



CHINA

# Quality Assurance in DUS examination as applied in the EU. The organisation of a quality audit. 欧盟DUS审查质量保障及审计程序

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# Introduction to the CPVO and QAS

## 简介：欧盟植物品种局（CPVO）、 质量审计服务（QAS）



## Community Plant Variety Office (CPVO):

### 欧盟植物品种局 (CPVO) :

Agency of the EU operational since 1995 and currently based in Angers, France. /// 1995年成立的欧盟机构，位于法国昂热。

#### Mission Statement:

#### 使命宣言:

**‘To deliver and promote an efficient Intellectual Property Rights system that supports the creation of new plant varieties for the benefit of Society’/// “设立、促进高效知识产权体系，支持植物新品种体系建设，造福社会”**



## Benefits of the CPVO EU-wide system /// CPVO: 欧盟体系的优势

- 1 application and protection covering all 27 EU countries  
1套申请和保护体系，涵盖27个成员国
- 1 fee payment for all 27 EU countries  
1项费用，面向27个成员国
- 1 technical examination valid for all 27 EU countries  
1次技术审查，适用27成员国
- 1 interlocutor between the breeder and the granting authority  
1位对接人，连接育种者和新品种审评机构



# CPVO Examination offices /// CPVO测试中心

- When the EU PVR system was created it was decided to use the **testing facilities** already existing in the **EU Member States**, for the assessment of the DUS criteria of candidate varieties /// 欧盟植物品种权保护制度规定使用**欧盟成员国**已有的**测试设施**，对待测品种进行DUS审查。
- Where no examination office within the EU is available for testing a particular species, the Office may collaborate with offices outside the EU /// 对于**欧盟内部**不具备测试中心的物种，CPVO可以与**欧盟外部**机构开展合作。





CPVO

Community Plant Variety Office



# DUS examination offices in the EU

## 欧盟DUS测试中心

 The red dots represent the headquarters of entrusted Examination Offices carrying out DUS technical examinations on behalf of the CPVO

