## **EUROPEAN COMMISSION** DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2017-6068

# FINAL REPORT OF AN AUDIT **CARRIED OUT** FROM 22 NOVEMBER 2017 TO 01 DECEMBER 2017 IN ORDER TO

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

## **Executive Summary**

This report describes the outcome of a DG Health and Food Safety audit carried out between 22 November and 1 December 2017 in order to evaluate the application of the organic production standards and control measures by a control body (CB) in Turkey. The audit in Turkey was complemented by an office audit at the CB headquarters in an EU Member State.

The report concludes that the CB overall applies the production rules and control measures for which it was recognised by the European Commission for the purpose of equivalence. Annual inspections are planned at the most suitable time and additional inspections are unannounced. The inspections observed were overall effective. The CB takes a large number of samples and follows-up all cases where the analytical results identify the presence of substances not authorised in organic production. When non-compliance is confirmed, adequate enforcement measures are generally applied by the CB.

However, the effectiveness of the control system applied by the CB is reduced as additional inspections and sampling at operators and physical checks on consignments for export to the EU are not always planned according to the risk profile of the operators. Moreover, the inspections focus only on the organic production and processing and neglect the management of the non-organic activity of the operators.

The delay in the feedback provided by the branch offices on the control activities carried out does not permit the CB Headquarters to have a proper overview of their implementation and therefore the CB cannot react as necessary to guarantee that all activities are implemented as planned. The CB was aware of this problem and, at the time of the audit, a new database management and certification system was being introduced to improve the situation.

The report contains recommendations to the CB aimed at rectifying the shortcomings identified and enhancing the implementation of the control measures.

# **Table of Contents**

1	In	trodu	ction	1
2	Oł	ojecti	ves and scope	1
3	Legal Basis			2
4	Background			2
5	Fi	nding	gs and Conclusions	2
	5.1	Org	ganic Production rules and Control measures	2
	5.2	Sui	rveillance and Re-Assessment	3
	5.3	Na	tional Authorities and National Legal Requirements	4
	5.4	Str	ucture and Organisation of the Control System	4
	5.4	4.1	Organisation and planning of controls	5
	5.4	4.2	Off-farm input verification system	8
	5.4	4.3	Handling of derogations and exemptions	8
	5.4	4.4	Sampling	10
	5.5	Lis	t of Organic Operators	11
	5.6	Co	ntrols on Organic Production	11
	5.6	5.1	Controls of operators	12
	5.0	5.2	Labelling	13
	5.0	5.3	Traceability	13
	5.7	$\mathbf{E}\mathbf{x}_{\mathbf{j}}$	port certification system	14
	5.8	Irre	egularities and Follow-up of EU notifications	16
6	Ov	verall	Conclusions	17
7	Closing Meeting			
8	Re	ecom	mendations	18

# ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AB	Accreditation Body
CA(s)	Competent authority(ies)
CB(s)	Control Body(ies)
COM	European Commission
DG AGRI	Directorate-General for Agriculture and Rural Development
EC	European Community
EU	European Union
HQ	Headquarters
MS	Member State(s)
OFIS	Organic Farming Information System
OSP(s)	Organic System Plan(s)
PG(s)	Producer Group(s)
PPP(s)	Plant Protection Product(s)

#### 1 Introduction

The audit took place from 22 November 2017 to 01 December 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 (DG AGRI) 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 Turkey.

An opening meeting was held on 22 November at the HQ of the CB. 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 these objectives, the following sites were visited:

Visits/meetings	Days	Comments	
Control Body			
HQ	3		
Branch office in Turkey			
On-Site-Visits			
Visit 1	1	Several farmers in a Producer Group	
Visit 2	2	Processor	

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 Turkey.

#### 5 FINDINGS AND CONCLUSIONS

#### 5.1 ORGANIC PRODUCTION RULES AND CONTROL MEASURES

## Legal requirements

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

- 1. At the time of the present audit, the CB was implementing version 10 of its production rules and control measures (hereinafter referred to as the CB standards), dated 10 June 2017. This is the most recent version of the CB standards, which was assessed by the CB Accreditation Body (AB) in July 2017. As stated in the summary of the standards, the organic requirements as set up in the EU organic legislation apply, although in some cases, different requirements may be applied in some non-EU countries in order to address country-specific conditions.
- 2. The audit team confirmed that the CB had notified to the COM version 10 of its standards. However, this notification took place following a request by the COM. Changes are notified when sending the annual report referred to in Article 12(1)(b) of Regulation (EC) 1235/2008 in February each year. The CB does not have a procedure in

place to notify the COM of any relevant changes made to the CB standards, and therefore is not in a position to fully comply with the requirement set out in Article 12(1)(a) of Regulation (EC) No 1235/2008. The CB stated that its understanding was that they could start implementing the new procedures once the AB had issued its positive assessment and that the notification could take place with the annual report. However, some months may elapse from the time the CB starts to implement the amendments to the procedure until such amendments are notified to and assessed by the COM.

