EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

UKRAINE

FROM 26 MAY 2015 TO 04 JUNE 2015

IN ORDER TO

EVALUATE THE SYSTEM OF OFFICIAL CONTROLS AND CERTIFICATION OF CEREAL SEED AND THEIR EQUIVALENCE WITH EUROPEAN UNION REQUIREMENTS

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Ukraine carried out from 26 May to 4 June 2015.

The objective of the audit was to assess the performance of the competent authority (CA) of Ukraine with regard to the implementation of national legislation and international standards for seed production controls and seed certification; and to evaluate whether the field inspections on cereal seed-producing crop satisfy EU requirements and whether cereal seed produced is equivalent to seed produced in the EU.

It is concluded that overall that official controls for seed production and certification of cereal seeds in Ukraine are organised appropriately. All activities are carried out by CAs official staff that have appropriate technical knowledge and experience in their field and no tasks are delegated.

All seed producers are registered and under frequent control of seed inspectors in the framework of the seed production controls. Controls of seed on the market are focused on the imported seed for further multiplication. Testing for Genetically Modified Organisms (GMO) presence is also carried out.

Field inspections of seed-producing crops and pre- and post-certification controls of seed are carried out appropriately, in line with Organisation for Economic Co-operation and Development (OECD) standards and satisfy EU requirements. Sampling and testing of seed is carried out appropriately according to International Seed Testing Association (ISTA) rules. Seed packages are sealed with official labels under official supervision and traceability in the seed certification process is ensured. However, some norms for the seed-producing crop and for the quality of cereal seed are not fully in line with EU requirements.

Overall, the national authorities responsible for implementation of seed certification in Ukraine are competent and operate appropriately. Once the above mentioned minor shortcomings have been addressed, seed produced in Ukraine can be considered equivalent to seed produced in the EU.

A recommendation to address the shortcomings identified during the audit is included in the report.

Table of Contents

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
Basic seed	Basic seed is the progeny of the pre-basic seed produced under the responsibility of the breeder. It is intended for the production of seed of the category certified seed, which satisfies prescribed conditions and quality standards for basic seed and its production is officially controlled.
CA	Competent Authority in the meaning of the Article 2(1)H of Directive 66/402/EEC
Certified seed	Certified seed has been produced directly from basic seed. It is intended for the production of further generations of certified seed or can be planted by farmers for grain (commodity) production. It satisfies prescribed conditions and quality standards for certified seed and its production is officially controlled.
DG SANTE	Directorate General for Health and Food Safety of the European Commission
DUS	Distinctness, Uniformity and Stability of a plant variety
EC	European Community
EU	European Union
FVO	Food and Veterinary Office
GMO	Genetically Modified Organism
ISTA	International Seed Testing Association
MoAPF	Ministry of Agrarian Policy and Food of Ukraine
OECD	Organisation for Economic Co-operation and Development
Pre-basic seed	Pre-basic seed is the progeny of the breeder seed produced under the responsibility of the breeder of a variety. It is intended for the production of seed of the category basic seed and satisfies prescribed conditions and quality standards for pre-basic seed.
SAIU	State Agricultural Inspection of Ukraine
SPVRP	State Service for Plant Variety Rights Protection
Triticale	Hybrids resulting from the crossing of a species of the genus *Triticum* and a species of the genus *Secale (*x*Triticosecale* Wittm. ex A. Camus)
UIPVE	Ukrainian Institute for Plant Variety Examination
UPOV	International Union for the Protection of New Varieties of Plants

Variety	Variety means a plant grouping (entire plants or parts of plants capable of producing entire plants) within a single lowest known botanical taxon, which can be defined by the expression of the characteristics that results from a given genotype, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged.
VCU	Value for Cultivation and Use of a plant variety

1 INTRODUCTION

The audit took place in Ukraine from 26 May 2015 to 4 June 2015. The audit team comprised two auditors from the Food and Veterinary Office (FVO), one observer from the Directorate General for Health and Food Safety of the European Commission (DG SANTE) unit G.7 and one national expert. The audit was undertaken as part of the FVO's planned audit programme.

An opening meeting was held on 26 May 2015 with the Ministry of Agrarian Policy and Food (MoAPF) and central Competent Authorities (CAs) responsible for seed production and certification. At this meeting, the objectives of, and the itinerary for the audit were confirmed and the control systems were described by the authorities. Representatives from the central CAs accompanied the audit team during the whole audit.

2 OBJECTIVES AND SCOPE

The objectives of the audit were to:

1. Assess the performance of the CA of Ukraine with regard to the implementation of national legislation and international standards for seed production controls and seed certification; and
2. Evaluate whether the field inspections on cereal seed-producing crop satisfy EU requirements and whether cereal seed produced is equivalent to seed produced in the EU.

The audit was undertaken in the context of the examination of the request by Ukraine to obtain recognition of the equivalence of the Ukrainian system for seed production with the standards applicable in the EU in relation to cereal seed to be used for agricultural crop production.

The table below lists sites visited and meeting held in order to achieve these objectives.

