

- By Jacob Cheptaiwa

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Introduction to seed legislation; Aspects of national legislation in production, processing and marketing

By Jacob Cheptaiwa

KENYA PLANT HEALTH INSPECTORATE SERVICE (KEPHIS)
SEMIS- NPPOs & NSCA Course 14th-19th September 2015

Introduction

- ▶ Appropriate seed legislation at the national or regional levels are essential to create an enabling environment for the development of the seed sector
- ▶ For the facilitation of safe trade in seed
- ▶ Enabling release & registration of Varieties and seeds that can be traded internationally
- ▶ Enables production of seed consignments that meet international requirements

Basis of Regulatory framework

- ▶ Agriculture and trade policies
- ▶ national laws
- ▶ Regional laws
- ▶ International conventions / treaties
- ▶ Scientific guidelines
- ▶ Criterias
- ▶ Norms
- ▶ Standard practice

Framework specific objectives

- ▶ standard and uniform variety testing procedures
- ▶ provide the regulations needed for varietal release and listing
- ▶ Provide procedures for seed production,
- ▶ Comprehensive and flexible certification guidelines
- ▶ Relevant and simpler seed export and import requirements

Aspects of seed legislation

- ▶ Establishment of national seed committee
- ▶ Designating a Seed certifying agency
- ▶ Specify role/powers of seed inspectors/analysts
- ▶ Establishment of national/state seed testing laboratory
- ▶ Pant variety testing and release
- ▶ Listing of released plant varieties
- ▶ Seed certification system
- ▶ Powers to set minimum standards for seed production, processing, testing and marking or labelling requirements
- ▶ Prohibition of the sale or supply of seed of any listed variety unless it fulfils the requirements of the act;
- ▶ Import and export procedures of seed
- ▶ The creation of Appeal Authorities to rule on decisions by a certification agency that are disputed.

Provisions in Kenyan seed law

The act Empowers the Minister:-

- ❖ Regulate transactions in seeds, including provision for the testing and certification of seeds (sec. 1)
- ❖ For the establishment of National Plant Variety list (sec.7)
- ❖ To empower the imposition of restriction on the sale of seeds of unlisted plant varieties (sec. 8)
- ❖ Establishment of seed testing stations (sec.11)
- ❖ To control the importation of seeds (sec. 15)

Provision cont'd

- ❖ To authorize measures to prevent injurious cross-pollination (sec. 16)
- ❖ Procedure on grant of plant breeder's rights. (sec. 17)
- ❖ Conditions for grant of rights. (sec. 18)
- ❖ Period for which rights are exercisable. (sec. 19)
- ❖ Nature of rights (sec. 20)

Provisions cont'd

- ❖ Protected plant varieties (sec. 21)
- ❖ Maintenance of reproductive material (sec. 22)
- ❖ Licenses (sec. 23)
- ❖ To establish a Tribunal to hear appeals and other proceedings and for connected purposes. (sec. 28)
- ❖ Offences and general penalty (sec. 32)

New provision (Amendments)

- ▶ Authorization of services to other competent bodies(S.3B.1 b)
- ▶ Regulation & certification of forest seeds & wild plants.(S.3.1 h)
- ▶ Maintenance & certification of high value crops(non attractive to private) (S.3.1 i)
- ▶ Integration & harmonisation of seed industry (S.31j)
- ▶ Emerging technologies protocol devt and application to seed prodn(S.16.2a &b)
- ▶ Compensation arising from seed pdn and sale
- ▶ Establishment of Plant genetic resource centre
- ▶ EDVs
- ▶ Plant protection aspects

Seed pdn aspects

- ▶ Registrations & verification of documents
- ▶ Seed certification scheme
- ▶ Seed production requirements
- ▶ Field inspection standards
 - Isolations
 - varietal purity
 - Disease tolerances
 - Pests tolerances
 - Weeds tolerances
 - Any other factor

Seed processing aspects

- ▶ Handling requirements of raw seed
- ▶ Moisture content
- ▶ Processing standards
 - seed physical purity
 - Degree of broken seed
 - Degree of rotten seed
 - Degree of discoloured
 - Other seed materials
 - weed seeds
 - Any other quality factor

Seed processing cont'd

- grading standards
- seed treatments
- seed packaging stds

Seed sampling
sealing and labelling

Seed testing

- Verification of the received samples (requirements)
- Purity analysis requirements
- Viability tests (through germination and the tetrazolium tests requirements).
- Moisture tests content requirements.
- Pathological test (fungal, bacterial and viral tests).
- Determination of seed marketability.

Seed marketing

- ▶ Seed seller registration
- ▶ Seed distribution channels
- ▶ Seed seller conditions
- ▶ Seed storage
- ▶ Stop sale orders
- ▶ Validity of certification
- ▶ Seed resampling
- ▶ Import and export requirements.

END

Thank you

Laws governing variety release, certification & seed import and export

By Jacob Cheptaiwa

KENYA PLANT HEALTH INSPECTORATE SERVICE (KEPHIS)

SEMIS- NPPOs & NSCA Course 14th-19th September 2015

Variety release

▶ Purpose

–The purpose of Release of cultivars is to introduce the newly bred varieties to the public for commercialization in the country and within region in which it is suitable.

