



## CPVO Audit Programme for EU-Examination Offices and procedure to assess non-EU based Examination Offices before initiating cooperation

24/10/2017

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### Outline

- CPVO and organisation of DUS examination
- CPVO Audit programme
- Entrustment requirements
- Audit mission - step by step
- Procedure to assess non EU-EOs

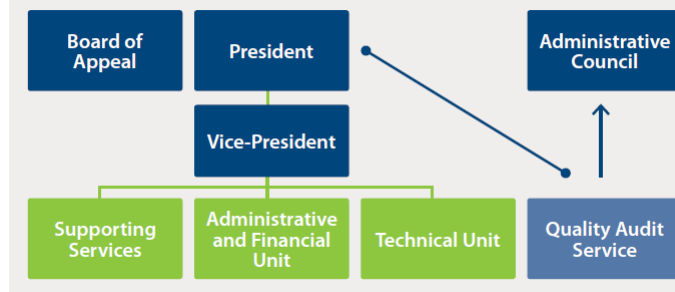
## Organisation of technical examinations within the EU

- Technical examinations are carried out by **entrusted** examination offices in the Member States
- Examination Offices are entrusted following and **Audit**
- The Audit is carried out by and independent audit service **QAS**
- The CPVO arranges for a technical examination and decides to which entrusted examination office a candidate variety is attributed for testing



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## Quality Audit service - QAS

An independent function to assess the competence of examination offices

- Under the authority of the Administrative Council
- Monitored by the Audit Advisory Board
- Staffed by CPVO personnel and external technical experts



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## Aim of the audit programme

**DUS test results** that are

- ✓ Reliable
- ✓ Comparable
- ✓ Repeatable

**Examination offices** that are able to demonstrate their competence.



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# CPVO approach

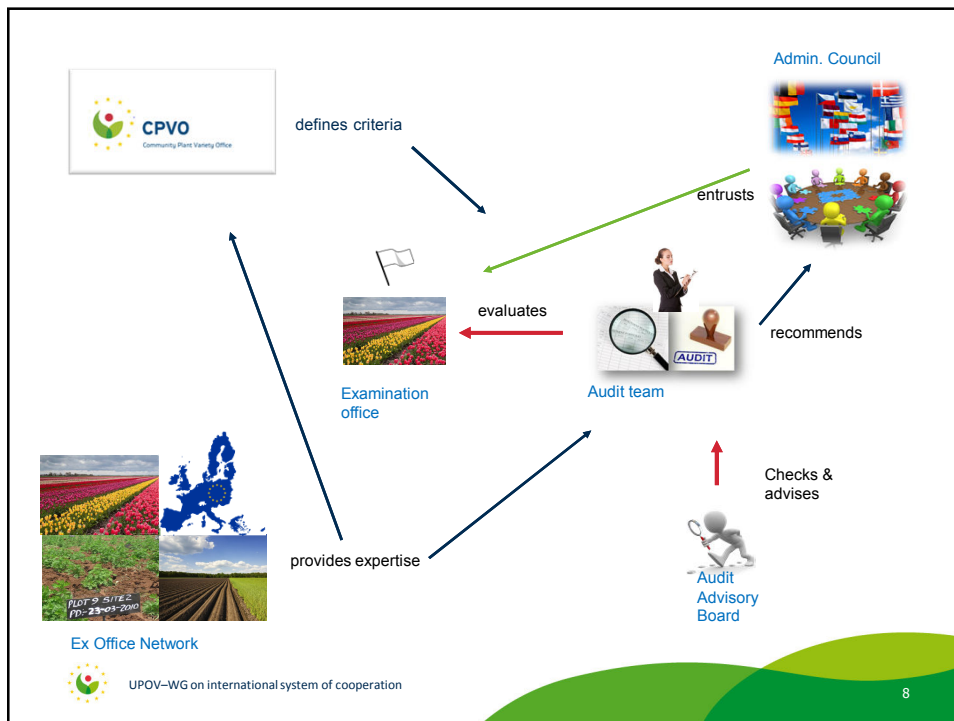
**QUALITY** - perceptual, conditional and often subjective?