3. The CB has detailed documented procedures in place to ensure adequate implementation of most of the production rules and control measures applied. However, the audit team noted that the CB lacks procedures to implement control measures related to certain topics (e.g granting of derogations for the use of conventional seeds, decisions on physical checks to be carried out on consignments exported to the EU). As a result, such control measures are either not implemented (see paragraph 65) or cannot be demonstrated to be adequately implemented (see paragraphs 34 and 35).

## **Conclusions on Organic Production Rules and Control Measures**

4. Although the CB has documented procedures in place to ensure adequate implementation of most of the production rules and control measures in the CB standards, the lack of such procedures for certain topics does not ensure the fulfilment of all CB obligations, including to notify the COM of any relevant change in the CB standards.

## 5.2 SURVEILLANCE AND RE-ASSESSMENT

#### Legal requirements

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

- 5. The CB is accredited to the standard ISO/IEC 17065 (of the International Organization for Standardization and the International Electrotechnical Commission), as required by EU Regulations, and is subject to annual surveillance by an internationally recognized AB. For this purpose, an office audit takes place once a year at the CB HQ, where any relevant changes in the CB standards are assessed by the AB. In addition, the AB undertakes regular surveillance of on-the-spot activities of the CB in non-EU countries. The last surveillance activity by the AB in the CB branch office in Turkey took place in August 2015 and included witnessing the performance of the CB during inspections at operators.
- 6. The most recent AB office audit at the CB HQ took place during May/June 2017. The report issued by the AB contained 6 non-conformities which had to be addressed by the

- CB before 1 August 2017. The audit team confirmed that the AB had closed the non-conformities on 15 August 2017 based on corrective actions taken.
- 7. However, the audit team noted the repetition of two of the non-conformities referred to in the AB report. The first related to the lack of proper verification of the fulfilment of the conditions by operators before being granted retroactive recognition of a previous period as part of the conversion period (see paragraph 35). The second related to the lack of adequate information received from operators in the Organic System Plans (OSPs) submitted by operators, in particular from Producer Groups (PGs) before inspections (see paragraphs 18 and 51).

#### Conclusions on Surveillance and Re-assessment

8. The CB undergoes regular on-the-spot evaluation, surveillance and multi-annual reassessment 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**

- 9. The audit team reviewed a number of files relating to the notification made by the CB to the authorities of the non-EU countries where it operates and confirmed that the CB fulfils its notification obligations under Article 11(3) of Regulation (EC) No 1235/2008.
- 10. In the case of Turkey, there are specific conditions that the CB has to comply with. All operators have to be certified to Turkish standards and the CB has to be accredited by the Turkish AB. Inspections must be carried out before a given deadline in the year. The CB must have a branch office with permanent personnel and be subject to annual supervision by the Turkish CA.

# **Conclusions on National Authorities and National Legal Requirements**

11. The CB takes necessary measures in order to respect the national requirements imposed on it.

#### 5.4 STRUCTURE AND ORGANISATION OF THE CONTROL SYSTEM

## Legal requirements

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

## 5.4.1 Organisation and planning of controls

- 12. The CB has its HQ in one EU MS and operates in non-EU countries by using a network of administrative branch offices. The CB may also hire inspectors in the countries where it operates without a branch office. The HQ has the role of organizing and co-ordinating the main aspects of the control system, as well as making the certification decisions. The branch regional offices may decide on certain control issues, such as the timing and selection of operators for the additional visits and sampling.
- 13. Branch offices may be regional or local. Local offices do not have access to the CB database management system and have to submit all relevant information, such as inspection reports, to the relevant regional offices. Regional offices are responsible for uploading the information onto the database. The CB HQ supervises the branch offices by carrying out internal audits (once a year to regional offices and once every two years to local offices). The supervision includes an office audit of one-day duration as well as witnessing the performance of the local inspectors.
- 14. According to the CB procedures, branch offices have to submit an overview report on their control activities twice a year (by 30 June and by 30 December each year). Although the information uploaded by regional offices might be retrieved at the HQ from the database, in practice the HQ waits for the feedback from the branch offices, which are usually received within several weeks. This is not effective as the CB does not have a timely overview of the control activities carried out during the year, thus limiting the possibility to react as necessary (e.g. the CB HQ would only know early in the year that all annual/additional inspections were not carried out in the previous year). Therefore the CB is not in a position to ensure that all control activities required by Article 65 of Regulation (EC) No 889/2008 are carried out. At the time of the audit, the CB HQ could not provide updated data on the state of play of the control activities carried out in Turkey, as data was only available up to mid-September 2017.
- 15. The audit team also noted some discrepancies between the data on the control activities submitted to the COM in the annual report and the data kept in the HQ and at the branch office in Turkey. The CB stated that in some cases, this had to do with a different reading of the requirements for reporting (e.g. result of samples indicating breach in the legislation were notified only in cases of established irregularities and not for potential irregularities not yet confirmed). However, the CB was aware of the limitations of the current database management, and at the time of the audit it had taken steps to implement a new database management system. According to the CB, the new database will significantly improve the access to the information uploaded by the branch offices.
- 16. According to the CB standards, all operators must receive a full-scope inspection at least once a year. The inspection must take place at the most suitable time of the year depending on the type of crops. The CB fixes the date of the annual inspection based on

the date where the previous inspection took place, unless the inspectors' feedback may suggest a different timing for the inspection. In any case, inspections have to take place at least two months before the expiry date of the current certificate. The audit team reviewed a number of files and confirmed that, overall, the timing of all annual inspections carried out to growers was adequate.

