment to decide if additional physical checks have to be performed.

83. Quantities declared in the request for CoI is deducted from the quantities notified annually by the operators in their OMP. This is to prevent the issuance of CoIs for greater quantities that the potential of production validated by the CB. If the operator wishes to increase his quota of production during the year (due to the evolutions such as new fields, addition of members to a PG or new processing capacities), this should be subject to a prior validation by the CB to avoid a negative mass balance when quantities requested in the CoIs are deducted.

84. Dedicated staff members use the EU data base TRACES.NT (TRAde Control and Expert System) to generate the CoI before printing and signing the original to be sent to the operator. They were aware of the legal requirements as well as how to proceed in cases of "*force majeure*" or exceptional circumstances preventing the electronic system from working (manual edition and endorsement of CoI and notification to COM).

85. The Chinese office also performs inspections and certifies operators in other countries such as Brunei, Cambodia, Hong Kong, Malaysia and Taiwan. The audit team found that an operator in Brunei was certified for the product categories C and D while the CB is only recognised by European Commission for category C in that country. This is not in line with Article 33 of Regulation (EC) No 834/2007.

Conclusions on export certification system

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

87. However, the Chinese site has issued a certificate for an operator in another country outside the scope of product categories for which the CB is recognised by COM.

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

88. The CB quality manual identifies "minor" and "major" non-compliances. For all non-compliances the operator is requested to put in place a corrective action plan to solve them. The "major" non-compliances are defined as those which "*impact or might impact the specifications of the product to be certified*". Some major non-compliances, as well as fraudulent and recurrent non-compliances, may lead to a suspension or total certification withdrawal.

89. An additional instruction describes how to deal with deviations detected which contradict the OS. In this instruction, the CB uses three different definitions: major non-compliance, non-compliance and minor issue. The instruction requests the submission to the CB of evidence of the establishment of a corrective action plan for (major) non-compliances. However, minor issues, which are considered easily correctable, are not checked by the CB before the next annual inspection.

90. Major non-compliances such as systemic failure of the operator/PGs, deliberate or recurrent violation of the OS or refusal of access to sites or records leads to denial, suspension or withdrawal of the certificate.

91. The catalogue of measures and sanctions includes a detailed description of non-compliances and related measures to be taken. The predefined sanctions depend on the nature and severity of the non-compliance (from no sanction and information to be provided to the CB for minor issues to suspension or withdrawal of certification in case of Major non-compliance).

92. The CB may consider non-compliances to requirements such as these to be "minor issues":

- Animal feeding: composition or origin of the raw materials.
- Holding of animals: group holding, natural light or ventilation.
- Farming: limit of maximum 170 kg of nitrogen per year and hectare, crops rotation or mapping of the plots.

- Processors: checks at reception of the organic status of inputs, use of equipment suitable for food processing or mapping of the processing and storage facilities.
- PGs: absence of conflict of interest, adequate knowledge for the internal auditors or level of performance of internal control inspections at the adequate period.

93. When at least one major non-compliance is detected, which may lead to the suspension or withdrawal of the certificate, the certification officer requests the support of the technical manager, who may confirm the application of the sanction or request the advice of the advisory committee. The advisory committee is scheduled at least 8 days after sending the letter to the operator (offering him the opportunity to submit his objections).

94. The audit team reviewed a number of files and noted that there were no time limits specified for operators to address the non-compliances. Examples include:

- Detection of major non-compliances in July 2016, letter notifying certification decision end of November 2016;
- Presence of pesticides confirmed in laboratory results received the 8 and 15 August 2017, notification to the client and simultaneous suspension of issuance of CoI or TC on 5 September with request to provide explanation before the 15 September 2017. 16 October letter to inform the operator of the proposition of withdrawal to be presented to the advisory committee (eventual objections to be submitted before 24 October). On 24 November (audit closing meeting), still no advisory committee decision and/or final certification decision.

95. The recurring detection of infringements in several production sites (use of herbicides, pesticides and treated seeds detected in 2016 and 2017) within a "project" considered as one operator (see paragraph 31) was also only evaluated on a case-by-case basis for the individual sites (reduction of the certification scope of the operator by withdrawing these sites from the annexes of the project certificate). The operator as a whole was not sanctioned proportionately following his lack of respect for commitments made to apply organic production rules.