–The procedure should ensure that only good, appropriate, new varieties are released by governments,

–Certification is to ensure that farmers get good quality seed,

–import and export regulations are to facilitate safe trade

Variety release procedure

- ▶ Designating agency to handle
- ▶ Applications
- ▶ Variety testing
- ▶ Data evaluation and reporting
- ▶ NPTC recommendations
- ▶ NVRC approvals
- ▶ Entry into National variety List (Gazettement)
- ▶ Commercialization

Variety release challenges

- ▶ Over regulation or poor regulation block release of varieties that could be beneficial to farmers
- ▶ Delays or long procedures
- ▶ Variety testing and release procedures not supported by law
- ▶ Vested interests
- ▶ Free flow of germplasm is affected

Seed certification procedures

- ▶ Registrations
- ▶ Field inspections
- ▶ Factory processing inspections
- ▶ Sampling
- ▶ Seed testing
- ▶ Seed labelling
- ▶ Post control
- ▶ Post certification survey

Seed import and export

- ▶ Registration
- ▶ Notification
- ▶ Obtaining PIP/Phytosanitary
- ▶ ISTA/acceptable test certificate
- ▶ Verification at entry/exit
- ▶ Sampling in case of import
- ▶ Testing (Pre-control/lab test)
- ▶ Commercialization

Laws applicable

- ▶ In case of Kenya
 - seed and plant varieties act Cap 326
 - Plant protection act cap 324
 - Noxious and invasive weeds AFFA act 2012

END

Thank you

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RATIONALE AND PROCEDURES FOR ACCREDITATION (ISTA, OECD, UPOV, ISO, WTO)

J.K. Cheptaiwa

KENYA PLANT HEALTH INSPECTORATE SERVICE (KEPHIS)

SEMIS- NPPOs & NSCA Course 14th-19th September 2015

PURPOSE OF ACCREDITATION

- ▶ Quality Assurance
- ▶ Standardized way of certification
- ▶ Building confidence and trust
- ▶ Increasing efficiency
- ▶ Promoting movement of seeds

What is Quality Assurance?

QA started in the 20th century

- Complex industries with 100% reliability targets
e.g arms, munitions, computers
- Then spread to mass production industries
eg cars, and to testing services

Instead of waiting until the product is made, and then checking if it is right QA is used to check all the steps in the process

If the processes are ok then the product will be ok

What is Quality Assurance?

- Company quality assurance (QA) is the means by which a seed company is satisfied that its products and services are maintained and enhanced, meeting customer and corporate expectations.
- Seed QA program provides a uniform and unbiased quality control systems and marketing tool for crop seeds merchandised as varieties lends or brands.
- Seed QA system makes everybody in the seed production and marketing chain responsible for seed quality.

Accreditation of Company Laboratories

Two routes:

1. Issuing domestic (national) certificates
2. Issuing international certificates

Same basic requirements in both cases

Based on QA principles

ISO Certification

ISO 9000 and ISO 9001:2008 are the standards used to CERTIFY companies in, for example, manufacturing or service industries.

Testing laboratories are certified using another standard - ISO 25 (now known as ISO/IEC 17025)

ISO 9000 and ISO 9001:2008 are the basic blueprint for Quality Assurance.

They cover areas of activity which have to be complied with in order to meet the standards

From ISO 9000 to ISO 17025

The ISO 17025 standard is used for the ACCREDITATION of testing laboratories eg chemistry or molecular biology.

It is based on ISO 9000 but places extra emphasis on:

- Staff competence
- Equipment control and calibration
- Appropriate methods and method development
- Mandatory referee tests (proficiency testing)

From ISO 17025 to the ISTA Standard

The ISTA Standard is adapted from ISO 17025 to meet the specific needs of seed labs.

It asks: "Is your system effective, are your staff competent, and are your referee tests ok?"

Specific features of the ISTA Standard include:

- Sampling
- Independence of labs
 - Use of ISTA Rules
- Staff competence
- Mandatory participation in the ISTA
- Referee test programme



PROCEDURE FOR ACCREDITATION

INTERNATIONAL SEED TESTING ASSOCIATION

ISTA

ISTA Membership

· Laboratories wishing to become members are requested to contact the ISTA Secretariat for the necessary application forms. The ISTA Executive Committee will then decide about the application and grant membership

Participation in the ISTA Proficiency Testing Programme

· All accredited laboratories have to participate successfully in the ISTA Interlaboratory Proficiency Testing Programme, consisting of at least three rounds per year

Establishment of a Quality Assurance System

· A laboratory that wishes to become accredited must set up a Quality Assurance System including documentation following the ISTA Accreditation Standard. This standard is based on ISO/IEC 17025 Standard and especially amended to meet the needs of seed testing laboratories.

ISTA Audit

· Prior to accreditation, and every three years thereafter, the laboratories are audited by two ISTA Auditors (system and technical) and based on the auditor's recommendation and the performance in the proficiency tests, accreditation is granted.

Authorisation to issue ISTA Certificates

· After having successfully fulfilled the requirements of accreditation, authorisation to issue ISTA Certificates is obtained through agreement of the Designated Authority.

Installation of a Monitoring Programme

· Upon decision of the government of each country a Monitoring System could be installed for company laboratories.

UPOV

- ▶ International Union for Protection of New Varieties of Plants
- ▶ Convention (1963, 1978, 1991) States
- ▶ Unified testing systems and protocol
- ▶ International treatment
- ▶ Must have a law, which must be accepted by the Council

World Trade Organization

- ▶ Nations must be members
- ▶ Monitors and movements of goods and services
- ▶ Intellectual property Key component
- ▶ Provisions for Sanctions

Role of seed sector players in high quality seed delivery

By J.K. Cheptaiwa

KENYA PLANT HEALTH INSPECTORATE SERVICE (KEPHIS)
SEMIS- NPPOs & NSCA Course 14th-19th September 2015

seed sector players

- ▶ Government(ministry of Agriculture)
- ▶ Breeder's /research institutions
- ▶ Seed companies
- ▶ Seed growers
- ▶ Seed industry Regulator
- ▶ Seed trade associations
- ▶ Seed distributors
- ▶ Donor agencies

