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**DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY**

Health and food audits and analysis

**DG(SANTE) 2018-6396**

**FINAL REPORT OF AN AUDIT**  
**CARRIED OUT**  
**FROM 12 JUNE 2018 TO 20 JUNE 2018**  
**IN ORDER TO**  
**EVALUATE THE IMPLEMENTATION OF THE ORGANIC PRODUCTION**  
**STANDARDS AND CONTROL MEASURES APPLIED BY A RECOGNISED CONTROL**  
**BODY OPERATING IN UKRAINE**

### ***Executive Summary***

*This report describes the outcome of a DG Health and Food Safety audit carried out between 12 and 20 June 2018 in order to evaluate the application of the organic production standards and control measures applied by a recognised Control Body (CB) in Ukraine.*

*The CB had taken measures to address the recommendations in the previous audit report. Overall, the CB is very active in relation to sampling and undertaking additional unannounced control of operators, significantly surpassing the minimum requirements. It fulfils its obligations relating to the Guidelines on additional controls on products originating from Ukraine, Kazakhstan and Russian Federation and destined for export to the EU. The investigations of notifications from the Organic Farming Information System were undertaken in a satisfactory manner.*

*At the time of the audit, the CB was unable to demonstrate the state of implementation of its control plan resulting in uncertainty about the exact frequency of controls at the riskiest operators as well as the suitability of the timing (seasonality) of inspections. This situation was partially mitigated by the large number of controls carried out by the CB. Regarding investigations by the CB in response to the detection of unauthorised substances, no on-site visit takes place to investigate suspected non-compliances. This is a significant weakness.*

*The CB frequently used estimated harvest yields in calculations relating to input / output which could negatively influence the reliability of the certificates of inspection. In relation to enforcement, non-compliances were not rectified in a timely manner and enforcement actions were not dissuasive leading to many situations of recurrent non-compliances existing over a long period of time.*

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

## Table of Contents

1	Introduction .....	1
2	Objectives and scope .....	1
3	Legal Basis .....	2
4	Background .....	2
5	Findings and Conclusions .....	2
5.1	Organic Production rules and Control measures .....	2
5.2	Surveillance and Re-Assessment .....	3
5.3	National Authorities and National Legal Requirements .....	3
5.4	Structure and Organisation of the Control System .....	4
5.4.1	Organisation and planning of controls .....	4
5.4.2	Off-farm input verification system .....	7
5.4.3	Handling of derogations and exemptions .....	8
5.4.4	Sampling .....	10
5.5	List of Organic Operators .....	11
5.6	Controls on Organic Production .....	11
5.6.1	Controls of operators .....	12
5.6.2	Traceability and input / output calculations .....	13
5.7	Export certification system .....	14
5.8	Irregularities and Follow-up of EU notifications .....	15
6	Overall Conclusions .....	18
7	Closing Meeting .....	18
8	Recommendations .....	19

## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AB	Accreditation Body
CA(s)	Competent authority(ies)
CB(s)	Control Body(ies)
CoI(s)	Certificate(s) of Inspection
DG AGRI	Directorate-General for Agriculture and Rural Development
EC	European Community
EU	European Union
HQ	Headquarters
ISO/IEC	International Organisation for Standardization/International Electrochemical Commission
MS	Member State(s)
OFIS	Organic farming information system
OS	Organic Standard
PPP	Plant Protection Products

## 1 INTRODUCTION

The audit took place from 12 to 20 June 2018 in order to evaluate the application of the organic production standards and control measures applied by a recognised control body (CB). The CB was selected for the audit by Directorate-General for Agriculture and Rural Development (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) and visits to operators certified by the CB in Ukraine.

An opening meeting was held on 12 June 2018 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 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 Commission as competent to carry out controls for the purpose of equivalence.
- to verify that the control measures recognised by the Commission as having equivalent effectiveness to that of the EU have been permanently and effectively applied by the CB.
- to follow up recommendations raised in the report 2015-7409.

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

Visits/meetings	Days	Comments
<b>Control Body</b>		
HQ	3.5	Opening and closing meeting and day to preparations for the closing meeting.
<b>On-Site-Visits</b>		
Visit 1	1.0	Farmer growing (legumes, cereals and oil crops)
Visit 2	1.0	Processor (cereals)
Visit 3	1.0	Farmer (fruit 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 Commission for applying, in non-EU countries, equivalent production rules as foreseen in Titles III and IV of Regulation (EC) No 834/2007 and control measures having equivalent effectiveness to that of the EU (Title V of Regulation (EC) No 834/2007). Consequently, the CB is included in the list of recognised CBs established in Annex IV to Regulation (EC) No 1235/2008. The audit focused on the CB's activities in the Ukraine.

The audit was undertaken as an input to the supervision of the CB by DG AGRI. The CB is recognised by DG AGRI for the purpose of equivalence in Ukraine. The CB was selected for the audit by DG AGRI based on a risk assessment. This was the second audit to this CB in Ukraine on organic production.

### **5 FINDINGS AND CONCLUSIONS**

#### **5.1 ORGANIC PRODUCTION RULES AND CONTROL MEASURES**

##### **Legal requirements**

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

##### **Findings**

1. The CB applies the most recent version (17 May 2017) of their production rules (here after referred to as the organic standard (OS)) which was notified to the Commission on 22 June 2017, which is in line with Article 12(1)(a) of Regulation (EC) No 1235/2008.

### **Conclusions on organic production rules and control measures**

2. The CB fulfils its obligation to notify the Commission of any changes that are made to the OS applied by the CB.

## **5.2 SURVEILLANCE AND RE-ASSESSMENT**

### **Legal requirements**

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

### **Findings**

3. The CB is accredited to the International Organisation for Standardization (ISO)/ International Electrotechnical Commission (IEC) 17065 and is subject to annual surveillance audits by an accreditation body (AB) in line with Article 33(3) of Council Regulation (EC) No 834/2007. The CB is re-accredited every five years. A valid certificate was presented to the audit team.
4. The most recent AB audit took place in May 2018 and a report was not available at the time of the audit. The most recent AB report available for 2017 did not identify any major non-compliances.

### **Conclusions on Surveillance and Re assessment**

5. The CB undergoes regular on-the-spot evaluation/surveillance/multi-annual re-assessment of its activity 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**

6. The CB has notified its activity to the national authorities of the countries where the CB is operating in.
7. The law on the production and circulation of organic agricultural products and raw materials No 425-VII came into force in January 2014 in Ukraine. The relevant implementing legislation is not yet in force.
8. The CB regularly reports to the Ministry of Agriculture in Ukraine on the number of operators and the surface areas certified as organic by the CB.

9. The law also requires the accreditation of the CB in Ukraine. An application had been submitted to the national AB which remains pending since 2015 by the Ministry of Economic Development and Trade of Ukraine.
10. In relation to suppliers of organic seed, there is a requirement in Ukrainian law, to be registered in the State Register of Seed and Vegetative Propagative Material Producers. In addition, all organic seed suppliers are required to be certified by a CB.