- 17. However, the branch office in Turkey could not confirm that all inspections had taken place at the planned time. At least three PGs had been planned to be visited in June-July but up to the time of the audit, the CB could not produce the inspection reports demonstrating that such inspections had taken place at the planned time. This is not in line with the CB procedures described in the previous paragraph. In addition, if these inspections were not carried out in 2017, this would only be known by the CB HQ when the branch office submits the summary report referred to in paragraph 14.
- 18. The CB does not require the operators to submit all necessary information required by Article 71 of Regulation (EC) No 889/2008 before a date fixed by the CB. The audit team reviewed a number of files and noted that the information submitted by operators in their Organic System Plans (OSPs) did not always include a full description of the unit as well of the precautionary measures applied to avoid the risk of contamination of the organic products, as required by Article 63 (1) of Regulation (EC) No 889/2008. Although the inspectors verify the adequacy of such precautionary measures during the inspections, the result of this verification is not always recorded (see paragraph 51). In addition, the database system in place does not allow for the CB HQ to monitor whether OSPs are submitted by operators in a timely manner before inspections.
- 19. The CB has a risk assessment method in place to decide on the operators to be selected for additional inspections and sampling. Inspectors are responsible for completing the risk assessment sheet, which can later be modified by the certifiers in the CB HQ. Early in the year, the CB HQ indicates to the branch office the number of operators to be selected for the additional controls, and it is up to the offices to select the operators as well as the timing for the additional controls and sampling. The audit team confirmed that the CB carries out additional, unannounced controls to 10% of operators under its control.
- 20. However, the risk assessment used by the CB to categorise the risk profile of operators is not adequate. The CB does not take into account one of the compulsory criterion in Article 65(4) of Regulation (EC) No 889/2008, namely operators' past records as regards compliance (see paragraph 70). Quantities produced by operators are not fully taken into account either. The CB had only identified a limited number of operators as being high risk (none in Turkey), even though some of these were large-size operators producing organic and non-organic products and having had severe non-compliance in the previous year. As a result, the risk assessment as designed by the CB does not serve as a good basis for determining the intensity of the announced and unannounced inspections, as required by Article 92c(2)(a) of Regulation (EC) No 889/2008.

- 21. In addition, operators with low risk profiles may be selected for the 10% additional controls before operators with higher risk profiles, which is not in line with Article 92c (2)(b) and (d) of Regulation (EC) No 889/2008.
- 22. The CB HQ does not evaluate the adequacy of the planning of the additional controls made by the branch offices. The audit team noted that such inspections were not necessarily planned taking into account the risk profile of the operators selected, as required by Article 92c(2)(d). In 2016 all additional inspections took place before the annual inspections while all the additional inspections were planned in 2017 in the last quarter of the year. This was not noted by the HQ. In addition, samples are always taken during the announced inspections, thus limiting their effectiveness (see paragraph 42).
- 23. The audit team reviewed a number of files as regards the recruitment, training and supervision of staff. All newly recruited staff have to undergo an induction period which includes theoretical and practical training as well as evaluation by senior inspectors, before they are allowed to carry out inspections on their own. In addition to the induction training, annual on-line training is provided to all inspectors.
- 24. The CB assigns the operators to be visited to inspectors based on their background, training and absence of any conflict of interest. All established inspectors have to be supervised at least once every four years by either senior inspectors (approved for this task by the HQ) or by the Quality Manager. In addition, all inspection reports are supervised by certifiers at the HQ. The results of such evaluations are recorded and where recurrent shortcomings are noted, this is notified to the branch office to be taken into account for the next training session. The audit team reviewed data related to the number of staff available in a number of non-EU countries and noted that the workload allocated to inspectors is reasonable.
- 25. The audit team reviewed a number of files pertaining to new operators under contract. In all cases, the CB requested all necessary information from the previous CB by whom the operator had been controlled, including the previous inspection reports. The manner in which the CB handled such files and the measures taken by the CB after carrying out the inspections was considered satisfactory by the audit team. For example, at the time of the audit, several operators had been suspended as they had been unable to implement effective corrective measures to address the shortcomings detected by the CB inspectors.