Their roles in high quality seed delivery

- ▶ Government
- ✓ Creating and promoting enable environment for players
- ✓ Facilitating research
- ✓ Providing advice and information services
- ✓ Undertaking reviews of policies & regulatory framework
- ✓ Facilitates collaborations between stakeholders

Role of breeders /research institutions

- ▶ Development of new crop varieties to address:
 - ✓ High yield attribute
 - ✓ Resistance (disease, pest, weeds and soil factors)
 - ✓ Climatic change
 - ✓ Adaptability
- ▶ Variety maintenance
- ▶ Regeneration of reproductive material

Role of seed companies

- ▶ Production
- ▶ Processing
- ▶ Packaging, branding and packing
- ▶ Marketing
- ▶ Import and export
- ▶ Sometimes variety development

Role of seed growers

- ▶ Specialized group of farmers with
 - Knowledge
 - Skill
 - Equipment
 - Own land or hire
- ▶ Facilitate bulking of certified seed

Role of Seed industry regulator

- ▶ New variety evaluation and release
- ▶ Variety registration
- ▶ Variety protection
- ▶ Registration of seed industry players
- ▶ Seed certification
- ▶ Enforcement of seed industry regulations and standards

Role of seed trade associations

- ▶ Forum for interaction and information exchange
- ▶ Represents seed industry players
- ▶ Promote seed industry interests (improvement of seed trade conditions)
- ▶ Promote self regulation
- ▶ Promote use of certified seed
- ▶ Liaise with government on matters affecting seed industry
- ▶ Advocate to
- ▶ Arbitrate in seed issues

Role of seed distributors

- ▶ Ensures availability of seed at right place at right time.
- ▶ Ensure storage & proper handling of seed
- ▶ Facilitators of information and technologies
- ▶ Important channels for seed movement traceability

Role of donors agencies

- ▶ Provide funding for
 - variety development
 - Seed system development and improvement
 - Policy and regulatory framework development and reviews
 - Seed industry infrastructure
 - National, regional and international seed rules, standards and procedures harmonization processes
 - Disaster seed relief programs

END

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EXERCISES ON COUNTRY EXPERIENCES ON SEED LAWS & REGULATIONS

BY J.K. Cheptaiwa

KENYA PLANT HEALTH INSPECTORATE SERVICE (KEPHIS)

SEMIS- NPPOs & NSCA Course 14th-19th September 2015

Introduction to Seed Legislation

- ▶ Farmers started off by gathering, then planting, then sharing, then selling
- ▶ Need for order
- ▶ Agriculture is critical hence regulation
- ▶ Seed is life
- ▶ Nation must plan – policy

Major Components of Legislation (regulatory framework)

1. Policy

- direction
- targets
- How to get there

2. Law or Act that stipulates

What

How,

Sanctions

3. Regulations

- Implement the law
- Gives minor details

What is a seed policy

- ▶ A national seed policy is a statement of principles that guide government action
- ▶ explain the roles of relevant stakeholders in the coordination, structure, functioning and development of the seed sector.
- ▶ serves as the overall framework for regulatory instruments, such as the seed law and related legislation.
- ▶ ensures that the government's vision is adequately reflected in day-to-day operations within the seed sector

Policy formulation

- The **effectiveness** of a seed policy depends on the capacity of government to **manage the policymaking** process, as well as the **full participation of seed sector stakeholders**.
- Difficulties in policy making due to **weak capacity** and **insufficient data**, rapidly changing **political context**, complex inter-relationships between different issues affecting the seed sector, and political pressures exerted by interest groups.

Policy formulation cont

- ▶ Sound policy requires a sequence of steps: careful problem analysis to determine the need for policy,
- ▶ a participatory formulation process based on a thorough assessment of relevant technical and institutional aspects of the seed sector.
- ▶ extent to which these steps are followed in practice varies greatly from country to country, and depends in large part on the institutions and administrative settings within which policy decisions are taken.

Structure of seed policy

- ▶ First the document must be clear and coherent, with effective use of language, style, etc.
- ▶ Second, the content of the document should be concise, to the point, action-oriented and organized around a logical and coherent structure.

Key Elements Seed Policy

Cover a broad spectrum of seed supply chain processes and activities

- variety development,
- seed production,
- seed quality assurance,
- agricultural extension,
- seed marketing,
- seed import and export,

Key elements of seed policy cont

- ▶ seed enterprise development,
- ▶ seed value chain,
- ▶ seed security,
- ▶ capacity building and
- ▶ seed legislation/standards.

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Policy implementation

- ▶ Process of putting the policy into practice, after it has been developed in agreement with all stakeholders.
- ▶ The seed policy formulation process will succeed if policy documents have influence on seed sector development.
- ▶ The three main conditions for successful seed policy implementation are.

Conditions for implementation

- ▶ designation of a government agency with responsibility for implementation;
- ▶ translating the policy provisions into an operational plan and guidelines;
- ▶ coordinating operations and resources within the responsible agency to achieve the intended policy objectives

Difference between seed policy and seed law

- ▶ Documents, instruments and procedures that regulate the seed sector, including seed policies, seed legislation, standards and procedures, are referred to as the “**seed regulatory framework**”.
- ▶ National seed policy sets out, in broad terms, the goals, targets and objectives of the government on a particular issue within or related to the seed sector, and identifies **the key methods** and **mechanisms** for achieving those objectives

Difference cont

- A seed law is one tool that can be used to implement the policy.
- Laws are more precisely drafted than policy doc
- set out specific standards, procedures and principles that must be followed.
- Laws establish an **institutional framework for enforcement**, including the powers and functions of public bodies as well as provisions to hold both public and private actors accountable

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Difference

- seed law defines the framework and essential principles that govern seed marketing.
- identifies the competent authorities,
- sets up prohibitions and obligations,
- stipulates registration and seed production systems and other quality requirements.