- Clear **criteria** – Entrustment requirements
- Formal **evaluation** – independent audit team
- **Decision** taken by different entity – Administrative Council
- Independent **review** – Audit Advisory board



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## CPVO Entrustment Requirements

Criteria allowing to evaluate the competence of examination offices (14 Chpts.)

1. The framework (Chpt 1-8,14)
2. Checking and acting (9)
3. Technical operations (10-13)



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## The framework

- Organisation, experience,
- Independence, integrity, confidentiality
- Cooperation with CPVO
- Personnel
- Subcontracting



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## Checking and acting

- Quality management
- Documentation
- Records
- Audits and reviews
- Corrective action
- Reporting



## Technical operations

- Facilities and equipment
- Test protocols and procedures\*
- Plant material
- Variety collections



\* Existing guidance translated into requirements



## Audit mission –step by step

- 1 multiannual audit planning
- 2 annual audit planning
- 3 audit sample and audit team
- 4 pre-audit communication
- 5 on-site visit
- 6 follow-up and audit conclusion
- 7 audit programme evaluation



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## 2. annual audit planning

- Even distribution, match of visit period and trialling activities
- Pre-selection of potential TEs
  - 1-2 of 31 Technical Experts (TEs)
  - Management of conflict of interest
  - Involvement of a maximum of TEs in a period of three years
  - Optimal scope-expertise match



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### 3. Audit sample variables

- Size of the EO (nb applications, nb staff)
- Nb of test sites
- scope complexity (new species, appl./species, demanding species, crop sectors)
- Incidents
- Previous audits (sample composition, findings)



### 4. pre-audit communication

- Audit announcement
- Scope and organisational changes at EO
- Draft audit time table





**Draft time table CPVO Entrustment Audit – UKS**  
10/11.05.2017

09.05.2017 travelling to Kosice; rental car, transfer to Spišské Podhradie  
Accommodation: Ubytovanie u Kastelana Palesovo namestie 47, 05304 Spišské Podhradie, 421 907 974 334

10.05. Meeting audit team and EO staff in Spišské Vlachy, 0800 hrs →first audit day  
Transfer to Spišská Bela  
Accommodation: S. Bela test station

11.05. departure from accommodation at 0730 hrs →Second audit day  
accommodation: Pension Barca, Gavlovcova 1, 04017 Kosice, 421 55 728 31 00

Day 1	Time	Activity	Attendance
	08.00 – 08.15	10.05 Spišské Vlachy, introduction to UKSUP, grasses and clovers	All* (GS to le;
	08.15 – 08.40	Opening meeting and introductions	All* (EO to le
	08.40 – 10.35	Administrative and organisational matters	GS, EO and I)
	08.40 – 10.30	DUS testing of forage crops	JW, staff
	10.30 – 10.45	1st wrap-up meeting assessment team	JW, GS
	10.45 – 11.15	Final questions and feedback to EO	All* (GS to le
	11.15	Transfer to Spišská Bela (Lunch break on the way e.g. in Pípod)	All*
	12.15 – 13.30	Spišská Bela, oats, triticale and potatoes	All* (GS to le;
	13.30 – 15.00	Opening meeting and introductions	All* (JW to le)
	15.00 – 15.30	DUS testing of oat/triticale and potatoes (assessment team may split if appropriate)	JW, GS
	15.30 – 16.15	2nd wrap-up meeting assessment team	All* (GS to le;
	16.15	Closing meeting day 1 Accommodation Spišská Bela	All*