- 26. The CB HQ does not have an up-to date overview of the activities carried out in Turkey as well as in other non-EU countries where it operates, which prevents the CB to react as necessary. At the time of the audit, the CB HQ was not in a position to demonstrate that all planned inspections had taken place and that all necessary operators' information is taken into account for the preparation of the inspections by the branch offices.
- 27. Although the number of additional unannounced controls is adequate, the risk assessment as designed and implemented by the CB does not serve as a good basis for

- the selection of operators for such controls. In addition, these controls are not always planned at the most suitable time according to the risk profile of operators.
- 28. Appropriate staff resources are allocated for the controls of operators and measures to ensure adequate performance of inspectors and the absence of any conflict of interest are in place and applied.

## 5.4.2 Off-farm input verification system

# Findings.

- 29. According to the CB standards, operators are responsible for using off-farm inputs containing only substances listed in the Annexes to the EU Regulations. Operators have to declare all off-farm inputs that they intend to use when submitting the OSP before the inspections take place. When new products are used, the CB has to evaluate their adequacy. Although conformity assessments issued by third parties are accepted by the CB, in practice this is used as a reference only and the CB takes full responsibility for evaluating the new products.
- 30. The audit team was shown a list of substances which have been subject to evaluation by the CB. The inspectors met by the audit team were aware of this list, which is used during the inspections at operators. In the event that inspectors encounter new products not included in the list or not known to them, they have to gather all relevant information for a decision to be taken by the HQ.

#### Conclusions

31. The CB applies adequately its production rules on off-farm input products, including adequate verification during the inspections at operators.

## 5.4.3 Handling of derogations and exemptions

- 32. According to the information provided by the CB in the most recent annual report submitted to the COM, the derogations most frequently granted by the CB relate to the use of conventional seeds and the retroactive recognition of a previous period as part of the conversion period. These derogations are granted by the CB HQ for all non-EU countries where the CB operates, including Turkey.
- 33. The audit team reviewed a number of files related to the two types of derogation mentioned in the previous paragraph. The audit team noted that the CB does not have a documented procedure describing how to apply for and grant such derogation. Operators are not requested to submit a separate application and the request can be made when submitting the OSP. They have to submit statements from three different suppliers in the

relevant country declaring that the seed requested by the operator was not available in organic form. In addition, a statement from the branch office is also needed to confirm the lack of availability of the seeds in question. Inspectors have to confirm during the inspections that the seeds used by operators were not treated with plant protection products (PPPs).

- 34. However, the CB does not have a procedure in place in order to handle the granting of such derogations. OSPs can be submitted at any time before inspections and the CB does not keep records to demonstrate that the derogations were granted before the sowing of the seeds, which is not in line with Article 45 (6) of Regulation (EC) No 889/2008. In addition, the audit team noted that in some cases, the CB granted the derogation without having all necessary information to confirm operators' compliance with the requirements in Article 45(5)(b) of the same Regulation. In two cases, the statements from the suppliers did not refer to the same seed varieties requested by the operators and there were no official statements from the branch offices confirming the unavailability of the seed in the country, as required by Section 2.6.3 of the CB standards.
- 35. As regards the retroactive recognition of the conversion period, the files reviewed by the audit team demonstrated that the CB overall granted the derogations according to its procedures. Operators may apply at the time of signing the contracts, and in this case a separate inspection may take place which may include the taking of soil samples. When the request is made by operators in subsequent years, it can be incorporated into the inspection report. In all cases, the CB requires operators to submit a number of documents proving adequate management of the land in the three previous years. The most recurrent document submitted by operators was an official certificate by the official department of agriculture, confirming that the land was not cultivated or that no off-farm inputs were used in the three previous years.
- 36. However, the audit team noted that in one case, the CB HQ granted a derogation to a PG in Turkey without having all the necessary information. The branch office had only partially translated the certificate issued by the local department of agriculture, which referred to one parcel having been cultivated in the previous years. The CB HQ accepted this finding and stated that from now on they would require that the entire document is translated by the branch offices.

## **Conclusions**

37. The CB lacks documented procedures for the granting of derogations for the use of conventional seeds. The lack of records on the decision-making process means that the CB cannot demonstrate that such derogations are granted before seeds are sown. In addition, the CB may grant derogations without proper verification of the fulfilment of the conditions by operators.