Meetings/visits		**Comments**
Competent Authority	Central	Ministry of Agrarian Policy and Food of Ukraine (MoAPF); State Agricultural Inspection of Ukraine (SAIU); State Service for Plant Variety Rights Protection (SPVRP); Ukrainian Institute of Plant Variety Examination (UIPVE)
	Regional	SAIU in Kiev, Cherkassy and Khmelnitsky region; UIPVE Bila Tcerkva and Uman
Others		Meeting with the representatives of seed producers and researchers/breeders, Kiev

Field visits	Field inspection	Kiev, Cherkassy and Khmelnitsky region
	Variety and control plot tests	Bila Tcerkva and Uman
	Seed sampling	Kiev and Khmelnitsky region;
	Laboratory	ISTA accredited laboratory, Kiev

3 LEGAL BASIS

The audit was carried out under the provisions of Article 16 of Council Directive 66/402/EEC.

3.1 RELEVANT EU LEGISLATION

Council Directive 66/402/EEC provides for the production with a view to marketing, and to marketing of cereal seed within the EU.

Council Directive 2002/53/EC provides for the registration of plant varieties of agricultural crops within the EU after they have been technically examined and notified to the Commission.

Council Decision 2003/17/EC provides conditions for field inspections concerning the seed-producing crops and conditions for seed produced in third countries to be considered equivalent to field inspections carried out in the EU and equivalent to seed complying with requirements of Directive 66/401/EEC, Directive 66/402/EEC, Directive 2002/54/EC and Directive 2002/57/EC.

Full legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the last amended version.

3.2 INTERNATIONAL RULES

The Organisation for Economic Co-operation and Development (OECD) develops and publishes harmonised procedures for seed production in international trade - OECD schemes for the varietal certification or the control of seed moving in international trade (hereafter referred to as OECD Seed Schemes). These schemes are recognised international benchmarks for varietal identity and varietal purity verification during the seed multiplication process.

The International Seed Testing Association (ISTA) develops and publishes standard procedures for seed sampling and seed testing - ISTA Rules for Seed Testing (hereafter referred to as ISTA Rules). These rules are recognised international benchmarks for seed testing and are used worldwide.

Relevant international standards are listed in Annex 2.

4 BACKGROUND

On 6 April 2011 Ukraine sent an official request to the European Commission in relation to obtaining recognition of their cereal seed production and certification as equivalent with seed produced in the EU. The list of species provided by Ukraine included the following eight cereal species: Oats (*Avena sativa* L.), Barley (*Hordeum vulgare* L.), Wheat (*Triticum aestivum* L.), Durum wheat (*Triticum durum* Desf.), Rye (*Secale cereale* L.), hybrids resulting from the crossing of a species of the genus *Triticum* and a species of the genus *Secale (*x*Triticosecale* Wittm. ex A. Camus) (hereafter referred to as Triticale), Sorghum (*Sorghum bicolor* (L.) Moench and Maize (*Zea mais* L.).

The European Commission has processed the Ukrainian request by assessing their national legislation and system of official controls for seed production and certification of cereal seeds. The assessment concluded that their legislation is adequate and that the seed production system, which is based on OECD Seed Schemes, is properly organised, which has allowed further steps in the processing of their request.

Ukraine participates in three OECD Seed Schemes. The OECD Council accepted Ukraine's admission to two OECD Seed Schemes for Cereals and for Maize and for Sorghum seed schemes in 2009. Ukraine expanded participation to the Crucifers and Other Oil and Fibre Species seed scheme in 2014.

There is one ISTA accredited laboratory for seed testing within the SAIU in Kiev. Ukraine has also been a member of the International Union for the Protection of New Varieties of Plants (UPOV) since 1995.

Unless otherwise stated, statistical data in this and the following chapters were provided by the Ukrainian authorities.

4.1 CURRENT STATISTICS ON THE PRODUCTION AND EXPORT OF SEEDS

Total production area of seed of agricultural crops in Ukraine was 1 098 000 ha with total production of certified seed of 2 037 000 t in 2014. Out of this quantity around 400,000 tonnes of certified seed was marketed and the remaining seed used by agricultural enterprises and seed companies for their own use. Agricultural enterprises in Ukraine are big, cultivating from some 30 000 to 500 000 000 ha of land with the size of the fields from 50 to 200 ha. There are no specialised seed producers in Ukraine, agricultural enterprises produce seed as one of their activities. In the table below there are production data from 2012 to 2014 for the seed of cereal species, subject to the request of recognition of equivalence.

Table 1: Seed production of cereal species in Ukraine from 2012 to 2014

Species	2012		2013		2014	
	Area of seed crops, 1 000 ha	Seeds produced, 1 000 t	Area of seed crops, 1 000 ha	Seeds produced, 1 000 t	Area of seed crops, 1 000 ha	Seeds produced, 1 000 t
Winter wheat	634.0	1 306.2	652.3	1 360.2	570.7	1 191.6
Winter barley	84.5	178.5	95.4	195.8	80.8	158.5
Winter rye	39.8	54.2	30.3	43.8	17.7	24.5
Spring wheat	26.0	60.6	13.9	39.6	14.8	26.0
Spring barley	201.5	452.3	169.0	380.0	149.4	261.0
Oats	32.9	51.6	21.5	47.2	21.3	28.8
Maize	29.4	110.2	40.5	114.7	43.1	108.0
Sorghum	0.4	1.7	0.4	1.1	0.1	0.6
Total:	**1 048.5**	**2 215.3**	**1 023.3**	**2 181.4**	**897.9**	**1 799.0**

Winter soft wheat is the main crop and seed production accounts for more than 50 % of seed produced in Ukraine, followed by barley and maize. Seed production of durum wheat and triticale is relatively small, around 1 000 ha of seed-producing crop annually per species.