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

11. The CB fulfils its obligation and, where required, has notified its activities to the authorities of Ukraine. The CB takes measures in order to respect the national requirements imposed on it.

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

#### **Legal requirements**

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

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

#### *5.4.1 Organisation and planning of controls*

#### **Findings**

12. Since the previous audit in 2015, this CB has expanded significantly. There have been changes in the organigram with an increased number of people working for the CB. The staff consists of inspectors, evaluators and eight newly created coordinators. The CB has doubled the number of operators it controls. Two additional regional offices have also been opened. Staff at the HQ are assigned to handle the activities of the other regions of Ukraine. There are two part-time inspectors in Belarus. For all other countries that the CB is listed for, inspectors from the HQ carry out control tasks. The main certification decisions are undertaken at the HQ.
13. In order to guarantee satisfactory communications between the various offices and inspection and certification personnel, the administrative structure has changed from a system overseen by one person to a system whereby eight group coordinators are responsible for eight different areas of activity; crops, new and domestic market, arable crops for export, horticulture, wild collection, beekeeping, complex processing and inputs. The detailed functions of these eight coordinators are described in the Document 'I-OT-3.1001 work of the certification department'.



### *Recruitment and training, evaluation of inspectors.*

14. At the time of the audit, the CB had a sufficient number of staff to carry out on-site inspections as well as office based evaluators responsible for reviewing inspection reports. All inspection reports are reviewed by an evaluator who cannot be the person who undertakes the inspections. In the event that an evaluator proposes changes to an inspection report, a notification is sent to the inspector and any changes must be confirmed by the inspector. The CB confirmed that none of its personnel had participated in a 'Better Training for Safer Food' training programme on Organic Production to-date, but would be interested in having the opportunity to do so.
15. New inspectors undergo theoretical and practical training on organic rules. In general, a new inspector accompanies an experienced inspector for ten inspections (five passive and five with more active involvement) and is shadowed by an experienced inspector for an additional five inspections. Evaluators are required to perform five passive inspections and five evaluations under the supervision of an experienced specialist.
16. All inspectors/evaluators undergo training annually. Experienced inspectors are trained in new product categories in order to ensure sufficient availability of resources. New inspectors as well as inspectors who were trained for new product categories are evaluated by senior inspectors.
17. The CB has implemented an online training platform. This is a comprehensive electronic learning system, whereby staff logins, timing and test results can be monitored, providing an overview of the training followed and completed by each inspector. This provides a 24/7 training resource to CB staff. In addition, the CB organises quarterly internal meetings where training is provided on specific topics which are attended by most of the staff. In 2017, approximately 15 training sessions took place. However, there was no signed participation list available but only an electronic record of presence.
18. To ensure timely completion of control reports, inspectors usually have a deadline of two weeks to submit their reports. If reports are submitted within 15 days inspectors are awarded a bonus payment and if reports are delayed and fail to meet the two weeks deadline, no bonus payment is applied. If more than 30 days elapse before a report is uploaded penalties are applied. Inspectors on freelance contracts are paid monthly based on the number of inspection reports uploaded in the CB database

### *Conflict of interest*

19. All staff and Committee members sign declarations relating to conflict of interest annually. The CB confirmed that there are sufficient numbers of inspectors and evaluators and their academic backgrounds range from, agronomists, food technologists, biologists and veterinarians. There is a Supervisory Board which is responsible for ensuring the impartiality of the CB activities through annual meetings, as well as undertaking assessment of impartiality risks.

*Risk assessment, planning of controls and timing of inspections*

20. At the time of the previous audit, a procedure (II.3-PR-02) for the risk categorisation of operators was in existence however, this had not been documented (Recommendation No 3 audit report 2015/7409). During this audit it was confirmed that this procedure is in place and was now being implemented. Part of the procedure consists of the use of an electronic tool used for a calculation of the risk value for each operator to determine a risk categorisation.
21. There are three risk categories for operators, high risk, medium risk and low risk. Each year the CB reviews the risk categorisation of each operator. The audit team noted that an operator is automatically categorised as high risk if it was the subject of an organic farming information system (OFIS) notification or the presence of an unauthorised substance was detected. In addition, previous non-compliances and mixed production of organic and conventional products are factored in. However, the volume of production is not directly assessed as part of this risk categorisation.
22. At the time of the audit, the CB could not demonstrate the overall number of high risk operators. However, after the audit this information was provided by the CB which illustrated that 8.5% of operators were categorised as high risk, 18.5% were categorised as medium risk, and 73% were categorised as low risk operators. All operators are subject to an annual control. In addition, high risk operators receive at least two additional controls and one sampling while medium risk operators receive at least one additional control.
23. The audit team noted that, according to the data supplied by the CB, it had complied with and even surpassed the requirement that at least 10% of operators are subject to unannounced controls per year and 5% of operators are selected for laboratory testing for the presence of non-authorised substances. In relation to additional inspections, more than 50% of operators were subject to such inspections. Regarding sampling, the number of samples taken exceeded the total number of operators. However, this data from the CB also included the additional official controls on products originating from Ukraine, Kazakhstan and Russian Federation as per the EU Guidelines agreed in November 2016.
24. The audit team had difficulty to obtain a clear overview of the implementation status of the 2018 control plan at the time of the audit. One contributory factor for this lack of clarity may have been the introduction of a new organisational structure. Originally there was one individual overseeing the data relating to all operators, however since the beginning of 2018 this activity has been distributed amongst eight co-ordinators, each co-ordinator dealing with the implementation of controls in the eight separate areas of activity.
25. Consequently it was impossible to establish if inspections or samplings were undertaken at the appropriate frequency, the appropriate time (seasonality) and whether such activities were targeting the correct operators, particularly as the control activities

undertaken as part of this audit were not always consistent with the CB's risk approach. For example, the audit team visited a medium sized operator producing fruit which was categorised as a low risk operator. However, this low risk operator was subject to an additional control and a sampling exercise contrary the overall risk strategy described by the CB.

26. The CB now has two group certifications in place, one of which is in the conversion phase of their application to becoming organic operators and the second is under evaluation by the CB as it has transferred from another CB. Group certifications are automatically categorised as high risk.

#### *New operators previously certified by other CBs*

27. There is a procedure (IL-PL-05) in place for handling the transfer of an operator from another CB. The CB confirmed that four operators had transferred from other CBs to this CB. In the past year, approximately 20 operators had left this CB and moved to other CBs. Evidence of file transfers was shown to the audit team.

#### **Conclusions on organisation and planning of controls**

28. Appropriate staff resources are allocated for the controls of operators and adequate measures to ensure the absence of conflict of interest are in place and applied.
29. Although the CB now has a documented risk categorisation methodology, some weaknesses still remain as the risk relating to volume of production is not taken into account which reduces the efficiency of the control measure to ensure that the CB's standard rules are effectively achieved. This weakness is mitigated to a certain degree due to the significant numbers of additional inspections and high sampling rate undertaken by the CB.
30. There are inconsistencies between the CB's description of its risk categorisation of operators and required control activities and what is implemented in practice.
31. The CB did not have easy access to the state of implementation of their 2018 control plan at the time of the audit.