Follow-up of EU notifications

96. The audit team reviewed the procedure in place to deal with "alerts", defined by the CB as "*any information with evidence questioning the conformity of a product or a batch certified and sold on the market*". This included the review of files concerning the recent Organic Farming Information System (OFIS) notifications and other categories of complaints.

97. The procedure includes guidelines on maximum duration for each step of the management of alerts:

- Reception, examination and acknowledgement of receipt of the alert to the notifying party on timeframe and action plan proposed: one week;
- Performance of the investigation: two to three weeks;
- Investigation's review, closing of the alert and answer to the notifying party: one week.

98. Major alerts (in case of suspicion/doubt of fraudulent or bad practices) are investigated by the CB. The others are subject to investigations by the operators and the findings and

explanations evaluated by the CB. If some information is missing for the examination of the case, the process is blocked until relevant information is provided (no dead line set).

99. The total duration of the management of an alert may therefore exceed the required 30 days to notify the European Commission about measures taken in relation to irregularities.

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

100. The CB effectively applies its procedures to handle infringements and irregularities identified at operators.

101. However, the effectiveness of the control system is reduced by the time spent between the detection of irregularities and the actions taken to prevent the commercialisation of non-compliant products and by the lack of clear mechanisms in the sanction catalogue of the CB to tackle projects with recurrent and intentional breach of the organic production rules.

102. The procedure to manage alerts does not respect the OFIS notifications deadlines.

6 OVERALL CONCLUSIONS

The CB is well organised, is appropriately staffed and has a well-developed document and computer system.

Controls required by the regulations and accreditation standards are generally well implemented and the objectives in terms of the minimum rate of controls and analyses are achieved.

However, a number of weaknesses undermine the control system, mainly dealing with risks associated with cross contamination (identification of risks and validation of prevention measures in case of parallel or conventional production nearby).

The deadlines to address non-compliances detected are not clearly established and tend to drawn out over long periods and for the OFIS notifications, do not respect the maximum numbers of days required by COM.

It was also noted the lack of clear mechanisms in the sanction catalogue to tackle clear breaches of organic production rules related to projects and more particularly of voluntary infringements.

7 CLOSING MEETING

A closing meeting was held the 24 November 2017 with representatives of the CB. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit.

8 RECOMMENDATIONS

No.	***Recommendation***
1.	Ensure that inspection takes place at the defined and adequate moment as required by Articles 65 and 90 of Regulation (EC) No 889/2008. *Recommendation is based on conclusion No 39* *Associated findings: No 30 and 33*
2.	Ensure that actions are taken immediately as required by Articles 91 of Regulation (EC) No 889/2008 to insure that only products in compliance with organic production rules are placed on the market. *Recommendation is based on conclusion No 64 and 101* *Associated findings: No 58, 59, 60 and 94*
3.	Ensure that information and activities of the operators are correctly evaluated as required by Articles 63 (2) of Regulation (EC) No 889/2008. *Recommendation is based on conclusion No 79* *Associated findings: No 73 and 74*
4.	Ensure that risks and means of prevention of cross contamination are correctly assessed to guarantee the respect of Article 26 of Regulation (EC) No 889/2008. *Recommendation is based on conclusion No 80* *Associated finding: No 75*
5.	Ensure that the CB respects the product scope of its recognition as listed in Annex IV of Regulation (EC) No 1235/2008 for the issuance of certification. *Recommendation is based on conclusion No 87* *Associated finding: No 85*
6.	Ensure that operators committing recurrent and/or intentional infringements are subject to adequate and timely sanctions to prevent the marketing of products not in compliance with the organic production rules as required by Articles 92d of Regulation (EC) No 889/2008. *Recommendation is based on conclusion No 101* *Associated finding: No 95*
7.	Ensure that responses to OFIS notifications are made in the allocated deadline as required by Article 15 (4) of Regulation (EC) No 1235/2008. *Recommendation is based on conclusion No 102* *Associated findings: No 97 and 99*

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=2017-6067

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. 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
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

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/