The export of seed is very low compared to the total seed production as detailed in Table 2 below.

Table 2: Export and import of seed (in tonnes) from 2012 to 2014

Crops	Marketing year					
	2012		2013		2014	
	Export	Import	Export	Import	Export	Import
Maize	6 694	na[1]	8 221	na	9 326	na
Sunflower	698	na	212	na	1 197	na
Winter wheat	78	na	130	na	251	na
Soybean	21	na	5	na	2 697	na
Total:	**7 491**	**62 076**	**8 568**	**70 030**	**13 471**	**81 287**

[1]**na** – data not available

The export of seed has increased slightly in the last three years. The main countries receiving the seeds are the Russian Federation, Belarus, Moldova, Turkey and Iran. The main seed species exported are maize, sunflower and soybean. As the majority of importing countries do not require OECD certification, only a small part of the exported seed was exported with the OECD certificate (517 t in 2012, 899 t in 2013 and 1 238 t in 2014). Importation of seed has increased in the same period and significantly exceeds exportation figures.

5 FINDINGS AND CONCLUSIONS

5.1 ORGANISATION OF SEED PRODUCTION CONTROLS

Legal requirements

Article 2(1)(H), 2(3), 3(3), 7(1), 7(1a) and 9(1) of Council Directive 66/402/EEC.

Point 1.3 of Common Rules and Regulations of OECD Seed Schemes lays down that the schemes rules and regulations shall be implemented in the participating countries under the responsibility of the national governments that will designate authorities for that purpose.

Findings

COMPETENT AUTHORITIES

1. The Ministry of Agrarian Policy and Food (MoAPF) of Ukraine is responsible for all agricultural and food activities, including plant varieties, seed production and seed certification.

2. The State Service for Plant Variety Rights Protection (SPVRP) under the MoAPF is responsible for the registration of plant varieties, for granting plant variety protection

and maintenance of the national register of plant varieties. Within the SPVRP, the Ukrainian Institute of Plant Variety Examination (UIPVE) implements the testing of plant varieties for Distinctness, Uniformity and Stability (DUS) and for Value for Cultivation and Use (VCU) and testing of seed in pre- and post- certification controls. The UIPVE has branches in each of the 25 regions ("Oblast") and 68 testing stations across Ukraine.

3. The State Agricultural Inspection of Ukraine (SAIU), as a body within the ministry, is responsible for seed production controls and seed certification and is the National Designated Authority for the OECD Seed Schemes. The SAIU and UIPVE signed the cooperation agreement in 2013 for conducting the pre- and post- certification controls. The Inspectorate has branches in each of the 25 regions and has on average one inspector per district ("Rayon").

NATIONAL LEGISLATION

4. Relevant national legislation for registration of plant varieties, seed production controls and certification is in place. The main basic and implementation acts including legally binding standards and methods are as follows:

- Law of Ukraine “On Seed and Planting Stock” No. 5397-VI of December 02, 2012, in new wording;
- Law of Ukraine “On Joining of Ukraine to the Scheme for Varietal Certification of Cereal Seed and the OECD Scheme for Varietal Certification of Maize and Sorghum Seed” of February 15, 2011, No. 3019-VI;
- Resolution No. 299 of the Cabinet of Ministers of Ukraine of 22 April 2013, “Temporary order on certification of seed and planting material” which is a basis for the implementation of OECD rules for seed production controls;
- Resolution No. 447 of the Cabinet of Ministers of Ukraine of 22 May 2013, “On Approval of Procedure of Seed Batches Marking” lays down the rules for the labelling of seed lots and packages;
- Order No. 115 of the Ministry of Agrarian Policy of Ukraine of 18March 2013, “On the Approval of the Procedure of Attestation of Economic Agents in Respect of the Right to Produce and Sell Seeds and Planting Material, Provision on the State Register of Seeds and Planting Material Producers”
- "Methods of Seed-production Grain (cereals) Crops Inspection" from 2010 and "Methods of Seed-production Maize and Sorghum Crops Inspection" from 2009, both methods for field inspections are harmonised with the OECD seed schemes and generally in line with EU requirements;
- Legally binding State Standard DSTU 4138-2002 for seed sampling and testing methods, which is not fully harmonised with the ISTA rules and State Standard DSTU 2240-93 for seed quality requirements which is broadly harmonised with EU requirements for seed quality norms.

5. As none of the state standards are fully in line with EU requirements and the procedures for their amendment are very long, the CA overcame this by adopting an order and a provision. According to the Order of the State Seed Inspectorate of Ukraine No. 26 of 11 March 2013 “On Sampling of Seed under ISTA rules”, sampling and testing of seed for export and OECD certification have to be carried out according to ISTA rules. To harmonise their norms for the seed-producing crop and for seed quality with EU requirements, Ukraine authorities approved in May 2015 "Provision on normative qualities of cereal seeds in Ukraine". The audit team noted that adopted norms are generally in line with EU requirements, however, there are a few cases where norms are slightly lower or some not specified (see also section 5.4. below).