## 5.4.4 Sampling

- 38. The CB implements an annual sampling programme with the aim of detecting the use of substances not authorized in organic production. The number of samples to be taken must be at least equal to 5% of the number of operators under contract in all the countries where the CB operates. The audit team confirmed that the number of samples taken by the CB largely exceeds the minimum numbers required by its standards.
- 39. In particular, a large number of samples are taken at individual members of PGs. This was considered by the audit team as a good practice (e.g. in a PG with several hundred members, the CB took samples from 113 members, which increases the likelihood of detecting any use of unauthorized substances). Samples are taken from individual members and combined into a composite sample which is sent to the laboratory. The audit team raised its concerns in some cases where the composite sample was made by using samples taken from up to 5-7 growers, with the risk that a PPP used by one of the growers could not be detected because of a potential "dilution" effect. The CB showed examples where the composite sample was made from less individual samples. The CB also stated that the fact that some of the composite samples taken showed presence of PPPs is an indication that this manner of sampling is effective.
- 40. The CB has documented procedures in place which serve as guidance for the inspectors for taking, preserving and sending the samples to the laboratories. The CB has a list of accredited laboratories to which the samples may be submitted, depending on the scope of accreditation. The audit team reviewed a number of files and confirmed that all laboratories used had adequate scope for the tests required by the CB. The choice of substances to be analysed for depends on the risk profile of the operators and the specific risks of the non-EU countries. The CB usually requests screening methods for the detection of PPPs but may also request the laboratories to test for substances that can only be detected by using single-residue methods (e.g. glyphosate).
- 41. The CB HQ decides on the minimum number of samples to be taken among the different categories of risk. The selection of the operators to be sampled is made by the branch offices. The audit team noted that samples are overall taken in a moment of the year where growers may use off-farm inputs such as fertilizers and PPPs.
- 42. However, most samples are taken during the announced inspections (all 2017 unannounced inspections were planned in the last quarter as explained in paragraph 22). This limits the effectiveness of the sampling, as operators know some weeks in advance the exact timing when the inspections will take place. An operator willing to use an unauthorized substance may adapt the timing of use accordingly, thus reducing the likelihood of detection by the CB. This could explain the systematic discrepancy between the analytical results obtained from samples taken by the CB in some non-EU countries, including Turkey (which showed low presence of unauthorized PPPs) and

- from samples taken by EU MSs from products coming from the same non-EU countries (which showed high presence of unauthorised PPPs).
- 43. The audit team observed sample-taking at one processor and noted that the inspector followed the CB sampling guidance. Sealed, identified bags were used as well as cooling boxes with ice-packs for a proper preservation of samples.

44. The CB has appropriate sampling procedures in place taking appropriately into account the results of risk assessment. A large number of samples for the detection of unauthorized products are taken by the CB. However, the fact that samples are taken mainly during the announced inspections limits the effectiveness of the sampling.

#### 5.5 LIST OF ORGANIC OPERATORS

## **Legal Requirements**

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

## **Findings**

- 45. The CB maintains a list of operators on its website which is regularly updated. The audit team noted that the list has been updated three times in the last 4 months. It contains all relevant information required by Article 11(3)(e) of Regulation (EC) No 1235/2008.
- 46. However, the audit team noted that the list also includes the operators whose contracts had been cancelled, and therefore who were no longer under control of the CB. This is not in line with the above mentioned article. The CB Quality Manager explained that this was a misunderstanding and that operators whose contracts had been cancelled will be removed from the list.

## **Conclusions**

47. The CB publishes on its internet website an updated list of operators subject to the control system. However, at the time of the audit this also included operators whose contracts have been cancelled, which is not in line with EU Regulations.

#### 5.6 CONTROLS ON ORGANIC PRODUCTION

#### **Legal Requirements**

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

Articles 23, 24 and 25 of Regulation (EC) No 834/2007.

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

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

Codex Alimentarius guidelines CAC/GL 32-1999 (Guidelines for the production, processing, labelling and marketing of organically produced foods), in particular Annex 3.

## **Findings**

## 5.6.1 Controls of operators

- 48. The audit team observed inspections carried out by the CB in Turkey. They were carried out at one company who has several processing plants and agricultural units in the country. For the purpose of controls, the CB considers these as separate certificate holders and issues individual certificates for each of these. Each agricultural unit is a project where a number of growers form part, subject to a single management by the certificate holder. In Turkey, the national regulation does not permit the CBs to inspect a sample of individual members in PGs. Therefore, the CB has to inspect 100% of the PG members, and keep records of the control activities carried out to them all.
- 49. The CB inspectors use a comprehensive report template which also serves as a checklist where all relevant requirements of the CB standards are contained. The template also contains information which is used for the certifiers to evaluate the performance of the inspectors (e.g. whether the inspection was carried out at processors at a time where organic processing took place). In addition to the inspection report, inspectors may attach a number of supporting documents (e.g. processing sheets, copies of invoices, analytical results of samples taken by operators). This is done to certifiers to take decisions based on objective evidence and not only on the judgments made by inspectors during the inspection.
- 50. The inspections observed by the audit team were overall adequate. The inspectors were knowledgeable and experienced, and were familiar with the CB procedures. The inspections covered most of the requirements of the CB standards. A representative number of documents were checked in order to confirm the accuracy of the records kept by operators. In the case of growers, the inspectors have to calculate an estimate of harvest for all plots (both in organic and in conversion status) and to record this estimation in the inspection sheet. These figures are then transposed to the plot list managed by the CB branch office, which will be the basis for the issuance of Certificates of Inspection for trade and export by the CB HQ (see paragraph 62). The plot list contains all relevant data of the individual farmers' plots, including size, status of the land and maximum potential production.
- 51. However, the audit team noted some systematic weaknesses in the performance of inspections. In the case of the inspections to growers, the visited sites had established a "buffer zone" to separate the conventional neighboring plots from their organic production. The products harvested from the trees used as buffer zones cannot be sent to

the associated processing plan. These precautionary measures were not described in the OSPs submitted by operators. Even if the inspector verified that the buffer zones had been harvested on different days than the rest of the organic plots, this verification including the quantities harvested were not recorded in the inspection reports of the individual growers. Nor was this information used to correct the missing information in the OSPs or deducted from the maximum quantities that can be harvested as organic in the plot list. This is not in line with Section 2.2 of D-EN\_001 of the CB standards, which requires the inspectors to assess all agricultural fields and crops.