Day 2	Time	Activity	Attendance
	10.15 – 10.30	11.05. Belusa, oilseed rape	All* (GS to le;
	10.30 – 10.45	Opening meeting and introductions	All* (EO to le
	10.45 – 13.00	Presentation of test station Overview of DUS arrangements - handling plant material, variety collection and tour of premises, use of protocols	JW, staff
	11.30 – 13.00	Organisational and QM matters	GS, staff
	13.00 – 14.00	Lunch break (Sandwich?)	All*
	14.00 – 14.45	Assessment team prepares closing meeting	JW, GS
	14.45 – 15.30	Overall closing meeting, presentation of audit conclusion	All* (GS to le;
	15.30	Transfer to Kosice	JW, GS

\* : Audit team and staff as determined by EO

JW Jennifer Wyatt, Technical Expert  
GS Gerhard Schuon, Audit Team Leader

Arrival Kosice: 09.05.2017 JW 1830 GS 1400  
Departure Kosice: 12.05.2017 JW 0535 GS 0500

Fourth draft: 23.03.2017

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## 5. on-site visit

- opening meeting
- assessment, interviews, inspection
- coordination amongst team members
- feedback to auditee, persons interviewed
- audit observations -> audit findings
- closing meeting



## 6. follow-up and audit conclusion

- Audit findings presented in closing meeting and **audit report**
  - Follow-up within defined period (12 weeks):  
corrective action report
  - Audit conclusion and report to AC
- > Entrustment decision by AC



## Examples of non-conformities

- Technical protocol in species XY not respected: no systematic observation of ploidy and disease resistance characteristics ...
- Insufficient records on conduct of DUS trials: primary observations and raw data recording erratic
- Variety collection of XY not representative and limited to varieties marketed in region ZZZ
- No defined policy for the constitution of the variety collections of species ABC
- ...



## 7. audit programme evaluation

- Covering a triennial period – audit cycle
- Identify improvement opportunities
- Reviewed entrustment requirements
- TE training programme



## PROCEDURE to assess non EU-EOs

- The CPVO may under certain circumstances make use of DUS reports established by a non EU EO (*legal basis article 27 of COM regulation 874/2009*)
- This applies in cases where:
  - There is no EO available to perform DUS test for the species in question in the EU (article 27.5a)
  - An EU-EO in the EU is entrusted, but the candidate variety has already undergone, or is in the process to undergo, a DUS examination at a non EU-EO (article 27.4).
- In both cases the AC consent is needed



## PROCEDURE to assess non EU-EOs

- There is **no entrustment** of non-EU-EOs
- Consequently QAS does not intervene
- AC consent should be based on a CPVO proposal
- CPVO proposal should be based on an CPVO assessment on the technical capacities of the EO in question



## PROCEDURE to assess non EU-EOs

- CPVO assessment :
  - Identification of a technical contact person
  - Information as regards independence, impartiality and integrity
  - Information as regards facilities and equipment
  - Information on experience with the species concerned (number of tests, since when); (27.4e & 27.6e)
  - The existing technical guideline and the way how the technical examination is conducted (27.4b & 27.6b)
  - The requirements as regards the submission of plant material (27.4a & 27.6a)
  - The agreement from the non EU EO to visit the trial in case of need (27.4c & 27.6c)



## PROCEDURE to assess non EU-EOs

- CPVO assessment :
  - The agreement from the non EU EO to provide preliminary, interim and final reports in accordance with article 27.4d and 27.6d respectively and in cases where the entrustment requirements so require
  - Information related to the existing reference variety collection (form, size, maintenance, composition, criteria which varieties to include in the collection)
  - Procedure on how reference varieties to be grown in the growing trial are selected



## PROCEDURE to assess non EU-EOs

- CPVO assessment :
  - CPVO might visit the EO
  - In case of no visit, CPVO needs to justify
  - CPVO may involve Crop experts from entrusted EOs



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- Report on assessment
- Annex an opinion of QAS



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- AC will take a decision



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- AC will take a decision



- CPVO enters into an agreement



**Thank you for your attention**

