



# **AEGIS:**

## Establishing a Quality Management System

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# Content of presentation



1. Decision mid-term meeting Steering Committee and subsequent actions
2. Background info and why we need a QMS
3. Principles of QMS
4. Elements of QMS
5. QMS components
6. Working Group responsibilities related to QMS
7. Development of operational and technical standards
8. Proposed actions

# Decision of SC to establish QMS

During its **mid-term meeting in Riga** the **SC** decided:

- “Development of **draft quality management systems** for the four model crops is vital.”

The **AEGIS Secretariat** took the following action:

- Prepare discussion paper (**i.e. this presentation**)
- Prepare framework docs as guides for development of crop (genepool) specific technical standards

## Statement on QMS in Strategic Framework paper:



“Accessions registered to the European Collection will be expected to be maintained at the **same quality level across institutes and countries** in order to allow trust and confidence in one another to prevail.

Thus advantages can be drawn from the diversity of expertise and crops that exist within the Region. Under the supervision of the AEGIS Advisory Committee **generic genebank management standards** will be developed as well as **an effective monitoring system**.

The respective Crop Working Groups will coordinate the processes of developing **crop or crop genepool specific technical standards** for the routine conservation operations.”

# Arguments why a QMS is needed - the QMS discussion paper



“ ..... the success of the implementation of AEGIS will depend on **the trust** that the partners can develop in each other.

This trust is dependent on collections **adhering to genebank management standards**.

It is also a **prerequisite for the process to agree on the sharing of responsibilities** between countries and associated institutions within and between countries.

Such **sharing of responsibilities is a key element of the establishment of a virtual but integrated European genebank system**, covering all areas and disciplines that relate to the effective conservation of genetic resources, .....”

# Arguments why a QMS is needed

## - the QMS discussion paper



- A related topic is one on the **sustainability** or continuity of collaborating genebanks
- It is required to establish a **clear understanding** among the model crop curators as well as at the ECPGR level on **what we actually understand a “quality management system” to be and to consist of.**

**Definition:** “A genebank QMS can be defined as a set of policies, processes and procedures required for planning and executing of the core business, i.e. the management of AEGIS, the virtual European genebank system”.

# Proposed principles of QMS (1)



1. **Quality assurance** is based on principle that you:
  - a. **Plan** - say what you do
  - b. **Do** - do what you say
  - c. **Check**- let an independent body check that you do what you say
  - d. **Act** - correct and improve what you say you do.
2. The QMS is based on the principle of **consensus**
3. With respect to the technical standards, agreement should be reached on what are **the "lowest" acceptable standards**, (i.e. standards that ensure long-term and secure conservation and availability of the germplasm)
4. **Capacity building efforts**, will be required to ensure the establishment of widely acceptable standards in all the genebanks hosting European Accessions.

# Proposed principles of QMS (2)



5. The QMS system should be as **little bureaucratic** as possible
6. The **performance monitoring** should be conducted by an ECPGR or independent body ??
7. With respect to the two previous principles the following **questions** need to be answered:
  - a. Should we aim at a monitoring system that is as: **decentralized** as possible, preferably based on **good record keeping**, **self-performance-assessment approach** and **“light reporting”** to the overseeing body??



# Proposed principles of QMS (3)



- b. What is the **role and responsibility** in the monitoring process of:
  - a. AEGIS **Associated Institutions**,
  - b. the **National Coordinator**, and
  - c. the ECPGR **Working Group** concerned
- c. To facilitate the development of an AEGIS QMS, would it help to consider to create a possibility for a genebank to have **only parts of its operation being “approved”** whereas other parts are kept “outside” the formal QMS “system”, at least for the time being?
- d. Other?

# Elements of QMS (1)



1. A **general description** of the various components and elements; how they **fit together**, who will be **responsible** for what and how the QMS will be **managed and governed**.
2. Well defined **genebank management procedures and practices**, to be **recorded by each genebank**, e.g. in its genebank manual.
3. **Technical standards** for the routine genebank operations (see below) **for each of the crops** (or groups of similar crops).

It should be mentioned that for some of the **genebank non-specific practices**, such as **safety duplication** and **distribution practices**, AEGIS has developed or will develop **specific strategies** that will define the technical standards for all genebanks and crops.