#### *5.4.2 Off-farm input verification system*

### **Findings**

#### *Off-farm input verification system*

32. Coordinator No 8 is responsible for the handling of all off-farm inputs for this CB. The relevant procedure in place is 'II.3-PR.-04\_Procedure \_inputs approval and certification'. The main off-farm inputs are fertilisers, plant protection products (PPPs) and feed materials. The CB publishes a booklet which is updated each year which contains all the permitted substances. An email with an electronic version of this publication is sent to each operator every year.

33. There is an obligation on the operator to apply to the CB for permission to use any off-farm input and this request must be approved by the CB prior to use by the operator and before bringing the substance onto the farm. If an operator requires authorisation for the use of an off-farm input not specified in the CB publication, there must be a clear justification for its need. This CB accepts off-farm inputs certified by other CBs, but carries out additional checks and may cross check with the other CB.
34. Although the operator profile should contain all records relating to off-farm inputs used by an operator, this was not the case in the two farms visited. The audit team noted that the inspector's checklist includes a point referring to off-farm inputs and the audit team verified that this action was addressed during the site visits.
35. The CB inspector observed at the fruit farm visited checked the paperwork submitted by the operator for permission to use certain inputs. The inspector asked about the source of horse manure and was informed that it came from a local racecourse, which may be inappropriate for organic production due to the potential for contamination with veterinary medicines. The inspector did not make any comment on this issue and did not verify if any evidence was available to consider it acceptable for organic production.

#### **Conclusions on off farm input verification system**

36. The CB applies its production rules on off-farm input products.
37. The CB inspectors observed generally verify the use of approved products during controls.

#### *5.4.3 Handling of derogations and exemptions*

#### **Findings**

38. Of the derogations granted by the CB in 2017, 79 % were for use of non-organic seeds, 20% related to retroactive recognition of the conversion period and less than 1 % were for non-organic ingredient in processing.
39. Since the previous audit, the CB had improved compliance with its own procedures in place for the handling of derogations relating to the use of untreated conventional seeds (II-PL-09 Policy Vegetative propagating material and seeds for cultivation in Organic Production Version 08 2017). The key change is that the CB has raised awareness amongst operators regarding the requirement to make a formal application to the CB to obtain a derogation to use conventional seeds that are not chemically treated. To facilitate compliance, the CB sends a reminder letter / email each year to ensure operators are aware of the requirements, in particular, that operators are aware that they must apply for permission to the CB before sowing any seeds. Operators must receive formal notification of a derogation being approved by the CB before they can proceed with sowing. This addresses recommendation No 5 of audit report 2015-7409.

40. The CB stated that there is a fundamental problem relating to the availability of organic seed in Ukraine, consequently derogations in this area are almost routine. In the event that the CB discovers the use of chemically treated seeds, sanctions are applied (see section 5.8).
41. The checklist that inspectors are provided with has a question which should trigger a review by the inspector when undertaking an on-site inspection to ensure that the operator obtained permission prior to the sowing of the seed. The audit team noted that this information was verified by the inspector during on-site visits.
42. In relation to derogations on retroactive conversion of land, the CB has a policy in place 'PL-001 Policy conversion period\_v4 on Retrospective Reduction of Conversion Period'. and provides a guide for inspectors, which contains a flow diagram starting with the question as to whether agricultural activity had taken place in the past three years on the territory.
43. For new operators, the field history (if any), field log and accounting documents must be carefully inspected for the application of substances which are not in compliance with organic production standards. Collection of soil / leaf samples for analysis must be required when there are any contamination risks.
44. The audit team requested information on the number of derogations relating to the retroactive shortening of the conversion period that were rejected in 2017 and the reasons for such rejections. The CB stated that there were a number of cases of rejection which included cases where the derogation was fully or partly refused. However, no register of such refused cases are recorded and the CB stated that the granting of retroactive derogations only occurs when there is sufficient evidence to justify it. This judgement is largely made on the basis of recommendations of CB inspectors from their on-site visits.
45. The audit team reviewed one case where an existing farmer with a good record was granted a full release from the whole conversion period. The CB stated that this situation is only used when additional fields are added to a farm already controlled by the CB. In this case, the operator was recommended to undertake a soil analysis as part of the decision. However, this is not obligatory. This is not in line with the CB's own standard which states that the maximum time granted in retrospective recognition is not more than 18 months.

<b>Conclusions on handling of derogations and exemptions.</b>
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| <ol style="list-style-type: none"><li>46. The CB mainly granted derogations for use of untreated conventional seeds in accordance with its production rules/procedures.</li><li>47. In relation to derogations on retrospective recognition of the conversion period, the CB does not implement its own procedure.</li></ol> |
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#### 5.4.4 Sampling

### Findings

48. The CB's sampling instruction (IL.2-WI-01 Version No 8 of May 2018) is a comprehensive document providing inspectors with clear instructions on all aspects of sampling. There are two staff members in the CB who are responsible for handling all issues related to sampling, laboratory contracts and interpretation of laboratory results. At the time of the audit, the CB had contracts with seven accredited laboratories.
49. Since the previous audit, the CB has made cool boxes available to all inspectors to preserve perishable samples during transportation which addresses recommendation No 6 (audit report 2015-7409). During site visits these cool boxes were generally used (see section 5.6.1).
50. The coordinators provide instructions to each inspector whether or not to take a sample during a specific inspection. Inspectors always have the right to sample on suspicion.. Although, the information provided in the 2017 annual report illustrates that this CB undertakes a large amount of sampling and analysis, these figures also include all sampling undertaken in relation to specific export requirements as described in the Guidelines on additional official controls on products originating from Ukraine, Kazakhstan and Russian Federation of 29 November 2016.
51. Whether the requirement that 5% of the high risk operators are subject to sampling is fulfilled is difficult to verify as the sampling strategy of the CB is not clear and there is no easy access to real time data on the implementation of the control plan. Similarly, it is difficult to confirm the extent to which sampling on suspicion was undertaken.
52. In the event that a laboratory detects the presence of an unauthorised substance from a sample taken by the CB, there is an operating procedure in place (II.3-PR-06 Operating Procedure for positive analysis) to handle such a situation. The first criterion addressed is whether the unauthorised substances level is  $<0.01\text{mg/kg}$  or  $>0.01\text{ng/kg}$  but less than the relevant maximum residue level. The procedure gives instruction for handling a first occurrence of a positive result as well as second and subsequent incidents. The sanctions prescribed for the various scenarios do not include any instruction to the CB inspector to investigate the situation on site. The CB uses the services of an EU based independent consultant to interpret the laboratory results and comment on the potential impact on the organic status of the products in question.
53. The audit team reviewed two files, one in which an unauthorised substance level of less than  $0.01\text{ mg/kg}$  was involved and one with an unauthorised substance level greater than  $0.01\text{ mg /kg}$  (see section 5.8).