红点：代表欧盟植物品种局受委托开展DUS审查的测试中心所在地

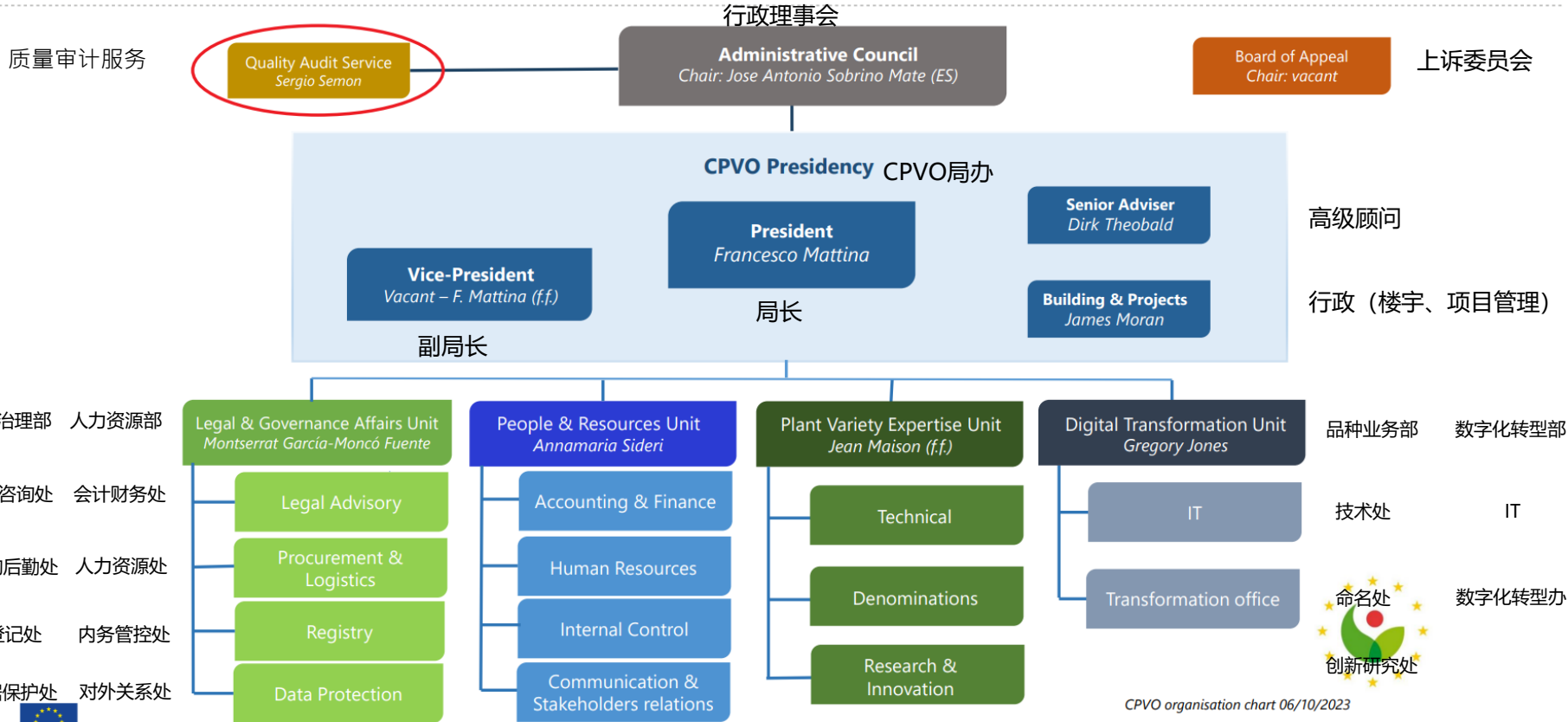


## Quality Audit Service - QAS /// 质量审计服务 (QAS)

An **independent** service of the CPVO to assess the competence of examination offices to achieve **entrustment/accreditation** /// QAS对测试机构的**委托 / 认证资质**进行评价，是欧盟植物品种局**独立部门**

- Under the authority of the Administrative Council (AC) /// 经行政理事会授权
- Monitored by the Audit Advisory Board (AAB) /// 由审计顾问委员会监督
- Staffed by 1 permanent CPVO staff (QAS Team Leader) and 32 external technical experts from EU examination offices /// 配备1位欧盟植物品种局人员 (QAS团队负责人) 和32位外部技术专家 (来自欧盟测试机构)







## Aim of the QAS assessment programme /// QAS评价项目的目标

**DUS test results** that are: /// **DUS测试**  
结果：

- ✓ **Reliable** /// **可靠**
- ✓ **Comparable** /// **可比**
- ✓ **Repeatable** /// **可复现**

**Examination offices** that are able to  
demonstrate their competence /// **测试**  
**机构能够证明其称职能力**



# CPVO approach /// CPVO的做法

**QUALITY** – perceptual, conditional and often subjective? /// **质量**：是否基于感性、附加条件、较为主观？

- Clear **criteria** – Entrustment requirements /// **明确标准**—委托测试要求
- Formal **evaluation** – independent audit team /// **正式评价**—独立审计团队
- **Decision** taken by different entity – Administrative Council /// **不同主体作出判定**—行政理事会
- Independent **review** - Audit Advisory Board /// **独立审核**—审计顾问委员会



# Auditing /// 审计



Structured, independent assessment to find evidence for an audit conclusion /// 结构化独立评价，查找形成审计结论的证据



Quality audits focus on the conformance with defined standards /// 质量审计侧重于是否符合既定标准



Proceed by conducting interviews, listening, identifying, detecting, gathering evidence, taking notes and comparing /// 审计方法包括访谈、探听、识别、检测、取证、记录、比较

# Entrustment Requirements

# 委托要求

# Entrustment requirements – legal framework

## 委托要求：法律框架

- **Regulation 2100/94 (Basic Regulation or BR) /// 第2100/94号欧共体理事会条例（基本条例或BR）**

Article 55 - The CPVO will ensure that Examination Offices (EO) entrusted by the Administrative Council (AC), shall carry out the DUS test of varieties of the relevant species. /// 第55条： 欧盟植物品种局将保证对相关物种之品种进行的DUS测试由行政理事会（AC）委托的测试机构（EO）完成。

Article 56 – Examination according to the decisions of the Administrative Council and instructions of the CPVO. /// 第56条： 审查应根据行政理事会的决定和欧盟植物品种局的指示进行。
- **Regulation 874/2009 (Proceedings Regulation or PR) /// 第874/2009号条例（程序条例或PR）**

Chapter III (Art. 13-15) – Entrustment proceedings. /// 第三章（第13–15条）： 委托程序
- **“Entrustment requirements for CPVO Examination Offices” /// “测试机构委托要求”**

Updated by the AC on 27 April 2022 /// 由行政理事会于2022年4月27日更新



# Entrustment requirements /// 委托要求

## Procedure /// 流程

- Entrustment procedure available on the [CPVO Website](#) /// 流程参见[CPVO网站](#)

## Objective /// 目标

- Criteria to evaluate competence of Examination Offices, are laid out in following 13 chapters /// 测试中心资质能力评价标准载明于后续13章内容中

## The structural framework /// 结构框架

- Chapters 1-7, 13 /// 第1-7章，第13章

## Implementation /// 实施方法

- Establishment of Quality systems at the Examination Offices: Chapter 8  
/// 测试中心质量管控体系建设：第8章

