CPVO

Community Plant Variety Office

CPVO Audit Programme for entrusted Examination Offices

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Quality Audit Team Leader – November 2017

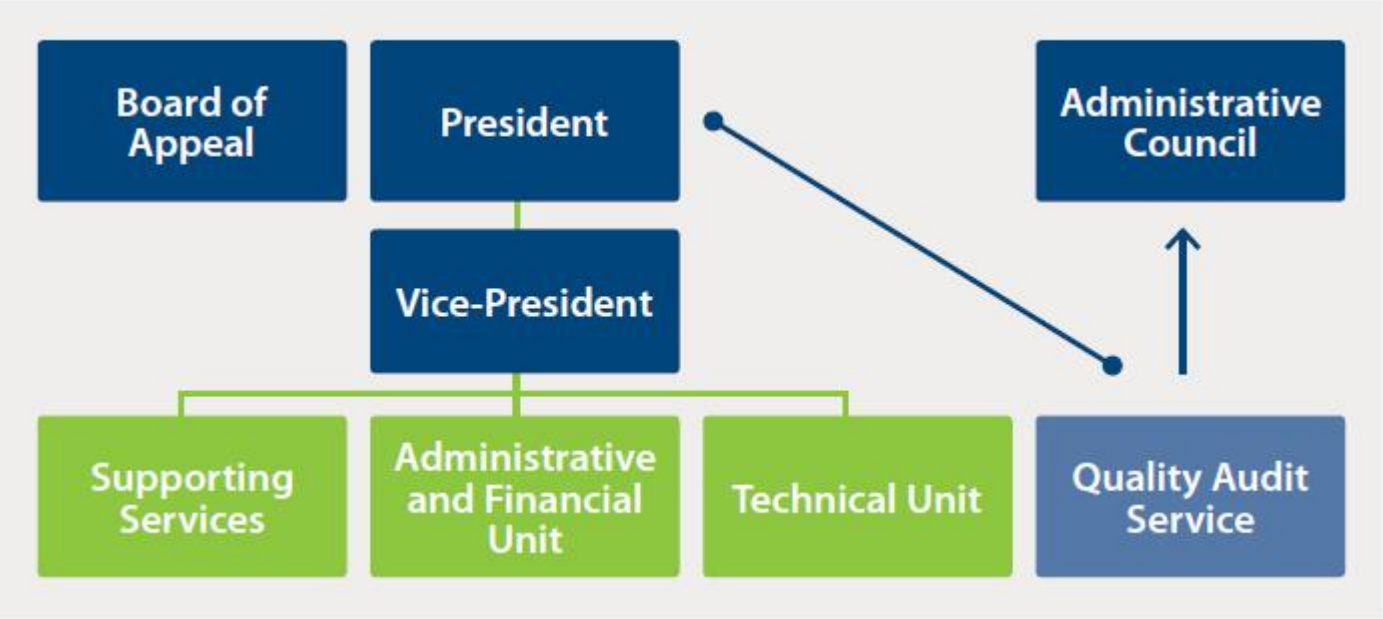
Outline

- CPVO
- CPVO Audit programme
- Entrustment requirements
- Audit mission - step by step

CPVO's Mission

- *To deliver and promote an efficient Intellectual Property Rights system that supports the creation of new plant varieties for the benefit of Society*

CPVO
Community Plant Variety Office



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

- Auditing

Structured, independent assessment to find evidence for an audit conclusion.

Quality audits focus on the conformance with defined standards.

Aim of the audit programme

DUS test results that are

- ✓Reliable
- ✓Comparable
- ✓Repeatable

Examination offices that are able to demonstrate their competence.

CPVO approach

QUALITY - perceptual, conditional and often subjective?

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

CPVO
Community Plant Variety Office
defines criteria
Admin. Council
entrusts
evaluates
Examination office
Audit team
AUDIT
recommends
Checks & advises
Audit Advisory Board
provides expertise
PLOT 9 SITE 2
PD:- 23-03-2010
Ex Office Network

CPVO Entrustment Requirements

Criteria allowing to evaluate the com-
petence of examination offices (14 Chpts.)

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

The framework

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

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

1. multiannual audit planning

- Risk associated with individual EOs (complexity and coverage of scope, subcontracting, recent changes)
- Risk associated with the current setup of the programme (most recent audit sample, current issues, scope extension)
- Incorporating changes required by AC or as result from programme review

2. annual audit planning

- Even distribution, match of visit period and trialling activities
- Preselection 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