Advise

- ▶ First, the national seed policy, which defines the government's overall objectives and an institutional structure for the sector,
- ▶ develop the seed law to implement the policy by providing legally binding enforcement.
- ▶ If a seed law is already in force, the development of a seed policy can provide important input into the revision of the seed law

Why the law

- ▶ The quality and the identity (variety) of seed cannot be reliably assessed by farmers at the time of purchase.
- ▶ Seed laws protect the farmer by establishing a legal obligation for the seller to guarantee the quality of seed by means of standardized inspection and testing procedures.
- ▶ Those procedures, which may consist of a certification system or accreditation and authorization procedures, protect and promote enterprises that engage in quality seed production.

EXERCISE

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SEED CERTIFICATION

- ▶ Do you have policy in place for seed certification
- ▶ What institutions do you have to assure quality in your country
- ▶ What systems for the seed companies
- ▶ What improvements would you propose for your situations

Registration of Seed Related Institutions

- ▶ What Institutions do you have in Place that promote Seed trade
- ▶ What are the requirements for registration
- ▶ If not in place, what do you need to do
- ▶ What would you prefer to put in place

AGREEMENTS TO FACILITATE SEED TRADE

J.K.Cheptaiwa

KENYA PLANT HEALTH INSPECTORATE SERVICE

(KEPHIS)

SEMIS- NPPOs & NSCA Course 14th-19th September

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2 types

1. International– Technical

- a. OECD Seed Schemes – Field certification
- b. ISTA laboratory methods
- c. IPPC disease movement

2. Regional – Trading blocks, Policy

- a. EAC / ASARECA
- b. SADC
- c. COMESA
- d. WASA

Introduction

EAC / ASARECA

- Rationalization and harmonization of seed policies, laws, regulations and procedures initiated in 1999.
- By the Eastern and Central Africa Program for Agricultural Policy Analysis (ECAPAPA), precursor to PAAP
- The process involved
 - national studies on key constraints
 - consultation on opportunities for improvements and
 - dialogue between the countries to reach common agreements.

Introduction cont.

- ▶ Technical agreements reached in 2002
- ▶ From 2002, individual countries have been modifying their policy environments to conform to the common agreements through review of policies, laws and regulations.
- ▶ But to date, changes minimal

HARMONIZATION OF SEED REGULATIONS

- ▶ ASARECA undertook study on regional seed markets in late 1990's
- ▶ Study showed seed markets were too small to attract investment
- ▶ Each country had different laws, policies, regulations and standards
- ▶ Harmonization was key to addressing the identified issues

Key areas

Five key areas were identified to restrict seed movement in region:

- Variety evaluation, release and registration process
- Seed certification
- Phytosanitary measures
- Plant Variety Protection
- Import/export documentation

Process

- ▶ National resource persons were hired to undertake country studies in 1999
- ▶ The country reports were discussed nationally
- ▶ The outputs were discussed with national policy makers

Process cont..

- ▶ Regional consultations held, with input from national and external resource persons
- ▶ Agreements were finally arrived at in June 2000
- ▶ These were summarized in ASARECA Monograph No. 4 of 2000

MECHANISM OF IMPLEMENTATION

- ▶ Seed Regional Working Group (S–RWG) established June 2001
- ▶ However, there was no progress
- ▶ S–RWG transformed to Eastern Africa Seed Committee (EASCOM) from Nov 2004, to include policy makers

COMPOSITION OF EASCOM

each ASARECA member had 4 reps as follows:

- National Seed Trade Associations
- National Certification Agencies
- Ministries of Agric policy dept
- Plant breeders assoc/NARI

Agreements

- Technical agreements were reached in the 5 areas in 2002.
- Additionally an independent National Designated Authority to oversee the agreements was recommended
- Little progress was achieved in implementation of the agreements
- Formation of EASCOM to effect implementation in 2004
- Members NDA, Seed Industry, Ministry (Policy) and Breeders
- Nature of agreements either **Legal** or **Procedural**

EASCOM's functions

- ▶ Influence review of seed policies, laws and regulations to implement agreements
- ▶ Strengthen national seed and plant breeders' associations
- ▶ Develop and maintain data bases and disseminate information to stakeholders
- ▶ Spearhead capacity building for seed industry stakeholders

EASCOM Functions cont.

- Represent seed industry in regional economic blocs – the East African Community (EAC) and the Common Market for Eastern and Southern Africa (COMESA) Committees
- Create an effective network of seed industry stakeholders in the region
- Enhance seed market development
- **Strengthen the Private–Public partnerships**

Progress in implementation of harmonization agreements in ECA countries

Policy milestone	Achievements by country to date	Work in progress
Enacted legislation (Seed Act) that accounts for harmonization agreements;	Burundi (Seed Act 2009), Kenya (Seed Bill revised in 2010), Madagascar Seed Act 1994 reviewed in 2010, Rwanda (Seed Act 2003), Tanzania (Seed Act 2003), Uganda (Seed and Plant Act 2006)	Review of: Sudan Seed Act 2006; Uganda draft Plant Variety Protection Bill of 2008; Ethiopia Seed Proclamation of 2006
Finalised seed Act implementing regulations;	Kenya (NPT Regulations 2009); Tanzania (Seeds Regulations 2007); Uganda draft Seed Regulations of 2010 to implement the Seed and Plant Act of 2006,	Rwanda, Burundi, Ethiopia, Madagascar
Finalised Plant Breeders Rights Act in accordance with UPOV 1991 and its implementing regulations	Ethiopia (PBR Proclamation 2006 requires significant revisions); Kenya (UPOV 1978), Tanzania and Uganda (largely UPOV 1991 compliant)	Burundi, Rwanda, Sudan, Madagascar, Eritrea, DRC have no pvp systems but are developing based on UPOV (1991) , Kenya has a draft Bill (1991 compliant)
Autonomous certification agency	Kenya Plant Health Inspectorate Service (KEPHIS), Tanzania Official Seed Certification Institute (TOSCI) and Plant Breeders Rights (PBR) Office in Tanzania in 2005	Uganda considering autonomous seed Service to oversee variety evaluation, release and registration Ethiopia's certification agency is under review with the seed proclamation based on the experiences of the other countries. There are efforts to have an independent body