RESOURCES

6. The SAIU informed the audit team that the number of seed inspectors has decreased in the last three years and there were 506 seed inspectors in place in 2014. As a consequence the average workload has increased and was around 2 000 ha of seed-producing crops per inspector with some 20 seed producers. The SAIU stated that due to staff decrease inspectors from other regions can be requested where needed.

7. All seed samples are taken by seed inspectors and analysed in district or regional seed laboratories of the SAIU. The total number of seed laboratories in 2014 was 455 with 838 seed analysts with an annual average workload of 570 samples per analyst. Testing of seed intended for the export is carried out in an ISTA accredited laboratory of the SAIU located in Kiev, which employs eight staff.

GUIDELINES AND TRAINING

8. In addition to the legally binding standards and methods listed above, technical guidelines of UPOV are used for DUS testing.

9. The SAIU informed the audit team that inspectors obtain a licence for performing seed controls having completed a three years course and passing an exam. The license is valid for three years and an exam and dedicated training is needed for its renewal. Seed inspectors are also trained annually according to the plan made by the regional SAIU. Training is held on the premises of regional institutes of agro-industrial development and inspectors pass an exam and obtain a certificate.

10. Inspectors, laboratory and other staff met by the audit team had appropriate knowledge about the relevant aspects of seed production controls and were well prepared for their tasks. The audit team did not identify any cases of facilities or equipment being inadequate.

REGISTRATION OF SEED PRODUCERS

11. According to the national legislation, seed producers must be registered to be allowed to engage in the production, processing and marketing of seed and must employ an agronomist to be in charge of the seed production. The Headquarters of the SAIU are in charge of the registration and the maintenance of the register. In the last three years, the number of registered seed producers decreased from 1 399 in 2012 to 912 in 2014. The renewal of the registration "attestation of seed producers" is done annually within the framework of the application for seed production.

12. The audit team met with a number of seed producers and representatives of seed producers associations at SAIU's headquarter in Kiev. Seed producers expressed their interest in the exportation of seed to the EU after Ukraine obtains the recognition of equivalence.

Conclusions on organisation of seed production controls

13. The CAs are clearly identified and there is a clear designation of responsibilities between the authorities involved in plant variety registration and seed production controls and certification.

14. Ukraine has adopted the necessary legislative and administrative measures to ensure that cereal seed produced is equivalent to seed produced in the EU. However, there are some differences regarding the norms for seed production and seed quality which are not in line with EU requirements.

15. Personnel had adequate knowledge, technical information and facilities available to implement the seed controls.

5.2 PLANT VARIETY REGISTRATION AND MAINTENANCE

Legal requirements

Articles 1, 4, 5, 7 and 11 of Council Directive 2002/53/EC.

Point 2 of Common Rules and Regulations of OECD Seed Schemes establishes that varieties shall be accepted into Scheme only if satisfactory results have been obtained by official tests (including comparative field tests) in at least one participating country. For all varieties, the tests must establish that the variety is distinct and that its generations used for production have sufficient uniform and stable characters. The tests must also establish that the varieties have acceptable value in at least one country.

Point 3.1 of Common Rules and Regulations of OECD Seed Schemes requires that in each country, an official list of varieties that have been accepted after the tests into the Scheme shall be published and revised annually.

Point 3.2 of Common Rules and Regulations of OECD Seed Schemes sets that only seed of listed varieties and parental constituents is eligible for certification.

Point 6.1(iv) of Common Rules and Regulations of OECD Seed Schemes lays down that the CA of the country of multiplication is responsible for making available to the seed crop inspectors and to the control plot recorders, the official or provisional descriptions of varieties before inspection and control plot recording takes place.

Findings

16. The UIPVE stated that the procedure for registration of plant varieties is the same for domestic and foreign bred varieties. After the administrative checks of the application and verification of the proposed denomination of the candidate variety the technical examination of candidate varieties is carried out. Testing of varieties for DUS and for VCU is carried out in the field and in the laboratory. Only varieties which are tested as distinct, uniform and stable and have appropriate VCU are registered in the State Register of plant varieties, according to the national seed law. When a variety is registered, it's standard seed sample is stored at the UIPVE and an official DUS description is made for further use in seed certification.

17. The UIPVE stated that they check the maintenance of registered varieties annually. The breeder is required to provide seed samples of their varieties. The seed sample is sown in the field and is compared with the standard sample and with the official description of the varieties. A variety is removed from the register if the breeder fails to provide the sample for the maintenance check or the results of maintenance testing show non-compliance with the standard sample and official description.

18. According to the national seed law, only varieties listed in the State Register of plant varieties suitable for dissemination are allowed to be imported, marketed, included in seed production and certification and used in cultivation. At the time of the audit 9 339 plant varieties were listed in the State Register of plant varieties in total, out of which 4 758 were domestic and 4 581 foreign varieties. In the case of cereals 2 783 domestic and foreign varieties were listed in total. The State Register includes only plant varieties without genetic modification and is publicly available on the web site of the SVPSU.

19. The audit team visited two testing stations and noted that:

    - Testing fields for DUS and VCU of winter cereal varieties, which included example varieties from UPOV test guidelines, were designed and maintained appropriately in line with OECD requirements;

    - Experts of the UIPVE met were experienced and knowledgeable and followed testing protocols. Log-books for DUS testing included the characteristics from respective UPOV test guidelines and certain observations were recorded.