Summary info on test volume	2014-17	finals	inte
	test repo	456	
nb. species under test in past three years	57		
nb. Applications/files per species (from 'new species query, and TLO website for current NSP)			
scope changes(new species with/without applications)	delete:	• *Malus domestica* Borkh.	
extension of scope for this assessment?	yes	• *Prunus amygdalus* Batsch x *Prunus per*	
		• *Prunus cerasifera* Ehrh. (Fruit and orna	
		• *Prunus cerasifera* Ehrh. x *P. dulcis* (Mill	
		• *Prunus domestica* L.	
		• *Prunus domestica* L. subsp. insititia (L.	
		• *Prunus* L. (*P. armeniaca* L. x *P. cerasifer*	
		• (*Prunus persica* x *Prunus davidiana*) x *P*	
	add:	• *Mangifera indica* L. (CSIC-La Mayora, M	
		• *Persea americana* Mill. (CSIC-La Mayor	
		• *Musa acuminata* Colla (Instituto Cana	
		• *Solanum tuberosum* L. (NEIKER, Vitoria	
sample of the last assessment:			
1. Check for recent additions to scope in "query_new_species_contracts" and on TLO site for current NSP	new species		
	Spiraea fritschiana C. K. Schneid. x S. japonica L. f.		
	Quercus rubra L.		
	Annona cherimola Mill.		
	Chaenomeles speciosa (Sweet) Nakai		
	Solanum habrochaites S. Knapp & D.M. Spooner		
	Sambucus x strumpfii Gutte (S. nigra L. x S. racemosa L.)		
	Matricaria recutita L.		

Test volume

Scope changes 1

Scope changes 2

Test volume

Test volume

M	N	O	P	Q
		finals	Interim	
Juglans nigra L.		8	1	
Citrus L.		3	4	
Eucalyptus globulus		3	19	
Prunus amygdalus B		1	2	
Olea europaea L.		2	10	
Prunus persica (L.) B		44	190	
Prunus cerasifera Eh		1	0	
Ananas comosus (L.)		1	0	
Vitis vinifera L.		8	51	
Medicago sativa L.		1	0	
Citrus reticulata Blar		9	11	
Prunus armeniaca L.		3	1	
Punica granatum L.		3	21	
Cucumis melo L.		18	20	
Zea mays L.		120	58	
Citrus sinensis (L.) O		5	12	
Citrus clementina hc		4	7	
Prunus salicina Lindl		4	1	
Helianthus annuus L		33	7	
Capsicum annuum L.		19	16	
Solanum lycopersicu		39	47	
Pisum sativum L.		6	0	
Cucumis sativus L.		4	2	
Citrus clementina hc		0	6	
Citrus latipes (Swing		0	3	
Solanum melongena		6	3	
Fragaria x ananassa D		11	5	
Citrus paradisi Macfa		1	3	
Vitis labrusca L. x V.		0	3	
Cynara cardunculus L		9	8	
Citrus unshiu Marcov		0	3	
Triticum aestivum L.		34	15	
Avena sativa L.		5	0	
Phaseolus vulgaris L.		0	1	
Lactuca sativa L.		8	10	

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

EO

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

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

date

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

Day 1

Time	Activity	Attendance
	10.05 Spisske Vlachy, introduction to UKSUP, grasses and clovers	
08.00 – 08.15	Opening meeting and introductions	All*(GS to lea
08.15 – 08.40	Presentation of UKSUP	All* (EO to le
08.40 – 10.35	Administrative and organisational matters	GS, EO and H
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 Spisska Bela (Lunch break on the way e.g. in Poprad	All*
	Spisska Bela, oats, triticale and potatoes	
13.15 – 13.30	Opening meeting and introductions	All*(GS to lea
13.30 – 15.00	DUS testing of oats/triticzle and potatoes (assessment team may split if appropriate)	All* (JW to le
15.00 – 15.30	2nd wrap-up meeting assessment team	JW, GS
15.30 – 16.15	Closing meeting day 1	All*(GS to lea
16.15	Accommodation Spisska Bela	

sample

Day 2

Time	Activity	Attendance
	11.05. Belusa, oilseed rape	
10.15 – 10.30	Opening meeting and introductions	All*(GS to lea
10.30 – 10.45	Presentation of test station	All* (EO to le
10.45 – 13.00	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 meting	JW, GS
14.45 – 15.30	Overall closing meeting, presentation of audit conclusion	All*(GS to lea
15.30	Transfer to Kosice	JW, GS

time table

team

*: 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

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 I

- Technical protocol in species XY not respected: no systematic observation of ploidy and disese resistance characteristics …
- Internal audit programme failed to cover some important vegetable species within the scope of entrustment (carrot and lettuce)

Examples of non-conformities II

- 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
- Confirm effectiveness and compliance
- Identify improvement opportunities

Evaluation results

- Reviewed entrustment requirements
- TE training programme
- Changes in QAS procedure manual
  - Appointment procedure for TEs
  - Integration of audit fees
  - Involvement of Audit Advisory Board

http://www.cpvo.europa.eu

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Quality Audit Service

The Quality Audit Service (QAS) performs assessments of Examination Offices independently of the management of CPVO. The output of the assessment process is a recommendation. Based on this recommendation, the CPVO Administrative Council takes its decision with respect to entrustment of an examination office for a defined set of species.

Document changes:
At the occasion of its meeting in October 2015, the CPVO Administrative Council approved the new version of the *QAS Procedure Manual*. Changes refer to the public access to assessment report documents. The members of the Administrative Council also approved the new version of the *Entrustment Requirements* with additional details for example on the living reference collection for fruit species or the subcontracting arrangements concerning DUS tests.

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Title	Downloads	Last update
Entrustment Requirements 2016	PDF	03 February 2016
QAS Procedure Manual	PDF	12 October 2015
Annex I entrustment requirements	PDF	11 January 2017

Thank you