### **Conclusions on sampling**

- 54. The CB has appropriate sampling procedures in place which are generally applied by the CB inspectors.
- 55. A large number of samples are taken, however the administrative systems in place do not permit a clear distinction to be made between samples taken as part of risk based controls, samples taken to comply with current EU export requirements for Ukraine and samples taken on suspicion.

## **5.5 LIST OF ORGANIC OPERATORS**

### **Legal Requirements**

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

### **Findings**

#### **List of Organic Operators**

- 56. The CB publishes, on its internet website, a list of operators in line with Article 11(3)(e) of Commission Regulation (EC) No1235/2008. At the time of the audit, this list was complete and contained all operators under the control of the CB. It also included those operators who are suspended. However, information relating to suspended or decertified operators is only accessible through an additional action and is not immediately visible. The information is updated every day in real time as this web site is connected to the CB's internal database.

### **Conclusions on list of organic Operators**

- 57. The CB publishes on its internet website, an updated list of operators subject to the control system.

## **5.6 CONTROLS ON ORGANIC PRODUCTION**

### **Legal Requirements**

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

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

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

Codex Alimentarius guidelines CAC/GL 32-1999 in particular Annex 3.

## Findings

### 5.6.1 *Controls of operators*

58. The audit team visited a large producer of crops, a medium sized producer of fruit and a medium sized cereal processing establishment which had activities at three different physical sites. The three inspectors observed were well qualified, knowledgeable and had a number of years of practical experience. Inspectors are provided with comprehensive checklists which they used appropriately.
59. In relation to prior notice of unannounced inspections, the maximum notice given is 24 hours and this generally applies to processing units, where a permit may be required in some cases. For inspections of agricultural holdings, a few hours of notice is normally given.
60. All operators are expected to inform the CB of any amendments or updates that should be made to their operator file prior to the announced annual inspection taking place. A significant element of an inspector's preparation for a site visit is a review of the operator file, which should contain information relating to derogations, off farm inputs, changes to maps, changes to farming activities as well as any other pertinent changes.
61. All three inspectors noted significant omissions relating to information that should be included in the operator file. Examples included, notification relating to the installation of a large irrigation system for use by crop grower, the existence of a new supplier at the processing plant and the absence of a wide range of records and documentation at the fruit producer.
62. An input / output calculation was undertaken by each inspector. The operators provided the relevant documents and the inspector undertook the calculation. Where issues were identified by the inspector, the operator reacted to any requests for clarification. (See section 5.6.2)
63. In the course of the inspection at the large crop producer, the inspector identified an error on the map of the farm. It appeared that the inspector was surprised that a conventional neighbouring field which was sown with corn was not clearly identified on the map.
64. The inspector noted a large number of non-compliances at the processing site. The most critical were failure to have adequate separation between the conventional and organic products, failure to maintain satisfactory documentation linking cleaning records and specific batches of processed cereal. In addition the operator had mistakenly mixed up green labels (signifying organic product) and red labels (signifying conventional product). These failings illustrated a serious breach of precautionary steps that are central to maintaining the status of the organic product. Although the inspector noted these non-compliances during the inspection observed, similar problems had been detected in previous inspections. The operator had been certified organic since 2009 and the continued existence of such severe non-compliances raises concerns. (See section 5.8).



65. At the fruit producer the input / output was calculated on the assumption that the sales invoices were equal to the harvest. This approach does not take into account the real production capacity of the area in question and would adversely influence the validity of the input/output calculation.

#### 5.6.2 *Traceability and input / output calculations*

66. In all cases of the input / output calculations undertaken by inspectors, the audit team noted that there were significant omissions. The approach used indicates that the calculation could only provide a partial view of the complete cycle of crop / product production to the entry point of EU. It was not obvious to the audit team whether or not the inspector factored in the theoretical harvest yield of a given crop per ha. The CB subsequently stated that all inspectors are provided with details of the average yield per ha for a given crop in each region. In the large crop producer visited, flooding had occurred and reseeding had taken place and it was unclear how inspectors might factor these issues into the input / output calculation.
67. The CB relies on the operator's product flow which is a declaration of the total harvest yield. The CB stated that the evaluators compare estimated yields collected during earlier inspections with the product flow. However, the audit team was not presented with any evidence of this. In addition, the CB stated that the estimation of harvest is only required from operators who export directly or supply to an exporter to the EU. Although the operator may export to other territories, the CB does not take into consideration these exports. The CB subsequently stated that there is a separate register for local transaction certificates however no evidence was presented to the audit team. This approach undermines the accuracy of any input / output calculation (see also section 5.7).
68. It was noted that the consignments for export can be traced to the operator but not always to the plot of land. The traceability to the plot is only ensured when there is a single crop per plot.

#### **Conclusions on control at operators.**

69. The CB inspectors met were competent and knowledgeable.
70. The CB has comprehensive procedures in place to guide inspectors through the inspection process and to a large extent the inspectors followed these.
71. The control measures in place do not ensure that the organic production standard is effectively achieved as the CB routinely provides notice of unannounced inspections to operators and does not undertake meaningful input / output calculation and traceability exercises.
72. Some longstanding shortcomings detected at the sites visited raise concerns about the effectiveness of enforcement (see section 5.8).

## **5.7 EXPORT CERTIFICATION SYSTEM**

### **Legal Requirements**

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

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

### **Findings**

#### **Export Certification System**

73. There is an Instruction for 'Preparation of the Package of Export Documents (II.4.OT-07 Version 1 May 2018)' in place for the certification of organic products for export to the EU. This describes the provisions for export of the organic products and includes all the relevant information required by the CB to issue a Certificate of Inspection (CoI). The CB takes samples as required by the EU Guidelines on additional official controls on products originating from Ukraine, Kazakhstan and Russian Federation of 29 November 2016.
74. The CB records the quantities for which they had issued a CoI and deducts this amount from the total estimated quantity reported by the operator. The CB stated that these estimated harvest quantities are also checked by CB evaluators to ensure that the harvest amount stated is reasonable for the particular region, crop and any climatic events. However, the CB inspector who visited the operator during the growing season would be the only credible, independent witness with first hand evidence of local conditions, (impact of flood, storms, frost, pests, if reseeded took place), that could affect the harvest quantity. There is no evidence available that this information is reported and factored into the system to update the harvest estimation provided by the operator. This gives rise to a situation whereby the CoI is issued based on an estimated harvest and not on the actual harvest.
75. As mentioned in section 5.6.2, the estimation of harvest is only required from operators who export or supply an exporter to the EU. Exports of organic product, to other territories is not reported by the operator nor recorded by the CB. This undermines the accuracy of the total actual harvest which in turn calls into question the reliability of the CoIs issued.

#### **Conclusions of export certification systems**

76. Although the CB has a system in place whereby CoIs are issued for organic products for export to the EU in compliance with Article 13 of Commission Regulation (EC) No 1235/2008, there is a risk that the CB issues excess CoIs inadvertently due to the use of unreliable production data.