## Technical capabilities /// 技术能力

- Chapters 10-12 /// 第10-12章



# Implementation quality systems /// 质量体系实施

- **Document control /// 文件管理**
- **Registry of activities/procedures /// 活动/程序登记系统**
- **DUS technical reports /// DUS技术报告**
  - Submitted according to schedule /// 按计划提交
  - Reference to the testing protocol /// 参照测试规程
  - Obligation to maintain data /// 数据维护义务
- **Internal audits and updates /// 内部审计和更新**
- **Corrective action measures /// 纠正措施**

# Technical capabilities /// 技术能力

- **Infrastructure: facilities and equipment /// 基础设施：设施设备**
- **Test protocols and procedures /// 测试规程/步骤**
- **Handling of plant material /// 植物材料处理**
- **Variety collections /// 品种集**





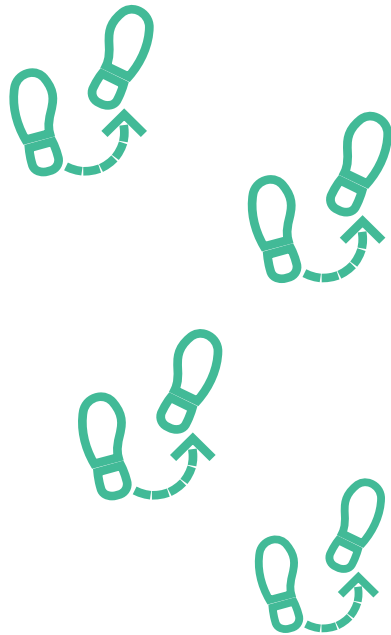
# QAS assessment in practice

## QAS评价实践



## Assessment mission – step by step /// 评价任务：逐步推进

- Multiannual audit planning /// 多年审计计划
- Annual audit planning /// 年度审计规划
- Audit sample and audit team /// 审计取样和审计团队
- Pre-audit communication /// 审计前沟通
- On-site visit /// 现场检查
- Follow-up and audit conclusion /// 后续及审计结论
- Audit programme evaluation /// 审计项目评价



# Multiannual audit planning /// 多年度审计计划

- **Three-year assessment cycle:** each of the 22 entrusted Examination offices audited at least once during that period /// **三年评估周期:** 22个委托测试中心在此期间至少接受一次审计
- Risk associated with individual Examination Offices (**complexity and coverage of scope, subcontracting, recent changes**) /// 测试中心相关风险 (**测试复杂度/范围、外协分包、近期变化**)
- Risk associated with the current setup of the programme (**most recent audit sample, current issues, scope extension**) /// 项目设计相关风险 (**最新审计取样、当前问题、测试范围扩容**)
- Incorporating changes required by Administrative Council or as result from programme review /// 应行政理事会要求或项目审计结果，实施相关整改



# Annual audit planning /// 年度审计规划

- Even distribution, match-up visiting period with DUS trialling activities /// 时间平均分布，检查周期与DUS试种周期匹配
- Preselection of potential Technical Experts /// 预选潜在技术专家
  - 1 or 2 of 32 Technical Experts (TEs) /// 32位技术专家中的一到两位
  - Management of conflict of interest /// 利益冲突管理
  - Involvement of a maximum of TEs in a QAS cycle (three years) /// QAS周期中（三年），尽可能增加技术专家参与人次
  - Optimal scope-expertise match /// 优化测试范围-专业能力匹配度
- All TEs receive specialised training in auditing techniques at start of each three-year cycle /// 所有技术专家在3年周期开始时接受审计专门培训



# Pool of QAS technical experts /// QAS技术专家库

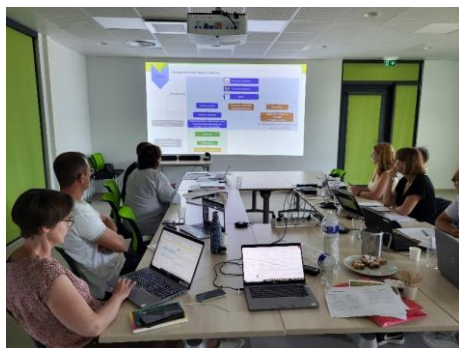


# On-site visit & audit /// 现场检查与审计

- Opening meeting /// 启动会议
- Assessment, interviews, inspection /// 评价、访谈、检查
- Coordination amongst team members /// 团队成员间协调
- Feedback to auditee, persons interviewed /// 向审计对象、访谈对象提供反馈
- Audit observations → audit findings /// 观察→发现
- Closing meeting /// 总结会议