## Elements of QMS (2)



4. An effective **system of “record keeping”** of to-be-verified and verifiable facts of the performed activities and **“performance reporting”** to ECPGR/AEGIS.
5. An independent **monitoring system**, including **indicators for quality assessment** and a **special body** to monitor the performance.
6. **Capacity building** is an important activity of a “system” that consists of many genebanks, operating under very different conditions etc. **In cases a genebank is interested to participate in AEGIS but not (yet) able to meet (all) the standards assistance will be provided to reach such standards.**

# Target areas for technical standards:



## Routine genebank management procedures and practices:

1. Collecting methodology
2. Regeneration methodology
3. Preparation for storage (e.g. drying regime)
4. Storage conditions (for various collection types)
5. Seed quality and viability monitoring
6. Germplasm distribution practices (an AEGIS strategy?)
7. Safety duplication (draft AEGIS strategy exists)
8. Information management (also an AEGIS strategy?)

# QMS System components (1)



1. The **system** itself, that establishes, manages, administers, encourages and monitors the implementation of the agreed policies, processes and procedures.
  - a. This system will cover the description of genebank practices, record keeping and reporting, monitoring and capacity building activities.
  - b. Bioversity International could develop a framework, in close consultation with selected Associated Institutions and the Working Groups.
  - c. AEGIS Advisory Committee plays an active oversight role and agreed draft will be submitted to ECPGR SC for endorsement.

## QMS System components (2)



2. The **technical operations** of conserving and facilitating the use of the selected accessions, including
  - a. establishment of agreed **technical standards**
  - b. Draft **proposals** should be developed by each Crop WG (or at the Crop Network level) for endorsement by SC
3. A **mechanism** that ensures **comparable quality of the technical standards** across WGs, e.g. an **independent scientific committee** that is appointed by the SC and that (possibly among other things) **approves and/or checks standards??**

# Some suggestions on process to develop operational/ technical standards:



1. **Inventory** of technical standards on routine operations in genebanks. **Inputs for this inventory** include:
  - a. **protocols** of ISO certified genebanks
  - b. **findings of Crop WG** who made inventories of procedures (such as the Brassica WG and possibly others)
  - c. **internal protocols** of genebanks (several CGIAR genebanks use protocols)
  - d. crop specific **regeneration guidelines** published and/or being developed with Global Crop Diversity Trust support
  - e. 'old standards' including regeneration guidelines (IPGRI, 1997) and FAO-IPGRI Genebank Standards (FAO/IPGRI, 1994)

# Some suggestions on process to develop operational/ technical standards:



2. To **assist** in making inventory Secretariat sent **framework tables** to collect “best practices” for a) **seed**, b) **tissue**, c) **field**, and d) **cryopreservation**
3. **Assess standards on their scientific merits** with respect to longevity and genetic integrity (especially regarding storage, viability testing and regeneration)
4. **Agree** on minimum set of technical standards for individual crops or group of crops
5. **Consider resource implications** for establishing and operating a QMS for individual crops/group of crops



# Proposed QMS related actions



1. **General observations** on establishing a **QMS** for model crop (incl. need for standing technical committee)
2. **Inputs into the design** of the **QMS system** (i.e. monitoring; reporting; role of WG; others?)
3. **Comments** on the proposed **principles, elements and components** of the QMS
4. **Recommendations** on “**generic**” **technical** (genebank management) **standards** (**possibly later**)
5. **Recommendations** on **crop specific technical standards**

A faint, stylized background illustration of a globe with a spiral and various icons. The globe is rendered in a light gray color and is centered on the page. A large, light gray spiral is overlaid on the globe, starting from the center and expanding outwards. Several icons are scattered across the globe, including a laptop, a smartphone, a tablet, and a person holding a device. The overall style is minimalist and modern.

■ Thank you

# Operational Costs for Collection Maintenance



**Objective:** Assessment of **operational costs** for collection management before and after AEGIS in order to be able to measure rationalization impact of AEGIS

**An expert** will assist Secretariat to:

1. Develop **methodological** framework (draft to be discussed at **meeting in Poland**)
2. Develop a **technical guide** for data collection and work with model crop curators to refine methodology
3. Secretariat to oversee **data collection** by curators
4. Provide a **framework for collation of datasets** by crop and genebank
5. Conduct data analysis and provide **summary report**