## 5.8 IRREGULARITIES AND FOLLOW-UP OF EU NOTIFICATIONS

### Legal Requirements

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

Title V and Annex IV of Regulation (EC) no 1235/2008

### Findings

#### Irregularities and Follow-up of EU notifications

77. The CB has a sanction policy (II-PL-04 Sanction Policy) in place. This clearly describes the various categories of sanctions ranging from 'Category I' where a deviation has been noted but there is no consequence for the current certification to 'Category V' where the deviation is sanctioned by suspension of the certification. The policy states *'in the case where the non-conformity indicated is not resolved during two or more years in a row, the sanction category should be increased'*.
78. When a non-compliance is detected by a CB inspector during an annual inspection, the operator is instructed to rectify the non-compliance. However, the rectification would not be verified by the CB inspector until the next scheduled inspection. In the case of severe non-compliances, such a significant time lag between the detection of an irregularity and verification by a CB inspector that the problem has been satisfactorily resolved carries a high risk of continued non-compliance.
79. The audit team reviewed two cases relating to the detection of unauthorised substances which are described here to illustrate some of the weaknesses detected in the CB's approach to handling irregularities.
80. When the level of contamination is  $<0.01$  mg/kg, the CB informs the operator that an unauthorised substance has been detected. The letter requests the operator to investigate how the contamination might have occurred and to describe the preventative measures that are put in place to avoid a repetition of the problem. However, in such instances of  $<0.01$ mg kg, the CB does not require the operator to report back to the CB on the findings of their investigation in order to enable the CB to assess the situation and take further actions if necessary. The verification of the actions taken by the operator to rectify the situation would not be undertaken until the next scheduled inspection.
81. In another file reviewed, where the level of contamination was greater than 0.01mg/kg, the product was blocked, and the CB informed the operator of the detection by letter. The operator was asked to undertake an investigation to establish the source of the contamination, put preventative measures in place and to report back to the CB when completed. The CB does not organise an on-site inspection to identify potential wrongdoing by the operator. The CB's procedure (II.3-PR-06) does not require an on-site visit to be performed which gives rise to a systemic failure in the approach to investigations. During the next scheduled inspection the CB inspector would review the outcome of the operator's own investigation and any preventative measures put in place.

82. Although the CB did apply a measure by decertifying the product in question, a proper investigation was not undertaken. The key omission noted was the failure of the CB to perform an onsite inspection as soon as possible after the evidence of presence of unauthorised substances becomes obvious. The importance of an on-site inspection did not appear to be fully understood by the CB. Referring to the case described in sections 80-81 and 85 the CB stated that they had discussed the matter and decided against such an on-site inspection. Their view was that the laboratory results were from a product that was harvested six months prior to sampling and therefore a site visit was unlikely to find anything. The CB did not consider whether additional evidence could be found through a site visit, for example, checking storage areas for unauthorised substances or verifying what became of the blocked batch. In addition, the CB did not know the circumstances of how the fruit was collected from the orchards (see section 85) and the juice was produced.
83. The CB has the possibility to use the services of an EU based third party consultant to interpret laboratory results and assess the potential impact on the organic status of the product. In relation to the above case in para 81 relating to apple concentrate, the issue was the presence of several unauthorised substances, for example, Tetrahydrophthalimide (THPI) which is a metabolite of the fungicide captan. In addition carbendazim was also detected at a level  $>0.01\text{mg/kg}$ . The consultant reported that in the case of carbendazim, the problem was most likely due to unavoidable pollution in the environment. In the case of the presence captan, the independent consultant stated that the organic status of the product was questionable. In this case the CB followed the opinion of the independent consultant. The CB decertified the lot on the strength of the presence of captan and this non-compliance was factored into the risk assessment and an on-site additional control was scheduled five months later, generating a time lag between detection and on-site follow-up.
84. The CB acted exclusively on the advice of the independent consultant without conducting its own on site visit to assess the situation. In addition, the CB stated that it would have released the blocked batch of product if the independent consultant had considered the problem to be due to unavoidable pollution for both unauthorised substances.
85. The operator in question is a juice processor which obtains its fruit from orchards that are spread over a wide area and which are not all managed by the processor. Part of the orchards, are conventional and are permitted to be treated with substances prohibited under organic production. In addition, a part of the processing is subcontracted to another operator. The processor stated that such high levels of contamination were due to the product being a concentrate.
86. There was evidence that recurrent non-compliances were not subject to more severe sanctions. In some cases there was a tolerance by the CB of recurrent non-compliances which were not acted upon. During this audit an operator which had been in operation as an organic and conventional processor since 2009 was found to have some serious shortcomings in relation to the separation of organic and conventional products. This

was reflected in the lack of signage in the storage area as well as inadequate record keeping. Although these non-compliances were noted by the inspectors, the fact that they were not rectified and continued to recur is not satisfactory.

87. The sanction applied in the case of an operator using chemically treated seeds was not dissuasive as the sanctions were as follows; first time used, the harvest is downgraded for the particular crop, second time used, the land is returned to conversion and third time used the operator is decertified.
88. The files reviewed by the audit team confirmed that the CB had carried out appropriate investigations with regard to OFIS notifications.

#### **Conclusions on irregularities and follow-up of EU notifications**

89. The CB generally applies its procedures on handling of infringements and irregularities and takes measures in cases of irregularities. Investigations in response to the detection of unauthorised substances rarely, if ever, include an on-site visit to investigate suspected non-compliances, which limits the credibility and reliability of the approach. In addition, where measures are applied there is evidence that the measures applied are not dissuasive resulting in operators failing to resolve irregularities in a timely manner. This overall approach generates a culture of leniency in particular towards those operators with recurring irregularities.
90. The follow-up of EU notifications is generally satisfactory.

## **6 OVERALL CONCLUSIONS**

The CB had taken measures to address the recommendations in the previous audit report. Overall, the CB is very active in relation to sampling and undertaking additional unannounced control of operators, significantly surpassing the minimum requirements. It fulfils its obligations relating to the Guidelines on additional controls on products originating from Ukraine, Kazakhstan and Russian Federation and destined for export to the EU. The investigations of notifications from the Organic Farming Information System were undertaken in a satisfactory manner.

At the time of the audit, the CB was unable to demonstrate the state of implementation of its control plan resulting in uncertainty about the exact frequency of controls at the riskiest operators as well as the suitability of the timing (seasonality) of inspections. This situation was partially mitigated by the large number of controls carried out by the CB. Regarding investigations by the CB in response to the detection of unauthorised substances, no on-site visit takes place to investigate suspected non-compliances. This is a significant weakness.

The CB frequently used estimated harvest yields in calculations relating to input / output which could negatively influence the reliability of the certificates of inspection. In relation to enforcement, non-compliances were not rectified in a timely manner and enforcement actions were not dissuasive leading to many situations of recurrent non-compliances existing over a long period of time.