Conclusions on plant variety registration and maintenance

20. The procedure for registration of plant varieties, criteria for admission to the national list of varieties and check of the maintenance of varieties are in line with EU requirements and OECD standards.

21. Official testing of plant varieties for their registration is carried out appropriately.

5.3 ORGANISATION OF SEED PRODUCTION CONTROLS

Legal requirements

Points C, D, E, F and G of Article 2(1) of Council Directive 66/402/EEC.

Article 2(1)(H) of Council Directive 66/402/EEC.

Article 2(3)(A)(a) of Council Directive 66/402/EEC.

Article 2(3)(B)(a) of Council Directive 66/402/EEC.

Article 7(1) of Council Directive 66/402/EEC.

Point 7.2.3 of Common Rules and Regulations of OECD Seed Schemes lays down that in the case of production of "Certified" category, the national designated authority may, under official supervision, authorise non-official inspectors to carry out field inspection with a view to seed certification.

Point 7.4.1.3 of Common Rules and Regulations of OECD Seed Schemes lays down that national designated authority may authorise non-official persons to carry out, under official supervision, seed sampling, fastening and labelling of seed containers.

Point 7.4.2.3 of Common Rules and Regulations of OECD Seed Schemes lays down that national designated authority may authorise non-official laboratories to carry out seed analysis under official supervision.

Common Appendix 5 of OECD Seed Schemes lays down conditions for operating activities of the seed certification process by authorised persons and laboratories under official supervision. These operating activities include field inspection of seed crops by authorised inspectors under official supervision and seed sampling and seed analysis by authorised persons or laboratories under official supervision.

Findings

22. The SAIU is responsible for official controls of seed production (field inspection, seed sampling and seed testing) and seed certification and no tasks have been delegated to private persons or laboratories. The seed inspectors of the SAIU are organised in regional branch offices and at least one inspector is assigned and responsible for a district territory.

23. According to the national legislation, all seed produced in Ukraine has to be officially certified, including the seed intended for the own use of the seed producers/agricultural entities which is not placed on the market or further distributed. The seed production controls and the applicable standards are the same for seeds produced for both purposes. In the case of the seed for own use, the seed packages are not marked with official seed labels and the seed quality document, which does not allow marketing, is issued after the seed is tested.

24. The implementation of the official controls of seed-producing crops (field inspections) and seed certification is carried out in line with the order on certification of seed and planting material. Main procedures for seed certification and the role of the certification authority are determined as well as obligations and deadlines for the applicants. The order also lays down that field inspection of those crops, for which Ukraine has joined the OECD Seed Schemes, are carried out according to the requirements of these schemes.

25. According to the rules, seed producers must send an application for the official controls of their seed production, at least one month before the sowing date to the regional SAIU. The applicant must submit information and data including the sowing plan of seed-producing crops, seed certificates for the seed to be used for sowing, licence agreement with the breeders and agreement with the SAIU for performing seed certification. The seed inspector who has territorial responsibility is assigned to carry out seed certification and he/she verifies the application and attached documents. The official DUS description of the varieties in seed production is obtained by the inspector from the database of the UIPVE. In the case of seed production for export, the applicant has to state the intention of obtaining the OECD certificate.

26. The SAIU stated that they officially sample, test and certify all imported seed used before sowing for further seed production (category pre-basic and basic seed). This is not the case for imported certified seed aimed for grain production. There are no additional controls of the seed on the market.

27. The SAIU also informed the audit team that control of Genetically Modified Organisms (GMO) presence in seed on the market is carried out. The SAIU laboratory carries out GMO testing. Samples of maize, soybean, oilseed rape, potato, tomato and sugar beet seed or propagating material have been taken for GMO presence. In 2012, 2 580 samples, in 2013, 1 970 samples and in 2014, 442 samples were taken and analysed. No non-compliant samples were identified in the last three years.

Conclusions on official controls of seed production

28. The organisation of seed production controls and certification in line with OECD and EU requirements. All controls in seed production and seed certification are carried out officially by the seed inspectors of the SAIU.

29. Appropriate controls are carried out for imported seeds intended for seed production and there is GMO testing in seed.

5.4 FIELD INSPECTIONS OF SEED-PRODUCING CROPS

Legal requirements

Points C, D, E, F and G of Article 2(1) of Council Directive 66/402/EEC.

Annex II, Part A point 1 to Council Decision 2003/17/EC.

Annex II, Part B points 5 and 6 to Council Decision 2003/17/EC.

Point 6.1(ii) of Common Rules and Regulations of OECD Seed Schemes lays down that the national designated authority of the country of multiplication is responsible for ensuring that the official description of the variety, or of the parental components, in the case of hybrid variety, is available before the seed crop inspection season commences.

Point 8.1.1 of Common Rules and Regulations of OECD Seed Schemes lays down that a part of every sample of basic seed and of a percentage of the samples of certified seed has to be checked in post-control tests. Tests have to be conducted immediately or in the season following the drawing of the samples.

Point 8.1.2 of Common Rules and Regulations of OECD Seed Schemes lays down that the percentage of post-control of certified seed is defined by the CA.

Point 8.3 of Common Rules and Regulations of OECD Seed Schemes lays down that the post control is mandatory for all samples of certified seed when the lot is to be used for the production of further seed generations.