- 52. The inspector also checked the records kept by growers with the names and quantities of fertilizers and PPPs used during the past year. The checks included the verification of the amounts of substances used (e.g. copper). However, the CB does not require the operators to keep records giving the reason of use of such off-farm inputs, which is not in line with Article 72 of Regulation (EC) 889/2008.
- 53. In the case of inspection to processors, the audit team noted that the inspection focused exclusively on the processing of organic products. No records were checked with regard to products harvested from non-organic plots. Although a comprehensive calculation of the input-output calculation was undertaken by the inspector, this only covered the organic processed products and the CB did not verify that products harvested from the non-organic plots and the quantities from buffer zones had not been sold as organic. This is not in line with Sections 2.2. and 2.3 of D-EN\_004 of the CB standards, which require the inspectors to verify the separation and verify all information of products from organic and non-organic production.

## 5.6.2 Labelling

- 54. The CB does not require operators to submit individual labels for approval. In cases where operators do so on a voluntary basis, the CB HQ evaluates the adequacy of the label and gives its approval. The usual case is that CB approves a system for issuance of labels by operators. During the inspection at the processor, the audit team noted that the inspector checked the models of labels to be applied on the products, which were in conformity with EU Regulations. The CB requires operators to use its code in the case that they are the operators carrying out the last preparation operation of the product, which is in line with EU Regulations.
- 55. However, the CB could not provide any evidence of verification of the final label applied on the final product for export, to confirm that it is the same label as in the model. Therefore, the CB is not verifying whether the system for issuance of labels is adequately implemented by operators.

#### 5.6.3 Traceability

56. The quality management system applied by the operator visited allowed for the traceability of any processed batch to a group of individual members which supplied the relevant batch. In the event of a problem detected from a given batch, the CB can trace

- back the processed product back to the group of growers who participated in the compilation of the batch.
- 57. During the inspection observed, the inspector sufficiently checked that all raw materials, intermediate products being processed and final products in store were adequately identified

- 58. The CB overall effectively applies the control measures in order to ensure that organic products imported from Turkey to the EU have been produced in accordance with production rules equivalent to those in the EU. However, the estimation of the maximum organic quantities that can be produced is not fully accurate and inspections at processors focus exclusively on organic products. This undermines the effectiveness of the control systems and may result in non-organic products being sold as organic.
- 59. Although the CB is aware of the models of labels to be applied by operators on the final products exported to the EU, no verification is carried out by the CB to confirm that the correct label models are applied in practice.
- 60. The implementation of the control measures by the CB allows for the traceability of each organic product at all stages of production, preparation and distribution.

### 5.7 EXPORT CERTIFICATION SYSTEM

## **Legal Requirements**

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

- 61. According to Turkish requirements, all transactions of organic products between operators must be covered by a transaction certificate. For the issuance of these certificates, operators have to submit supporting documents to their CBs (e.g. invoices of purchases and sales, proof of organic origin of products purchased, processing sheets, etc). In this manner, the CB is aware of the origin of all quantities purchased by its operators from operators under control of other CBs. This also allows the CB to know all quantities sold by its operators to destinations other than the EU market.
- 62. Transaction certificates are not needed for the issuance of Certificates of Inspection when all operators involved in the preparation of the consignment for export are under control of the CB itself. As described in paragraph 38, the CB keeps records (in an excel sheet) of all quantities which can be produced by individual growers. When exporters apply for a Certificate of Inspection to be issued, they have to submit the processing sheets and the traceability documents tracing back the processed products back to the