## **7 CLOSING MEETING**

A closing meeting was held on 20 June 2018 with representatives of the CB. At this meeting, the DG Health and Food Safety team presented the main findings and preliminary conclusions of the audit.

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

## 8 RECOMMENDATIONS

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

No.	Recommendation
1.	<p>Ensure that control measures are applied effectively in order to achieve the CB standard, and in particular to take actions to include the quantity of product as part of the calculation to determine the risk categorisation of all operators.</p> <p><i>Recommendation is based on conclusion No 29</i></p> <p><i>Associated finding; No 21</i></p>
2.	<p>Ensure that the risk based approach developed is applied in a consistent manner, and that real time data is available on the implementation status to the control plan as required by the CB's own procedures.</p> <p><i>Recommendation is based on conclusion Nos 30, 31</i></p> <p><i>Associated findings Nos 22, 23, 24.</i></p>
3.	<p>Ensure that derogations for the retrospective shortening of the conversion period complies with the CBs own procedures.</p> <p><i>Recommendation is based on conclusion No 47</i></p> <p><i>Associated findings No 45</i></p>
4.	<p>Ensure that control measures are applied effectively in order to achieve the CB standard, and in particular to take action to overcome the routine practice of providing prior notice to operators of additional controls.</p> <p><i>Recommendation is based on conclusion No 71</i></p> <p><i>Associated findings Nos 59</i></p>
5.	<p>Ensure that control measures are applied effectively in order to achieve the CB standard and in particular to take actions so that input/output calculations and traceability exercises are undertaken in a meaningful way.</p> <p><i>Recommendation is based on conclusion No 71</i></p> <p><i>Associated findings Nos 66, 67</i></p>
6.	<p>Ensure that control measures are applied effectively to achieve the CB standard, and in particular to take actions to use accurate documentary checks including in particular actual harvest records for the products concerned when issuing CoIs.</p> <p><i>Recommendation is based on conclusion Nos 76</i></p> <p><i>Associated findings Nos 74, 75</i></p>

7.	<p>Ensure that enforcement measures are applied effectively in order to achieve the CB standard and in particular to take appropriate measures in a timely manner in cases of irregularities.</p> <p><i>Recommendation is based on conclusions No 72, 89</i></p> <p><i>Associated findings; Nos 64, 77-87</i></p>
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The competent authority's response to the recommendations can be found at:

[http://ec.europa.eu/food/audits-analysis/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2018-6396](http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2018-6396)



**ANNEX 1 – LEGAL REFERENCES**

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

## ANNEX 2: STANDARDS QUOTED IN THIS REPORT

Reference	Title	Publication
ISO/IEC 17065:2012	Conformity assessment -- Requirements for bodies certifying products, processes and services	<a href="http://www.iso.org/">http://www.iso.org/</a>
Codex Alimentarius guidelines CAC/GL 32	Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods	<a href="http://www.codexalimentarius.org/standards/list-of-standards/">http://www.codexalimentarius.org/standards/list-of-standards/</a>
Codex Guidelines CAC/GL 50- 2004	General Guidelines on sampling	<a href="http://www.codexalimentarius.org/standards/list-of-standards/">http://www.codexalimentarius.org/standards/list-of-standards/</a>



**EUROPÄISCHE KOMMISSION**  
**GENERALDIREKTION GESUNDHEIT UND LEBENSMITTELSICHERHEIT**

Gesundheits- und Lebensmittelaudits und Analysen

**DG(SANTE)/2018-6396 – RS**

**AUSZUG AUS DEM BERICHT ÜBER EIN AUDIT DER GD GESUNDHEIT UND  
LEBENSMITTELSICHERHEIT IN KONTROLLSTELLEN**

**12. - 20. JUNI 2018**

**BEWERTUNG DER VON EINER ANERKANNTEN KONTROLLSTELLE IN DER UKRAINE  
ANGEWANDTEN STANDARDS UND KONTROLLMASSNAHMEN FÜR DIE  
ÖKOLOGISCHE/BIOLOGISCHE ERZEUGUNG**

**HINWEIS: DIES IST – IN DEUTSCHER ÜBERSETZUNG – EIN AUSZUG AUS DEM BERICHT ÜBER DAS OBEN GENANNTÉ AUDIT.  
VERBINDLICH IST NUR DIE LANGFASSUNG DES ORIGINALBERICHTS (DG(SANTE)/2018-6396).**

**ZUSAMMENFASSUNG**

*Dieser Bericht enthält die Ergebnisse eines Audits, das die GD Gesundheit und Lebensmittelsicherheit vom 12. bis zum 20. Juni 2018 durchgeführt hat, um die Anwendung der Standards für die ökologische/biologische Erzeugung und die Durchführung der Kontrollmaßnahmen durch eine anerkannte Kontrollstelle in der Ukraine zu bewerten.*

*Die Kontrollstelle hatte Maßnahmen zur Umsetzung der Empfehlungen aus dem Bericht über das vorausgegangene Audit ergriffen. Insgesamt führt die Kontrollstelle sehr viele Probenahmen und zusätzliche, unangekündigte Kontrollen der Unternehmer durch, wobei sie die Mindestanforderungen signifikant übersteigt. Sie erfüllt ihre Verpflichtungen aus den Leitlinien für zusätzliche Kontrollen von Erzeugnissen mit Ursprung in der Ukraine, Kasachstan und der Russischen Föderation, die für die Ausfuhr in die EU bestimmt sind. Die Ermittlungen aufgrund von Meldungen im Informationssystem für ökologischen Landbau wurden auf zufriedenstellende Weise durchgeführt.*

*Zum Zeitpunkt des Audits war die Kontrollstelle nicht dazu in der Lage, den Stand der Durchführung ihres Kontrollplans zu belegen, was zu Unsicherheiten über die genaue Häufigkeit der Kontrollen bei den mit den meisten Risiken behafteten Unternehmern führte und die Frage aufwarf, ob die Kontrollen zu einer geeigneten Zeit (Saisonabhängigkeit) durchgeführt wurden.*

*Diese Situation wurde teilweise durch die große Zahl an Kontrollen entschärft, die die Kontrollstelle durchführt. Im Hinblick auf die Ermittlungen durch die Kontrollstelle zeigte sich, dass sie keine Besuche vor Ort durchführt, wenn nicht erlaubte Stoffe festgestellt werden, um in Bezug auf einen vermuteten Verstoß zu ermitteln. Dies stellt einen erheblichen Mangel dar.*

*Die Kontrollstelle hat für die Input-Output-Berechnungen häufig geschätzte Ernteerträge verwendet, was sich negativ auf die Zuverlässigkeit der Kontrollbescheinigungen auswirken könnte. Hinsichtlich der Durchsetzung wurde festgestellt, dass Verstöße nicht rechtzeitig behoben wurden und die Durchsetzungsmaßnahmen nicht abschreckend waren, so dass es viele Fälle wiederkehrender Verstöße gab, die über einen langen Zeitraum anhielten.*