National Seed Trade Association	Burundi (COPROSEBU) 2009, Sudan (SSTA) 2008, Ethiopia (ESTA) 2005, Rwanda (STAR) 2003 revived in 2010, Kenya (STAK) 1982, Madagascar (AMPROSEM), Uganda (USTA) 2003, Tanzania (TASTA) 2002, DR Congo revived the Interprofessional Association of Seeds Producers of Congo (AISC) in 2010	
Acceded to OECD and ISTA seed testing rules	Kenya is a member to both	Burundi, Tanzania and Uganda are in the process of acceding to OECD and ISTA Ethiopia, Madagascar and Rwanda considering South Sudan is shifting from the American classification system to OECD
Developed quarantine pest list	Burundi, Ethiopia, Kenya, Madagascar, Rwanda, Sudan, Tanzania, Uganda	Publishing of the KE, UG, TZ as the ET is being finalized
Simplified export/import documentation procedures	Burundi, Sudan, Madagascar, Tanzania, Uganda	Kenya, Ethiopia to put theirs in place

The 2008 Victoria Declaration of COMESA Ministers of Agriculture

- *Member States commit to harmonizing, within two years, seed trade regulations in the region and to finalize a regional protocol for the protection of new varieties of plants within the same period;*
- *It urges member States and development partners to work in collaboration with the COMESA Secretariat to implement the decisions of this Victoria Declaration on Agriculture, together with all decisions of the Ministers as contained in the Report of the Fifth Meeting of the Committee of Ministers.*

COMESA harmonization initiative

- ▶ Formation of COMRAP–ACTESA, a specialized agency for inputs (COMESA)
- ▶ Harmonization in the 4 areas, except PVP left out with 12 selected crops
- ▶ 6 technical workshops held, and a validation workshop
- ▶ Agreements to Ministers by end of July
- ▶ Hopefully will fast track implementation

Issues

- Under EAC, free goods movement, seeds and plant materials excluded
- Agreements are yet to be incorporated in national laws and regulations
- Biosafety laws and regulations need to be urgently included in activities
- Under EAAPP we may still find restriction in technology movement within region, technology from RCoE's to others
- What is our role in ensuring success of EAAPP

Issues

- How do we assist each other in the region, e.g. reaching EAC secretariat to incorporate agreements, use of standards committee at EAC
- Expand to other crops
- Can we have regional offices for PVP
- Can we influence the process and policy environment to implement agreements

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Third party participation in seed quality

By Jacob Cheptaiwa

KENYA PLANT HEALTH INSPECTORATE SERVICE
(KEPHIS)

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Introduction

- ▶ Designated authority may authorize persons who are under its direct and exclusive authority.
- ▶ Laboratories may also be authorized to carry out seed analysis as required under the seed regulations.

Requirements for designated authority

documented procedures, which describe the way in which it applies its authorization criteria.

- ▶ details of the procedures for assessing applicants for authorization;
- ▶ details of the procedures for auditing authorized personnel or laboratory;
- ▶ details of the appeals procedures;
- ▶ details of the procedures for withdrawal and cancellation of authorization
- ▶ A published description of the authorization system is advisable
- ▶ required facilities in terms of technical expertise and equipment to undertake the authorization.

General requirement for applicant

- Demonstrate capacity on infrastructure
- Demonstrate capacity on staffing
- Assure on independence
- Assure on confidentiality

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Knowledge and skills required

- ▶ Applicants should have the following knowledge and skills:
- ▶ **Knowledge of:**
- ▶ the seed schemes;
- ▶ the methods of field inspection and field standards for the crop species for which authorization is sought.
- ▶ The varietal characteristics of the varieties to be inspected
- ▶ **Skills in:**
- ▶ use of varietal characteristics to confirm varietal identity of seed crops;
- ▶ detection, characterization and quantification of varietal impurities in seed crops

Training

- ▶ Applicants for authorization should and need only undergo training appropriate to the aspects, which they would be authorized to undertake.

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Examinations

- ▶ Applicants should satisfy the Designated Authority of their competence to become authorized in examinations. The following two types of examination can be used:
- ▶ a written examination to test knowledge of principles and procedures
- ▶ a practical examination to test field inspection skills, sampling skills and testing

Knowledge & skill maintenance

- ▶ Authorized personnel need to maintain their knowledge and skills by:
- ▶ Undertaking regular inspection of crops sampling and testing,
- ▶ Participating in periodic retraining and,
- ▶ Keeping up to date copies of certification scheme rules and crop inspection procedures sampling, and testing procedures and being familiar with any changes

Monitoring and audit procedures

- Check inspections
- Check sampling
- Inter-lab test
- Inspection Audits
- Sampling audits
- Testing audits
- Re-examination
- Documentation
- Laboratory tests and pre- and post control plots

Monitoring and audit procedures

- ▶ Additional requirements and methods for monitoring to reduce the risks of non-compliance may be introduced.
 - Audits will examine adherence to the appropriate sampling and testing procedures and methods and include checks on documentation, as well as the examination of company records on label and seal.
- ▶ A proportion of seed lots sampled by the accredited seed samplers or tested by authorized seed laboratories must be check sampled by official seed samplers and check tested in an official laboratory respectively.
- ▶ This proportion will be at least 10%.