# On-site assessment activities /// 现场审计活动



## Follow-up and audit conclusion /// 后续及审计结论

Audit findings presented in closing meeting and audit report /// 总结会议和审计报告中指出审计发现点

Follow-up within defined period (12 weeks): corrective action report /// 规定时间内 (12周) 形成整改报告

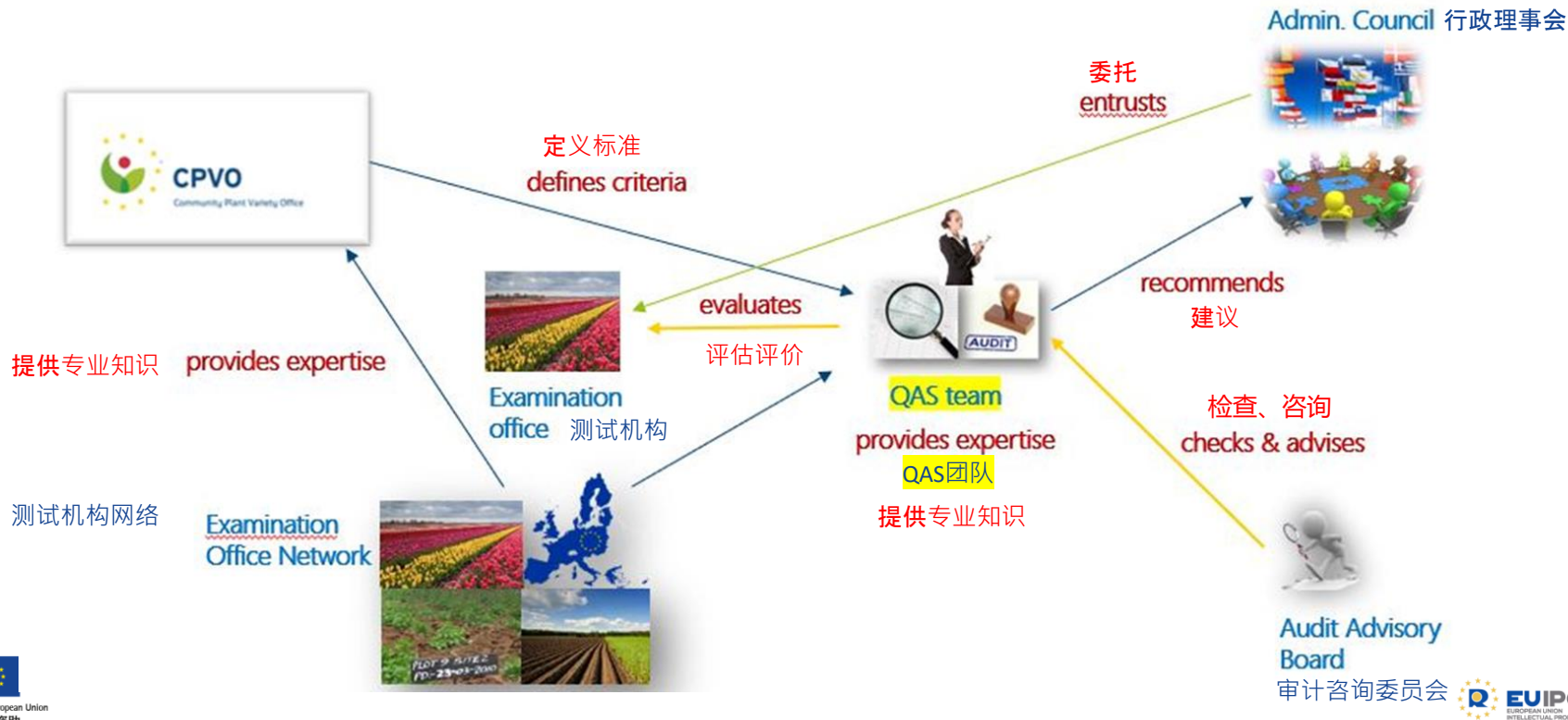
Audit conclusion and report to AC /// 审计结论及报告提交行政理事会

Entrustment decision by AC /// 行政理事会宣布委托决定





# QAS assessment workflow /// QAS评价工作流程



## The Entrustment Requirements and the QAS assessments result in: /// 委托要求和QAS评价能够：



- ✓ Improvements in the quality of DUS tests /// 提高DUS测试质量



- ✓ Independence and credibility in the performance of DUS tests /// 加强DUS审查独立性、可信度



- ✓ Possibility to use subcontractors with a guarantee that there will not be a conflict of interests /// 在保证不发生利益冲突的前提下允许外包





# CPVO

Community Plant Variety Office

## Community Plant Variety Office

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