*In dem Bericht wird der Kontrollstelle empfohlen, wie die festgestellten Probleme gelöst und die Durchführung der Kontrollmaßnahmen verbessert werden können.*

#### **EMPFEHLUNGEN**

Die Kontrollstelle wird aufgefordert, innerhalb von 25 Arbeitstagen nach Eingang dieses Auditberichts genaue Angaben zu den durchgeführten und den geplanten Maßnahmen zur Umsetzung der nachfolgend aufgeführten Empfehlungen vorzulegen und anzugeben, bis wann die Maßnahmen abgeschlossen sein sollen („Maßnahmenplan“). Die Kontrollstelle sollte:

Nr.	Empfehlung
1.	<p>sicherstellen, dass die Kontrollmaßnahmen wirksam angewendet werden, um den Kontrollstellen-Standard zu erreichen, und insbesondere Maßnahmen ergreifen, damit für die Berechnungen zur Ermittlung der Risikokategorie aller Unternehmer die erzeugte Menge einbezogen wird.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 29</i></p> <p><i>Damit zusammenhängende Feststellung: 21</i></p>
2.	<p>sicherstellen, dass der entwickelte risikobasierte Ansatz auf konsequente Weise angewendet wird und dass zum Durchführungsstatus des Kontrollplans Echtzeitdaten zur Verfügung stehen, wie es in den eigenen Verfahren der Kontrollstelle gefordert wird.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerungen 30, 31</i></p> <p><i>Damit zusammenhängende Feststellungen: 22, 23, 24</i></p>
3.	<p>sicherstellen, dass Abweichungen für eine rückwirkende Verkürzung des Umstellungszeitraums mit den eigenen Verfahren der Kontrollstelle übereinstimmen.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 47</i></p>

	<i>Damit zusammenhängende Feststellung: 45</i>
4.	<p>sicherstellen, dass die Kontrollmaßnahmen wirksam angewendet werden, um den Kontrollstellen-Standard zu erreichen, und insbesondere Maßnahmen ergreifen, damit zusätzliche Kontrollen den Unternehmern nicht routinemäßig vor der Durchführung angekündigt werden.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 71</i></p> <p><i>Damit zusammenhängende Feststellung: 59</i></p>
5.	<p>sicherstellen, dass die Kontrollmaßnahmen wirksam angewendet werden, um den Kontrollstellen-Standard zu erreichen, und insbesondere Maßnahmen ergreifen, damit Input-Output-Berechnungen und Überprüfungen der Rückverfolgbarkeit auf aussagekräftige Weise durchgeführt werden.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 71</i></p> <p><i>Damit zusammenhängende Feststellungen: 66, 67</i></p>
6.	<p>sicherstellen, dass Kontrollmaßnahmen wirksam durchgeführt werden, um den Kontrollstellen-Standard zu erreichen, und insbesondere Maßnahmen ergreifen, damit genaue Dokumentenkontrollen insbesondere auch der aktuellen Ernteaufzeichnungen für die betreffenden Erzeugnisse durchgeführt werden, wenn die Informationen über die Herkunftsländer herausgegeben werden.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 76</i></p> <p><i>Damit zusammenhängende Feststellungen: 74, 75</i></p>
7.	<p>sicherstellen, dass Kontrollmaßnahmen wirksam durchgeführt werden, um den Kontrollstellen-Standard zu erreichen, und insbesondere im Fall von Unregelmäßigkeiten rechtzeitig geeignete Maßnahmen ergreifen.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerungen 72, 89</i></p> <p><i>Damit zusammenhängende Feststellungen: 64, 77 - 87</i></p>

Die Stellungnahme der zuständigen Behörde zu den Empfehlungen ist abrufbar unter:

[http://ec.europa.eu/food/audits-analysis/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2018-6396](http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2018-6396)

# Competent Authority response to the report recommendations received 24 August 2018

## ANNEX

Response of the Control Body to the recommendations of report ref. DG(SANTE)/2018-6396-MR of the audit carried out from 12 June 2018 to 20 June 2018 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised Control Body operating in Ukraine

1	<p>Ensure that control measures are applied effectively in order to achieve the CB standard, and in particular to take actions to include the quantity of product as part of the calculation to determine the risk categorisation of all operators.</p> <p>Recommendation is based on conclusion No 29 Associated finding; No 21</p>	<p>According to the system of equivalency, equivalent control measures to those required within the EU are applied in <i>*Please note that it has been necessary to delete this text in order to protect the provisions of Article 339 of the Lisbon treaty as regards confidentiality</i> and "International Accredited Certification Bodies Equivalent European Union Organic Production &amp; Processing Standard for Third Countries" (IACB Standard, version 17) is used for certification. All the Policies and Procedures of <i>*the CB</i> are developed aiming to cover all the requirements stated in the present Standard.</p> <p>IACB Standard does not contain specific requirements for the risk categorization, therefore <i>*the CB</i> has developed system which includes parameters for risk categorization of operators based on the own practical experience identifying all important relevant parameters to be considered. However, following requirements of the original EU Regulation 889/2008 article 65 and the Recommendation of the audit results the list of parameters for risk assessment of operators will be revised and completed with the parameter of the quantity of products concerned.</p> <p>However, management changes and implementation of all the necessary technical steps require some period of time. The preparatory work has been already started and is planned to be completed by the end of 2018. Updated risk categorization system will be fully implemented since 01.01.2019.</p>
2	<p>Ensure that the risk based approach developed is applied in a consistent manner, and that real time data is available on the implementation status to the control plan as required by the CB's own procedures.</p>	<p>According to the system implemented by the <i>*CB</i> Risk Categorization of each operator is calculated automatically by the program based on the criteria defined in the</p>

Competent Authority response to the report recommendations received 24 August 2018

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No	Recommendation	Action Proposed by the Control Body
	<p>Recommendation is based on conclusion Nos 30, 31 Associated findings Nos 22, 23, 24.</p>	<p>II.3-PR-02 Procedure for risk assessment of the Operator. Group Coordinator is responsible for implementation of risk category of the operator in the inspection plan and for further action needed. However due to the fact that system of the Group Coordinators was implemented just recently and following recommendations of the Audit results in order to improve coherency between written documents and practical implementation following corrective measures are put into actions:</p> <ol style="list-style-type: none"> <li>1. Following improvements are made from the pilot phase of the functioning of the system of Group Coordinators (start of preparation 01.09.2017 implementation since 01.03.2018): <ul style="list-style-type: none"> <li>- number of groups will be reduced;</li> <li>- the system of reporting by coordinators to the manager of certification department is under revision. The new head of certification department started to work on 04.07.2018.</li> </ul> </li> <li>2. Part for verification of the application of Risk Assessment system is added to the Internal Audit.</li> </ol> <p><i>I-FO-4.2.001-003 IA check list, noncompliance report, summary results v6 is attached</i></p>
3	<p>Ensure that derogations for the retrospective shortening of the conversion period complies with the CBs own procedures. Recommendation is based on conclusion No 47 Associated findings No 45</p>	<p>With purpose to improve coherence of the written Policy and practical implementation of the approach of <i>*the CB</i> for retrospective shortening of the conversion period and following recommendation of the Audit results the following corrective</p>