Point 8.4 of Common Rules and Regulations of OECD Seed Schemes lays down that when a control plot is a pre-control, the CA is not entitled to certify seed derived from the lot concerned if the results from the plot test show that varietal identity or purity has not been maintained.

Findings

30. The SAIU informed the audit team that seed inspectors are present and supervise the sowing of seed-producing crops. They check documents and labels of respective seed lots used for sowing.

31. The preliminary field inspection is carried out at the appropriate development phase of the crop (e.g. at ear emergence of cereals) to check whether the seed-producing crop is suitable for final field inspection. During the preliminary field inspection the seed inspector checks the varietal identity against the official description of the variety. Additional requirements such as previous cropping, isolation distance, presence of weeds and that of other varieties or plant species and infestation of pests and diseases are also checked.

32. The seed inspector issues a report of the preliminary inspection which includes recommendations and deadlines to address any shortcomings found. When the seed producer addresses them adequately, the crop is accepted for final field inspection. The crop is rejected in the case of not meeting the norms (e.g. too high number of off-types, infestation with pests or diseases).

33. Detailed procedures for performing field inspection, including conditions to be satisfied by the crop, are laid down in "methods" for cereals from 2010 and for maize and sorghum from 2009, which have been prepared, taking into account relevant OECD Seed Schemes. In addition to these methods, Ukraine authorities approved in May 2015 "Provision on normative qualities of cereal seeds in Ukraine" which includes requirements and standards for the seed-producing crop as well standards or conditions for seed which are generally in line with EU requirements or stricter in some cases. However, there are a few cases where norms are not in line with EU requirements (Article 2(1) of Council Directive 66/402/EEC):

    - Isolation distance for the category certified seed for sorghum is lower, as well varietal purity for hybrids of maize as parental lines;
    - The content of seeds of other plant species for the category certified seed for maize, the content of seeds of other cereal species and the presence of specified weeds.

34. The SAIU informed the audit team that a seed inspector carries out the final field inspection of the seed-producing crop. For cereal crops there is one visit at the appropriate development phase of the crop (e.g. grain filling/waxy stage) and at least four for maize. The inspector selects for detailed inspection sample areas to cover the whole area of the field and its configuration. Ten sample areas, of 20 m^2 each, are selected for the field of up to 50 ha and one additional sample area for each additional 10 ha of the field. The inspector performs a detailed inspection in each sample area to determine the number of productive stems, the varietal purity of the crop, the number of off-types, contamination with weeds, pests and diseases. Data for each sample area are recorded in a field log-book and if requirements are met the inspector produces a report of final inspection, based on which the certificate for the seed-producing crop is issued. In the case of non-compliance, the crop is rejected.

35. The SAIU informed the audit team that they apply stricter rules for the field inspection of seed-producing crops intended for the export or OECD certification. The maximum

size of such fields is limited to ten ha and in addition to that, detailed inspection is carried out on ten sample areas per field.

36. The audit team observed three demonstrations of field inspection, including winter wheat and winter barley seed-producing crops and noted that:

    - Inspectors met were experienced and knowledgeable and confirmed their regular contacts with and presence at the seed producing entities and following up the seed-producing crops;
    - Field inspections demonstrated, including the checking of the varietal identity and purity and determination of sample areas were appropriate, in line with OECD requirements.

37. The audit team noted that the system for post control testing of samples of produced and certified seed is in place. According to the national procedure for seed certification, samples from all produced seed lots of category pre-basic and basic seed and on average 10 % of samples from seed lots of certified seed category are included in the post control testing which is in line with OECD requirements. Seed samples taken from the imported seed are not included in the post control testing. The UIPVE informed the audit team that some 5 500 samples were tested in 2014 and some 4 500 in 2015. More than half of the samples tested in 2015 were for wheat, followed by barley, maize and all other plant species.

38. The UIPVE stated that all plants on every control plot are subject to inspection with the view of establishing their conformity with the characteristics of the standard sample and variety DUS official description. Observations are carried out daily and are done at the development phase, when expression of characteristics can be clearly established. Some of the morphological characteristics, like for the ear and grain in cereals, are observed after the harvest in the laboratory.

39. Based on the log-book records the UIPVE prepares the report on post-control examination and sends it to the regional SAIU. Seed inspectors prepare the post-control protocol and determine the compliance of control samples with the national norms for varietal identity and purity and inform the client and the UIPVE. A seed lot is rejected when the post control test is negative.

40. The audit team visited two testing stations with the post certification control tests for winter cereals and noted that:

    - Design of field tests and maintenance of control plots of 6 m^2 (1.5 m x 4 m) with 2 000 plants per plot was in line with OECD requirements. Standard samples for each plant variety were sown alongside the control samples for comparative assessment in the field;
    - Log-books included all characteristics from the UPOV technical guidelines and for every seed sample/control plot includes the code of expression of the characteristic from the official variety DUS description;

- The maximum number of allowed off-types per control plot was in line with the OECD requirements;
- Experts met were experienced and technically skilled for performing the post-controls.

Conclusions on field inspections on seed-producing crops

41. Field inspections on seed-producing crops are organised and carried out appropriately, in line with OECD standards. However, norms for the seed-producing crop and for quality of cereal seed are not fully in line with EU requirements.