- growers which produced the raw materials. The quantities delivered by each grower are deducted from the list in the excel sheet.
- 63. However, the basis to calculate the quantities which can be certified is the plot list referred to in paragraph 51, which is not fully accurate as it includes all quantities that can be produced, also including quantities from buffer zones which cannot be sold as organic.
- 64. At the time of the audit, the CB had, at its own initiative, modified the document used for implementing the increased control measures decided by the COM for consignments originating from Ukraine and the neighbouring countries. The measures are now to be applied also for consignments originating from China and Turkey. This means that the CB has to take samples from each consignment from products indicated in the guidance issued by the COM (mainly cereal grains and oil seeds) for the detection of unauthorized PPPs. This was considered as a good practice by the audit team, as it addresses the risk that consignments originating from Ukraine and neighbouring countries are not subject to the increased control measures when they are exported to the EU via Turkey. However, the procedure does not include the possibility of taking samples from products other than those referred to in the increased control measures, which are not representative of the production in Turkey.
- 65. At the CB had not yet implemented a risk assessment to decide to carry out physical checks on the consignments exported to the EU from all the non-EU countries where it operates, including Turkey. This is not in line with Article 13(4) of Regulation (EC) No 1235/2008. The CB stated that sampling may be decided as a follow-up measure after detection of a major NC or when an operator has been involved in notifications of irregularities several times. However, this measure had not been applied in the case of one exporter reviewed by the audit team, who had been notified several times in 2016 and in 2017. Although the branch office showed to the audit team some cases where samples had been taken in 2017 from consignments to be exported to the EU, the lack of a procedure does not ensure that physical checks are systematically carried out based on a risk assessment.

66. Although the system for issuing Certificates of Inspection for export to the EU is overall adequate, the estimation of maximum quantities that can be certified for export is not fully accurate. In addition, the CB has not yet established a procedure to decide on physical checks to be carried out on consignments for export to the EU. These shortcomings reduce the effectiveness of the system in place.

#### 5.8 IRREGULARITIES AND FOLLOW-UP OF EU NOTIFICATIONS

## **Legal Requirements**

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

- 67. The CB has established definitions of what minor and major irregularities are and what the consequences are for each case. For example, when inspectors find minor deviations in the operators' compliance which do not endanger the organic status of the product, certificates can be issued by the CB and the corrective actions proposed by operators should be followed up during the next inspection. When the organic status of the product may be at risk, certification can only be issued after verification of the fulfilment of the requirement by operators. In the case that the organic status of the product is already affected, the CB cannot issue certification for the products affected. In more severe cases or where a major non-conformity is repeated, the certification can be suspended for the entire operation.
- 68. The CB has a draft document where concrete measures are described in cases of operators' non-compliance with specific requirements of the CB standards. This document is intended as guidance for inspectors and is in the process of being developed. The audit team noted that in some cases the measures were detailed but in other cases (e.g. when operators used conventional seeds without having been granted derogation and/or when there was organic seed available) there was not a description of the consequence of the non-conformity. Nevertheless, the files reviewed by the audit team showed that the CB took adequate measures when severe irregularities were detected. At the time of the present audit, some operators were suspended by the CB following the detection of severe irregularities in the first inspection after the signing of the contracts.
- 69. The CB has a documented procedure to decide on measures to be taken when the analytical results show the presence of unauthorized PPPs. The document is not in line with EU Regulations, as actions are only foreseen when the PPP is detected above 0.001 ppm. However, in practice this procedure is not followed by the CB, as any presence of unauthorized PPP which is reliably detected by the laboratories (above the quantification limit) leads to actions taken by the CB. In the case of Turkey, the national requirements require that any presence of PPP reported by the laboratory must be necessarily followed-up. In the files reviewed by the audit team, the CB used the counter-sample to confirm the presence of the PPPs. All operators involved in the cases were requested to provide further information and the CB evaluated the circumstances of each particular case. Where the presence of the PPP could not be explained by spray-drift from conventional neighbours or for the long-term presence of the PPP in the soil, the CB de-

- certified the affected batches of products and/or downgraded the plots where the products have been farmed to undergo in-conversion period.
- 70. However, in the cases where measures were taken against the operators, this information was not fed back into the risk assessment. For example, one operator who was found of committing fraud in one non-EU country did not have its risk category increased and remained as medium-risk operator for the following year's planning.
- 71. The audit team reviewed a number of files relating to the follow-up of notifications made by EU MS in the Organic Farming Information System (OFIS), and noted that the actions taken by the CB were overall adequate. In one case the CB focused only on one of the potential root causes of the contamination (old batch of tea kept in the premises of a processor) and did not follow the other possible source of contamination (new batch of tea which was mixed with the old one). In all the other cases, the measures taken were considered to be adequate. These involved carrying out additional inspections and/or the taking of additional samples where necessary, as well of de-certification of the involved batches.
- 72. The CB has significantly improved its compliance with the deadlines for submitting the replies into OFIS. The improvement is explained as the CB has a specific procedure and had contracted two people who are responsible since early 2017 for the management of the OFIS cases notified to the CB. The audit team reviewed a number of files and noted that the majority of the cases notified in the previous 6 months had been replied to either in the 30 days deadline or slightly above this deadline.

- 73. Although the catalogue of measures to be applied in cases of severe irregularities has not been fully implemented by the CB yet, the measures applied in practice by the CB are overall effective.
- 74. The CB has modified its procedures to follow-up OFIS notifications with the result that actions taken are overall adequate and compliance with the deadlines for submitting the replies into OFIS have been significantly improved.