# Competent Authority response to the report recommendations received 24 August 2018

## ANNEX

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N°	Recommendation	Action Proposed by the Control Body
		<p>measures are taken into actions:</p> <ol style="list-style-type: none"> <li>1. Working group to revise <i>*the CB Policy for Conversion Period</i> is organized;  On July, 18 2018 the Ukrainian Law on Basic Principles and Requirements for Organic Production, Circulation and Labeling of Organic Products № 5448-d was adopted. The law defines requirements to the retroactive shortening of conversion period which are stricter than those included in the <i>*CB internal Policy</i>. To meet named requirements <i>* the CB's Policies</i> will be revised accordingly.</li> <li>2. Section for additional verification of the interpretation of the <i>*CB</i> approach by the inspection certification specialists is added to the internal audit check list.  <i>I-FO-4.2.001-003 IA check list, noncompliance report, summary results v6 is attached</i></li> <li>3. For the autumn, 2018 additional training for inspection certification staff "Policy <i>*the CB</i> on the conversion period and its practical implementation" is planned.  <i>I-OT 3.8.001_Annual training_ is attached</i></li> </ol>
4	Ensure that control measures are applied effectively in order to achieve the CB standard, and in particular to take action to overcome the routine practice of providing prior notice to operators of additional controls. Recommendation is based on conclusion No 70	According to the system of equivalency, equivalent control measures to those required within the EU are applied in <i>*the CB</i> and "International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for



Competent Authority response to the report recommendations received 24 August 2018

ANNEX

Response of the Control Body to the recommendations of report ref. DG(SANTE)/2018-6396-MR of the audit carried out from 12 June 2018 to 20 June 2018 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised Control Body operating in Ukraine

N°	Recommendation	Action Proposed by the Control Body
	Associated findings Nos 59	<p>Third Countries" (version 17) is used for certification. IACB Equivalent Standard doesn't define certain rules for conducting unannounced inspection. Taking into account relevant inspection experience and some bureaucracy barriers *the CB interprets unannounced inspections as an inspection when inspector doesn't inform operator about coming visit at all or where it is necessary inform operator beforehand but not earlier then 24 hours before inspection.</p> <p><i>II.2-PR-05 Procedure for certification planing_v2_en. Section 6.3.1.</i></p>
5	<p>Ensure that control measures are applied effectively in order to achieve the CB standard and in particular to take actions so that input/output calculations and traceability exercises are undertaken in a meaningful way.</p> <p>Recommendation is based on conclusion No 71</p> <p>Associated findings Nos 66, 67</p>	<p>With purpose to improve approach of *the CB for the calculation of input/output balance by inspection certification staff and following recommendation of the audit results the following actions are put into practice:</p> <ol style="list-style-type: none"> <li>1. The specialist for input/output balance is defined to provide additional training for inspection certification staff in the autumn 2018;</li> <li>2. Detailed instruction and practical exercises will be elaborated and introduced in the on-line training tool Asnovator;</li> <li>3. All the inspection reports are amended by relevant part to be filled in by inspector and checked by evaluator for calculation input/output balance.</li> </ol> <p><i>Inspection reports is attached.</i></p>

# Competent Authority response to the report recommendations received 24 August 2018

## ANNEX

Response of the Control Body to the recommendations of report ref. DG(SANTE)/2018-6396-MR of the audit carried out from 12 June 2018 to 20 June 2018 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised Control Body operating in Ukraine

No	Recommendation	Action Proposed by the Control Body
6	<p>Ensure that control measures are applied effectively to achieve the CB standard, and in particular to take actions to use accurate documentary checks including in particular actual harvest records for the products concerned when issuing COIs.</p> <p>Recommendation is based on conclusion Nos 76</p> <p>Associated findings Nos 74, 75</p>	<p>II 2-E-002 Inspection report_Wild collection_v9_enua.doc  II 2-A-002-05 Inspection report crop production_Annex to the InspReport_enua_v3.docx  II.2-B-002-EU Inspection report for animal husbandry_v6_enua.docx  II.2-CD-002 Inspection report_Processing and/or Export Operations incl wine_v10_enua.docx  II.2-F-002 Inspection Report Apiaries_v6_enua.doc  II.2-H-002 Inspection Report Aquaculture_v7_enua.docx</p> <p>4. The new system of continued maintenance of the input/output balance is in the process of implementation.</p>
		<p>In order to ensure verification of the quantities of product to be exported and issuing COIs taking into account harvest data the following measures are put into actions:</p> <p>1. All the Inspection Reports are amended by relevant part for cross checking export data from the office and data provided by operator on place by inspector.</p> <p>Relevant Inspection Reports Forms are attached</p> <p>2. The information concerning the exact actual quantities of exported products which is put into the Product Flow Calculation is under three levels of verification - by inspector, by evaluator, and by person responsible for issuing COIs.</p> <p><i>Products_flow_Example exported products 2017 is attached.</i></p> <p>3. Inspector evaluates estimated harvest provided by operator</p>

# Competent Authority response to the report recommendations received 24 August 2018

## ANNEX

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N°	Recommendation	Action Expensed by the Control Body
		<p>during inspection by default considering region, weather conditions, and typical yield per crop. All inspectors of the <i>*CB</i> approved for crop production have agronomic background and are able to distinguish possible potential yield from the unreal data. When inspector notifies abnormal figures he is becoming curious and evaluates reasons for providing such data closely. The second step of yield data verification is performed on the level of evaluator. During evaluation process evaluator compares data provided in the inspection report and general average data got from the official statistics of the Agrarian Ministry as well as considering <i>*the CB</i> data on organic operators.</p> <p>However to improve the system of harvest verification <i>*the CB</i> initiates collecting annual indicative yield data for main crops per region. The collected data will be introduced through File Maker system and will be of free access for inspectors and evaluators online.</p>
7	<p>Ensure that enforcement measures are applied effectively in order to achieve the CB standard and in particular to take appropriate measures in a timely manner in cases of irregularities.</p> <p>Recommendation is based on conclusions No 72, 89</p> <p>Associated findings; Nos 64, 77-87</p>	<p>Following to the recommendation <i>*the CB</i> starts process of revision of the Sanction Policy particularly on the cases of severe non-compliances and intermediate monitoring of the effectiveness of corrective actions taken by operator. Additionally, special attention will be put on cases relating to the detection of unauthorized substances and to reporting back by the operator to the <i>*CB</i> to assess situation and take further actions if necessary. In order to assure that irregularities are resolved by operators in a timely manner approach for unannounced inspection in cases where detection of unauthorized substances take place will be revised.</p>

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*\*Please note that it has been necessary to delete this text in order to protect the provisions of Article 339 of the Lisbon treaty as regards confidentiality*