42. Post-control testing of produced certified seed is appropriate.

5.5 SEED SAMPLING AND TESTING

Legal requirements

Points C, D, E, F and G of Article 2(1) of Council Directive 66/402/EEC.

Article 3(3) of Council Directive 66/402/EEC.

Article 7(1) of Council Directive 66/402/EEC.

Article 7(2) of Council Directive 66/402/EEC.

Article 8(1) of Council Directive 66/402/EEC.

Article 9(1) of Council Directive 66/402/EEC.

Annex II, Part B point 1 to Council Decision 2003/17/EC.

Annex II, Part B points 2.1 and 2.2 to Council Decision 2003/17/EC.

Point 9.3.1 of Common Rules and Regulations of OECD Seed Schemes lays down that the seed packages have to be sealed (fastened) at the time of sampling and the contents identified by the person taking the sample or under his supervision. For not finally certified seed, the packages have to be sealed by the person normally taking samples for certification or under his supervision.

Findings

43. The SAIU informed the audit team that a seed inspector is present and supervises the harvesting of seed. Measures are taken by seed producers to guarantee the identity of the seed and to prevent any mixing while harvesting, transporting and stocking in the warehouse.

44. The representatives of the seed producers visited stated that they have their own system of quality control of seed and record keeping. Every incoming truck of the harvested

seed is sampled and quick seed analyses are made in their own seed laboratory before allowing unloading.

45. Seed processing (cleaning, sorting, and calibrating) of the seed is usually done in one work operation including packing and labelling. The SAIU stated that seed inspectors are present and supervise the processing and packing of the seed. Pre-basic and basic seed must be packed into bags, which are sealed by simultaneously stitching together the official seed labels with the tops of the bags. Certified seed is usually packed in big bags and sealed with the attachment of a self-adhesive official label at the top and at the bottom of the bag. In addition, one label is also put into the bag/package.

46. The SAIU stated that seed producers apply for the seed sampling after processing of the seed and formation of the seed lots. Due to the work flow of the seed processing facilities, the seed is packed directly after the processing and seed lots are generally sampled from sealed packages. Automatic seed samplers are not used in Ukraine and all seed samples are taken manually.

47. The SAIU stated that seed inspectors take samples for domestic market according to the national standard (see paragraph 4) and samples are analysed in a district or regional seed laboratory. Sampling of seeds intended for export or OECD certification is carried out only by ISTA accredited samplers using ISTA methods and samples are analysed in the ISTA accredited laboratory. At the time of the audit there were 25 ISTA accredited seed samplers, some of them were staff of the ISTA laboratory and the rest were seed inspectors across Ukraine. Due to the low volume of seed exported, the number of ISTA accredited seed samplers appears to be sufficient.

48. The audit team visited the ISTA accredited laboratory and observed seed sampling at two seed producing facilities and noted that:
    - The ISTA accredited laboratory has adequate equipment and laboratory space and performs testing of seed samples under anonymity. It has eight staff and tested some 300 samples for export in 2014;
    - Inspectors met confirmed their presence at the seed producing entities during the harvest, processing and packing of seed;
    - The maximum weight of a seed lot (20 t) and the minimum weight of a sample for seed analysis are in line with Article 7(2) of Council Directive 66/402/EEC;
    - Seed sampling processes observed were carried out appropriately, in line with the relevant national and ISTA methods. The selection of packages to be sampled, the number of incremental samples taken and the division of the primary sample were done appropriately;
    - Inspectors checked the homogeneity of the seed lot by comparing the incremental samples. They stated that they stop sampling if they find out that the seed lot is not homogenous;
    - Equipment and tools for sampling were appropriate and inspectors taking samples were technically skilled;

- Samplers generally took three samples, one for the laboratory analysis, another for the post-control where applicable and a third as a control sample to remain with the seed producer. Seed samples were closed and sealed and sampling reports were produced.

Conclusions on seed sampling and testing

49. Formation of seed lots is carried out in line with EU requirements.

50. Sampling of seed for export is carried out appropriately in line with ISTA rules and tested in ISTA accredited laboratory.

5.6 LABELLING AND SEALING OF PACKAGES AND ISSUING OF CERTIFICATES

Legal requirements

Article 3(1) of Council Directive 66/402/EEC.

Article 10(1) of Council Directive 66/402/EEC.

Article 11a of Council Directive 66/402/EEC.

Article 12 of Council Directive 66/402/EEC.

Annex II, Part A points 2 and 3 to Council Decision 2003/17/EC.

Annex II, Part B points 3, 3.2, 3.4, 3.5 and 4 to Council Decision 2003/17/EC.

Point 6.1(v) of Common Rules and Regulations of OECD Seed Schemes lays down that the CA of the country of multiplication is responsible for ensuring that the appropriate OECD labels are attached to the packages of the produced seed lots.

Point 7.6 of Common Rules and Regulations of OECD Seed Schemes lays down that the CA issues for each lot of basic and certified seed approved under the OECD Scheme, certificates for varietal purity and for seed quality analysis results. These two certificates shall carry the same OECD reference number.

Point 7.9.1 of Common Rules and Regulations of OECD Seed Schemes lays down that seed after field approval, but before final certification as basic or certified seed, has to be identified in sealed containers by the special label as not finally certified seed.

Point 11.4 of Common Rules and Regulations of OECD Seed Schemes lays down the conditions under which the re-packing and re-sealing can take place.