SCOPE OF AUTHORIZATION

- ▶ Authorized seed inspectors and samplers and testing employed by a company will only be allowed to inspect and sample seeds belonging the particular company.
- ▶ Unless there is an agreement between companies for extending service to other.

Withdrawal of authorization

The following are examples where authorization may be suspended or withdrawn:

- ▶ if false or misleading information has been provided in the application for authorization
- ▶ if false or misleading information has been provided in a report
- ▶ if there is evidence from surveillance activities that the inspector does not meet the required standard of competence.

Other action

- ▶ In some cases, the Designated Authority may require authorized inspectors to undergo corrective training and re-examination

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Appeals

- ▶ The Designated Authority will operate an appeals procedure to enable a review of decision not to license, suspend, or to withdraw authorization.
- ▶ The appeal process should not have costs or procedures, which discriminate against any person, company or entity.

Specific for lab

- ▶ laboratory in premises and with equipment officially considered to be satisfactory for the purpose of seed testing and scope
- ▶ laboratory shall have a seed analyst-in-charge who has direct responsibility for the technical operations
- ▶ necessary qualifications for technical management of a seed testing laboratory

Cont,d

- ▶ laboratory shall carry out seed testing in accordance with current regulations
- ▶ The laboratory shall be: an independent laboratory or
- ▶ A laboratory belonging to a seed company
- ▶ laboratory's performance of seed testing shall be subject to proper supervision

Con,d

- ▶ A proportion of the seed lots entered for the official certification under the authorisation shall be check-tested by official seed testing
- ▶ comparing the results of seed samples tested officially with those of the same seed lot tested under official supervision

END

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Quality assurance for seed companies & exercise.

By Jacob Cheptaiwa

KENYA PLANT HEALTH INSPECTORATE SERVICE (KEPHIS)

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What is Quality?

The extent to which requirements or expectations are met:

- requirements may be stated or implied
- quality: in products and services

What is Quality Management?

Definition

“Activities aimed at directing and running (controlling) an organisation regarding quality

Quality plan

- ▶ **Explains how an organisation intends to apply the quality policy, to**
- ▶ **achieve the quality objectives and to meet quality system requirements**

Quality control

- ▶ **Set of activities or techniques to ensure that quality requirements are**
- ▶ **being met**

Quality improvement

- ▶ **Enhance the capability to fulfil quality requirements**

Quality assurance

- ▶ **Set of activities to demonstrate that an organisation meets**
- ▶ **all quality requirements”**

Why do we need quality assurance?

- ▶ The bottom line!!

Our customers must have confidence in the quality of our product/service which must be:

- - **Reliable**
- - **Relevant**
- - **Reproducible**

SEMIS - UNION

Why do we need quality assurance?

How do we get our customers to trust us?

- ▶ We must have good test methods
- ▶ We must have laboratories which apply these test methods correctly and uniform

How to assure Quality?

- ▶ Document control
- ▶ Proficiency testing
- ▶ Review of tenders, requests and contracts
- ▶ Audits
- ▶ Review by the management

Building blocks of a QA system

- ▶ **Q-Manual (Level A)**

Describes the quality system in accordance with the stated quality policy and objectives and the accreditation standard

- ▶ **Documented quality system procedures**

- (Standard operation procedures) (Level B)**

Describes the activities of individual functional units

- ▶ **Other quality documents (Work instructions, forms, reports, etc.) (Level C)**

Consists of detailed work documents

How to prepare SOP's

- ▶ Standard operation procedures shall enable users to perform the work by following the description. The volume and degree of detail should be adapted to the needs of the personnel.

General design

- 1. Purpose.
- 2. Scope.
- 3. Definitions and abbreviations.
- 4. Related documents and references
- 5. Responsibilities
- 6. Process description
- 7. Records
- ▶ The same structure may be followed for technical and non-technical procedures.

How to prepare flow charts

- ▶ Flow charts are helpful to visualise a process.
- ▶ Preferably, a very limited number of symbols is used
- ▶ to ensure that it is easily understood. Responsibilities
- ▶ might be assigned as well

How to prepare flow charts

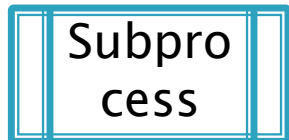
Boxes used for flow chart:



