Quality Management System for AEGIS

DRAFT for discussion

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Introductory comments

In the Strategic Framework discussion paper the following statements are included regarding the establishment of a quality management system and the elaboration of quality standards across Europe:
"*After the rationalization process, and by following the **AEGIS agreements on quality standards for conservation**, which will increase transparency and mutual trust, it is expected that collections will be managed more effectively and efficiently" and*

*"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."*

The long-term, safe and appropriate conservation of genetically unique and important germplasm accessions and their continued availability for breeding and research are the main components of the goal of AEGIS. It is further foreseen that these tasks will be performed according to common and agreed quality standards. Indeed 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, including the facilitation of using these resources.

A related topic is one on the sustainability or continuity of collaborating genebanks. If one ask the question what one needs to know of a given genebank before entrusting important tasks to them there is, apart from the operational procedures that need to meet 'my standards', the issue of continuity; can one rely on it that five years from now the collaborating genebank will still follow these procedures or is there a possibility that new genebank management decides that AEGIS standards are not that important?

In view of the above and as agreed upon by the ECPGR Steering Committee during its mid-term meeting in Riga in September 2006 to "develop draft quality management systems for the four model crops" as a vital step in the establishment process of AEGIS it was felt important 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. Consequently, this discussion paper has been prepared with the intention of initiating a wide discussion within ECPGR and its various bodies that are actively participating in the shaping and establishment of AEGIS and subsequently in the management of the European genebank system.

Definition of a QMS

A genebank QMS can be defined as a set of policies, processes and procedures required for planning and execution of the core business, i.e. the management of AEGIS, the virtual European genebank system. QMS integrates the various internal processes within the organization and intends to provide a process approach for project execution. QMS enables the associated institutions, countries and ECPGR bodies to identify, measure, control and improve the various core business processes that will ultimately lead to improved AEGIS performance (adapted from Wikipedia, March 2008). Annex I provides an overview of quality management organizations and awards that provide more details on some of the aspects described below.

Principles of the QMS

In order to develop the QMS in an efficient manner a number of principles have been recognized that should underpin the system we want to put in place:

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 will ensure long-term and secure conservation and availability.
4. Capacity building efforts, possibly both from within the genebank or country as well as from outside, will be required to ensure the establishment of widely acceptable standards in all the genebanks hosting European Accessions.
5. The QMS system should be as little bureaucratic as possible.
6. The performance monitoring should be conducted by an ECPGR or a completely 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, a self-performance-assessment approach and a "light reporting" to the overseeing body?
    b. What is the role and responsibility of the AEGIS Associated Institution, the National Coordinator and the ECPGR Working Group concerned (see suggestion below) in the monitoring process?

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 the QMS

The following elements are being recognized as essential components of a genebank quality management system (QMS):

1. A **general description** of what the QMS consists of, how the various components and elements 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** (see target areas for technical standards below), to be recorded by **each genebank** in its genebank manual.
3. **Technical standards** for the routine genebank operations as per the list of target areas listed below **for each of the crops** (or groups of similar crops). It should be mentioned that for some of the non-genebank 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.
4. An effective system of "**record keeping"** of to-be-verified facts of the performed activities and "**performance reporting**" to the System.
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.

QMS System components

The QMS will have several rather different but complementary components.

- The first is the **system** that establishes, manages, administers, encourages and monitors the implementation of the agreed policies, processes and procedures. This system will cover points 1, 2, 4, 5 and 6 above and a framework could be developed by Bioversity International, in consultation with selected Associated Institutions and the Working Groups. It is foreseen that the AEGIS Advisory Committee plays an active oversight role during the development phase and that the agreed draft will be submitted to the ECPGR Steering Committee for its endorsement.
- The second component deals with the **technical operations** of conserving and facilitating the use of the selected accessions and includes the establishment of agreed **technical standards**, the **planning of the activities** as well as their **implementation**. This will cover point 3 above and draft proposals should be developed by each Crop WG (or at the Crop Network level).
- A third component deals with the mechanism that might be needed to ensure a across Working Groups use of comparable quality of the technical standards, i.e. an independent scientific committee that is appointed by the Steering Committee and that (possibly among other things) checks or approves the standards.

Working Group responsibilities

The operations are being planned and overseen by the respective Working Group (or the Lead institute). The proposed responsibilities of each Working Group with respect to the QMS include:

1. Draft and agree on crop specific technical standards and assess applicability of generic management standards
2. Prepare/coordinate implementation of (annual?) conservation action plan
3. Oversee and encourage improvement of data quality and coverage of AEGIS accessions
4. Survey institutes (i.e. capacities and availability)
5. Implement crop conservation work plans, e.g.:
    a. manage central crop database
    b. coordinate collecting activities
    c. coordinate characterization/ evaluation
6. Crop WGs can decide to delegate the responsibilities listed under point 5 above to an European Coordinating Lead Institution (for each crop genepool). Such a Coordinating Lead Institution operates under the supervision of the respective Crop WG.

Some suggestions on process to follow to establish 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)
2. Assess standards on their scientific merits with respect to longevity and genetic integrity (especially regarding storage, viability testing and regeneration)
3. Agree on minimum set of standards for the individual crops or group of crops.

Target areas for technical standards:

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
7. Safety duplication
8. Information management

Whereas most of the above mentioned target areas are crop specific (i.e. certainly areas 1-5); the remainder three (i.e. 6-8) seem to be more generic which would justify to develop AEGIS strategies for each of them.

Need to secure financial resources in order to constantly improve the standards
There will be a need to carefully consider cost implications of each and every step in establishing and operating a QMS and these costs will have to become an integral part of operating AEGIS.

Annex I
Quality management organizations and awards (as identified through google on the internet):

The International Organization for Standardization's ISO 9000:2000 series describes standards for a QMS addressing the principles and processes surrounding the design, development and delivery of a general product or service. Organisations can participate in a continuing certification process to ISO 9001:2000 in order to demonstrate their compliance with the standard, which includes a requirement for continual (i.e. planned) improvement of the QMS.

(ISO 9000:2000 provides guidance on Quality principles and on the common language used by quality professionals. ISO 9004:2000 provides guidance on improvement methods. It can be seen that neither of these standards can be used for certification purposes as they provide guidance, not requirements).

The Malcolm Baldrige National Quality Award is a competition to identify and recognize top-quality U.S. companies. This model addresses a broadly based range of quality criteria, including commercial success and corporate leadership. Once an organization has won the award it has to wait several years before being eligible to apply again.

The European Foundation for Quality Management's EFQM Excellence Model supports an award scheme similar to the Malcolm Baldrige Award for European companies.

In Canada, the National Quality Institute presents the 'Canada Awards for Excellence' on an annual basis to organisations that have displayed outstanding performance in the areas of Quality and Workplace Wellness, and have met the Institute's criteria with documented overall achievements and results.

The Alliance for Performance Excellence is a network of state, local, and international organizations that use the Malcolm Baldrige National Quality Award criteria and model at the grassroots level to improve the performance of local organizations and economies. NetworkforExcellence.org is the Alliance web site; browsers can find Alliance members in their state and get the latest news and events from the Baldrige community.