Findings

51. The SAIU stated that seed labels bear a serial number. Seed producers apply to the SAIU for the assignment of the label serial numbers for the individual seed lot after the final field inspection and formation of the seed lots. The SAIU headquarters assign the

serial sequence numbers based on the number of packages per seed lot and record them in a central register. A printing facility has been designated to print seed labels. When seed producers order the seed labels at the printing facility they provide also the allocated label serial numbers which are printed on the back side of the labels.

52. The SAIU stated that the seed inspector in charge allocates the unique number of the seed lot before the labelling of packages is carried out. The seed lot number is composed of the figures which identify Ukraine, the region, the district and the inspector, the running number of the field inspection and the year of seed production. When the seed producer receives a bunch of blank labels, the inspector fills in the first label for each seed lot with the allocation of the seed lot number and the rest of the labels are filled in by the seed company.

53. The SAIU stated that the seed inspector issues a seed certificate after obtaining the seed laboratory testing results. The seed certificate includes the main identification data for the seed including the seed lot number and results of seed laboratory analyses. Seed producers can market the seed when they obtain the seed certificate. The OECD certificates are issued centrally at the SAIU headquarters based on field inspection certificate and are accompanied by the Orange ISTA certificate.

54. A seed certificate is valid for four months and the re-sampling and re-testing of seed for the renewal of the seed certificate is done officially by the SAIU. A re-tested seed lot receives the new certificate, which bears the same lot number and is generally not relabelled.

55. The SAIU stated that on the issuance of the seed certificates the inspector cross-checks the produced quantity of certified seed with that planned at the time of the application for the seed certification. In the case of discrepancies, the planned quantity is taken as a maximum certified quantity.

56. Regional SAIU offices regularly send the lists of issued seed certificates to the headquarters where a register is kept.

57. The audit team noted that the layout, colour pattern and information required for the OECD labels are in line with the OECD requirements. Labels for the domestic market have the same colour as well. Labels are made of paper and can be torn up easily.

Conclusions on labelling and sealing of packages and issuing of certificates

58. Seed packages are sealed and labelled appropriately, in line with EU requirements.

59. The system for issuing the seed certificates gives assurance for the varietal identity and quality of the seed and is carried out in line with the OECD standard.

6 OVERALL CONCLUSIONS

Overall official controls for seed production and certification of cereal seeds in Ukraine are organised appropriately. All activities are carried out by CAs official staff that have appropriate technical knowledge and experience in their field and no tasks are delegated.

All seed producers are registered and under frequent control of seed inspectors in the framework of the seed production controls. Controls of seed on the market are focused on the imported seed for further multiplication. Testing for GMO presence is also carried out.

Field inspections of seed-producing crops and pre- and post-certification controls of seed are carried out appropriately, in line with OECD standards and satisfy EU requirements. Sampling and testing of seed is carried out appropriately according to ISTA rules. Seed packages are sealed with official labels under official supervision and traceability in seed certification process is ensured. However, some norms for the seed-producing crop and for quality of cereal seed are not fully in line with EU requirements.

Overall, the national authorities responsible for implementation of seed certification in Ukraine are competent and operate appropriately. Once the above mentioned minor shortcomings have been addressed, seed produced in Ukraine can be considered equivalent to seed produced in the EU.

7 CLOSING MEETING

A closing meeting was held on 4 June 2015 with representatives of the MoAPF and CAs. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The MoAPF accepted these and expressed their willingness to immediately address the shortcomings which were identified.

8 RECOMMENDATIONS

The competent authorities of Ukraine are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendation set out below, within twenty five working days of receipt of this audit report.

No.	Recommendation
1.	Ensure that norms and standards for the cereal seed-producing crops and for seeds are harmonised with EU requirements as required by Article 2(1) of Council Directive 66/402/EEC. *Recommendation based on conclusion 14 and 41.* *Associated findings 5 and 33.*

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 2002/53/EC	OJ L 193, 20.7.2002, p. 1-11	Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species
Dir. 66/402/EEC	OJ L 125, 11.7.1966, p. 2309-2319	Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed
Dec. 2003/17/EC	OJ L 8, 14.1.2003, p. 10-17	2003/17/EC: Council Decision of 16 December 2002 on the equivalence of field inspections carried out in third countries on seed-producing crops and on the equivalence of seed produced in third countries
Dir. 66/401/EEC	OJ L 125, 11.7.1966, p. 2298-2308	Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed
Dir. 2002/54/EC	OJ L 193, 20.7.2002, p. 12-32	Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed
Dir. 2002/57/EC	OJ L 8, 14.1.2003, p. 74-97	Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants

ANNEX 2 - STANDARDS QUOTED IN THE REPORT

International Standard	Title
OECD Seed Schemes Maize and Sorghum	OECD Schemes for the Varietal Certification or the Control of Seed Moving in International Trade , Rules and Regulations 2015 Edition, OECD scheme for the varietal certification of maize and sorgum seed, Organisation for Economic Co-operation and Development
OECD Seed Schemes Cereals	OECD Schemes for the Varietal Certification or the Control of Seed Moving in International Trade, Rules and Regulations 2015 Edition, OECD scheme for the varietal certification of cereal seed, Organisation for Economic Co-operation and Development
ISTA Rules	International Rules for Seed Testing 2015, The International Seed Testing Association