To indicate start and end of process



An activity with an input and an output



An activity that can be represented in a flow chart on its own



A process with two possible outcomes, i.e. Yes or No

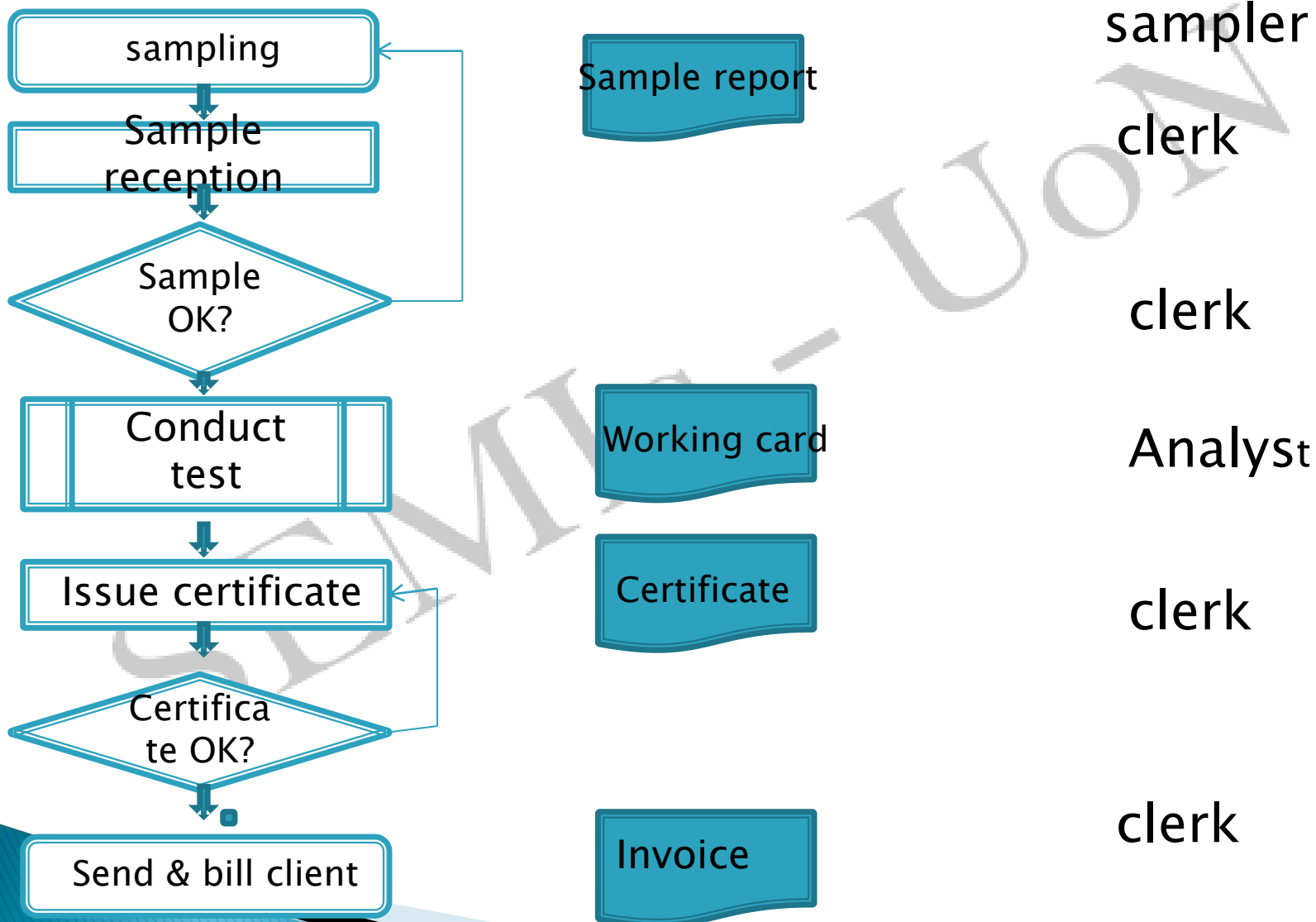


An information and its medium that results from or supplements a process



To indicate the direction and the sequence and relation between processes

Example process flow chart



Standard Operation Procedure



- **K** – keep
- **I** – it
- **S** – short
- **S** – simple



QA in seed testing

- ▶ 1. Seed sampling
- ▶ 2. Sample reception
- ▶ 3. Moisture
- ▶ 4. Purity
- ▶ 5. Germination
- ▶ 6. Storage of samples
- 7. Integrity of data
- 8. Training of staff
- 9. Equipment
- 10. Record keeping
- 11. Verification of the system

Seed sampling

- ▶ System for approval of lot identification
- ▶ Monitoring the uniformity of the seed lot and refuse of
- ▶ sampling and testing if doubt exist concerning uniformity
- ▶ Authorization of samplers
- ▶ Training program
- ▶ Up to date lists of samplers
- ▶ Monitoring the samplers
- ▶ Describe procedure cancellation authorization of samplers

Sample reception

- ▶ Unique sample number
- ▶ Up dated list of qualified seed samplers for ISTA samples
- ▶ Procedure for unusual conditions of samples
- ▶ Logbook to fill out non conforming samples
- ▶ Training of staff
- ▶ Record keeping

Purity

- ▶ Balances, Blowers
- ▶ Dividers, Seed counter
- ▶ Training of staff
- ▶ Personal logbook
- ▶ Seed collection
- ▶ Approval system/Examination for analysts
- ▶ Procedure performance of analysts
- ▶ Record keeping

Germination

- ▶ Temperature control incubators
- ▶ Use of ISTA Rules and handbook
- ▶ Training of staff
- ▶ Approval system/Examination for analysts
- ▶ Maintenance of equipment
- ▶ Record keeping

Storage of samples

- ▶ At least 1 year after issuing an ISTA Certificate
- ▶ Temperature and humidity control of storage facilities
- ▶ Pest control
- ▶ Dispatch of samples
- ▶ Who is responsible for the storage section

Integrity of data

- ▶ Storage and protection of data
- ▶ Information of data to clients
- ▶ Access for data (Password computer)
- ▶ Only issue certificates on species which are listed in the Rules
- ▶ And for which the lab is accredited
- ▶ Signature of responsible person

Training of staff

- ▶ Matrix where competence is layed down
- ▶ Inventory of training (annual performance talk)
- ▶ Personal logbook of training of each analyst
- ▶ Layed down limits of responsibilities of staff
- ▶ Up to date rules, handbooks, manuals, instructions and reference data
- ▶ Replacement
- ▶ Maintenance of experience

Equipment

- ▶ The laboratory must be fit for the purpose of seed testing
- ▶ A full range of equipment for the test being done should be
- ▶ provided
- ▶ The equipment must be maintained in working order and
- ▶ where necessary, regularly calibrated
- ▶ Registrations of calibration must be kept
- ▶ Entrance control new equipment

Records

- ▶ Up to date records of staff and training records
- ▶ Keep records for at least 6 years
- ▶ Use inerasable pen
- ▶ Correction of mistakes in records must not be erased but crossed out
- ▶ Calculations must be checked systematic