## **6 OVERALL CONCLUSIONS**

The CB overall applies the production rules and control measures for which it was recognised by the European Commission for the purpose of equivalence. Annual inspections are planned at the most suitable time and additional inspections are unannounced. The inspections observed were overall effective. The CB takes a large number of samples and follows-up all cases where the analytical results identify the presence of substances not authorised in organic production. When non-compliance is confirmed, adequate enforcement measures are generally applied by the CB.

However, the effectiveness of the control system applied by the CB is reduced as additional inspections and sampling at operators and physical checks on consignments for export to the

EU are not always planned according to the risk profile of the operators. Moreover, the inspections focus only on the organic production and processing and neglect the management of the non-organic activity of the operators.

The delay in the feedback provided by the branch offices on the control activities carried out does not permit the CB HQ to have a proper overview of their implementation and therefore the CB cannot react as necessary to guarantee that all activities are implemented as planned. The CB was aware of this problem and, at the time of the audit, a new database management and certification system was being introduced to improve the situation.

## 7 CLOSING MEETING

A closing meeting was held on 30 November at the Turkish branch office with representatives of the CB. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit.

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

#### 8 RECOMMENDATIONS

No.	Recommendation
1.	Ensure that any changes in the measures applied by the CB are notified to the Commission thereof, as required by Article 12(1)(a) of Regulation (EC) No 1235/2008 and that accurate information on the control activities is submitted to the Commission in the annual report referred to in Article 12(1)(b) of the same Regulation.  This recommendation is based upon conclusion No 4  Associated finding No 2 and 15
2.	<ul> <li>Ensure that the management of the information on the activities carried out worldwide allows for the CB to guarantee that:</li> <li>All planned controls are carried out, as required by Articles 65(1) and 65(4) of Regulation (EC) No 889/2008;</li> <li>All information necessary for the preparation of the audits is received before a date decided by the CB, including the information referred to in Article 71 of Regulation (EC) No 889/2008 as well in Article 63(1) of the same Regulation.</li> <li>This recommendation is based upon conclusion No 26</li> <li>Associated findings No 7, 14, 17, 18 and 51</li> </ul>
3.	Ensure that the risk assessment implemented by the CB serves as a good basis for determining the intensity of the announced and unannounced inspections,

	as required by Article 92c(2)(a) of Regulation (EC) No 889/2008, and in particular that all compulsory criteria referred to in Article 65(4) of the same Regulation are taken into account for the risk assessment.  This recommendation is based upon conclusion No 27  Associated finding No 20
4.	<ul> <li>Ensure that:</li> <li>additional control visits carried out in accordance with Article 65(4) of Regulation (EC) No 889/2008 of at least 10 % of operators under contract in accordance with the risk category are performed, as required by Article 92c(2)(b) of the same Regulation;</li> <li>the selection of operators to be submitted to unannounced inspections and visits is determined on the basis of the risk analysis and that these are planned according to the level of risk, as required by Article 92c(2)(d) of the same Regulation.</li> </ul>
	This recommendation is based upon conclusion No 27  Associated findings No 21 and 22
5.	Ensure that derogations are only granted to operators in line with documented procedures and only after all necessary information has been verified by the CB, to ensure the fulfilment of all conditions by operators.  This recommendation is based upon conclusion No 37  Associated findings No 34 and 36
6.	Ensure that the planning of samples includes taking samples during unannounced controls as appropriate, according to the risk profile of operators, in order to comply with Article 65(2) of Regulation (EC) No 889/2008.  This recommendation is based upon conclusion No 44  Associated finding No 42
7.	Ensure that the list of operators contains the information required in Article 11(3) of Regulation (EC) No 1235/2008, in particular that only operators under contract are listed.  This recommendation is based upon conclusion No 47
	Associated finding No 46

8.	Ensure that inspections are effective and cover all requirements of the CB standards, and in particular that
	<ul> <li>Inspectors record the results of assessment of the precautionary measures applied by the operators in line with Section 2.2. of D-EN_001 of the CB standards;</li> <li>Inspectors verify records on the reason for use of fertilizers and PPPs, in line with Article 72 of Regulation (EC) No 889/2008;</li> <li>Inspections cover the handling of non-organic products by operators, as required by Sections 2.2. and 2.3 of D-EN_004 of the CB standards.</li> </ul>
	This recommendation is based upon conclusion No 58
	Associated findings No 50, 51 and 52
9.	Ensure verification of the labels applied by operators on the final product for export, to guarantee that only labels complaining with Article 24 of Regulation (EC) are used by operators.
	This recommendation is based upon conclusion No 59
	Associated finding No 55
10.	Ensure that documented risk assessment is implemented to decide on the physical checks carried out to the consignments for export to the EU, as required by Article 13 (4) of Regulation (EC) No 1235/2008.
	This recommendation is based upon conclusion No 66
	Associated finding 63, 64 and 65

# ANNEX 1 – LEGAL REFERENCES

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

# ANNEX 2: STANDARDS QUOTED IN THIS REPORT

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