END

Thank you

SEMI-S-UON

Exercise: Planting flowchart

- ▶ Time of planting,
- ▶ Seed Rate,
- ▶ Method of sowing,
- ▶ Depth of sowing,
- ▶ Verification of seed type,
- ▶ Seed treatment,
- ▶ Machine effectiveness,
- ▶ Machine cleaning,
- ▶ Seed packaging and labels preservation

Exercise: Crop husbandry flowcart

- ▶ Weeding
- ▶ Disease and pest control
- ▶ Nutrition
- ▶ Rouging
- ▶ Detasselling
- ▶ Supplemental pollination
- ▶ Irrigation
- ▶ Notification for official inspection
- ▶ Crop Compliance checks
- ▶ Inspection advice implementation

Exercise: Harvest and Post Harvest flowchart

- ▶ Time of harvest
- ▶ Harvesting mode (machine or hand)
- ▶ Separation of males and females (hybrids)
- ▶ Identification of harvested raw seed
- ▶ Shelling
- ▶ Packaging and marking
- ▶ Transportation
- ▶ Separation from admixture
- ▶ Samples for post harvest tests
- ▶ Post harvest soil monitoring

Exercise: Seed processing flowchart

- ▶ Seed Intake registration
- ▶ Seed handling
- ▶ Seed drying
- ▶ Seed cleaning
- ▶ Seed grading
- ▶ Assessment of quality
- ▶ Seed treatment
- ▶ Seed sampling
- ▶ Seed packaging
- ▶ labelling

Internal quality requirements for seed companies

Jacob cheptaiwa

KENYA PLANT HEALTH INSPECTORATE SERVICE
(KEPHIS)

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Management committment

- ▶ Management Policy statement.
- ▶ Owning up by staff management objectives.
- ▶ Designate people responsible for each step of the process.
- ▶ Designate a representative of the quality system
- ▶ Periodically review the quality system
- ▶ Provide the necessary resources (material and human) to achieve the objective

DOCUMENTED QUALITY SYSTEM

- ▶ The entity/company should have a documented quality system that describes its regulations, organizations, working procedures and seed standards .
- ▶ The quality system should have a quality manual.

CONTRACT REVIEW

- ▶ The entity/company shall:
 - Have documented procedures to assure that the requirements for certified seed production and testing contracts can be carried out, before their approval
 - Define and document the contract requirements

DOCUMENT CONTROL

- ▶ The entity/company should have procedures to control the documents related to quality system (either internal or external).
- ▶ These documents should be:
 - Approved and reviewed by authorized personnel.
 - Identified in a way that assures their validity.
 - Include in a list of references to indicate the latest versions and who has copies.
 - Subject to controlled modification
 - Replaced when needed
 - Copied and distributed in a controlled manner

PURCHASING

- The seed company should have documented procedures to control purchases that could affect the quality of certified seeds.
- The supplier should have the capability to meet the requirements specified by the seed company.
- The entity/company should have a system to evaluate and select suppliers, based on background and capabilities to meet the requirements.
- Maintain a record of suppliers.

IDENTIFICATION, TRACKING AND SEED LABELLING

- ▶ Tracking of each seed lot from harvest through conditioning
- ▶ Records of all field activities from planting of the initial/parent seed through to harvest
- ▶ Results of each sampling and inspection event –field through final seed lot sample testing.
- ▶ Conformity status of each lot
- ▶ Conformity to seed certification requirements for labeling
- ▶ Destination of non-conforming lots

CONTROL OF PROCESSES

- procedures for cultivating, inspecting, transporting, storing, sampling, analyzing and labeling of certified seeds.
- These procedures should include maintenance of necessary equipment.
- The procedures should output meet the criteria and minimum standards of certification regulations:

CONTROL OF EQUIPMENT THAT COULD AFFECT THE QUALITY OF SEEDS

The entity/company shall:

- ▶ Identify the critical equipment in the production process (field, processing, laboratory)
- ▶ Identify the conditions of the equipment's in calibration
- ▶ Keep records of the calibrations
- ▶ Establish the frequency of the calibration for the equipment
- ▶ Keep records of the lots of seeds affected by equipment not calibrated, and verify when this equipment has been calibrated.

CONTROL OF NON- CONFORMITY SEEDS

- documented procedures to indicate how the non-conformity lots are kept separated.
- Records of non-conformity lots must indicate their causes, and final destination of these lots.

CORRECTIVE ACTIONS

- ▶ Detect problems in the products and processes
- ▶ Keep records of problems
- ▶ Investigate their causes
- ▶ Implement effective solutions
- ▶ Keep records of actions adopted to prevent repetition of the problem

MOVEMENTS, STORAGE, BAGGING AND DEPARTURE OF SEEDS

procedures to:

- ▶ Assure that the seed is maintained in good conditions from its harvest to its departure
- ▶ Control quality periodically
- ▶ Control and record seed movements

RECORDS OF QUALITY MAINTENANCE

- ▶ records of training,
- ▶ calibration,
- ▶ corrective actions,
- ▶ evaluation of contracts,
- ▶ and internal audits).
- ▶ Management reviews

Cont

The records should be:

- ▶ Filed for the time period established in the procedures
- ▶ Corrected in a controlled way
- ▶ Easily accessible

INTERNAL AUDITS

- The internal audit program that covers all the stages of the production process
- The audits should be programmed to function at critical moments of each activity
- carried out by persons independent to those tasks.
- The results of these audits must be recorded
- the corrective actions should be implemented.

TRAINING

The entity/company should have:

- ▶ A training program, which covers technical aspects and regulations of seed certification systems.
- ▶ Records of training.
- ▶ A system that allows training needs to be evident.

CUSTOMER COMPLAINTS

The entity/company should:

- keep records of complaints related to: seed quality,
- suggestions provided to the customers,
- and corrective actions/responses.

Continuous improvement program

END

THANK YOU