Quality System for AEGIS

Approved by the ECPGR Steering Committee

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Preface

An earlier version of this discussion paper was tabled and discussed at the 11th meeting of the ECPGR Steering Committee in Sarajevo, Bosnia and Herzegovina. The Steering Committee made the following decisions that relate to the establishment of a Quality System for AEGIS. The decision letters (a-e) below correspond to the decision numbers 5-9 under the AEGIS section of the final report and they provided the basis for the revision of this discussion paper.

- The development of a quality system for the management of the dispersed European Accessions received due attention of the SC and was considered necessary for the proper implementation of AEGIS. The SC further noted that AEGIS should aim at "minimum agreed standards" to be achieved and asked the authors of the discussion paper "Quality Management System for AEGIS" to revise the document with this aspect in mind, as well as the notion that the emphasis of the quality management should be on guiding and advising the partners rather than monitoring their performances. Therefore, capacity building should be a central activity while developing the quality management system.
- 2. The SC suggested that the Secretariat, in collaboration with the WGs, should develop a template to be used by the Associate Members when they describe their current collection management practices in the form of an operational genebank manual.
- 3. The SC further advised the authors of the aforementioned discussion paper to revisit the time frame that was proposed so as to allow for the active participation of the partners in the development of the various quality system elements, including: 1) the minimum technical standards, 2) a system of record-keeping of the way management activities are actually performed, and 3) an effective guiding and advisory approach at the AEGIS level.
- 4. In relation to the quality system and the suggestion to establish a Standing Technical Committee, it was agreed to revisit the role of the AEGIS Advisory Committee in this respect and the SC suggested incorporating the conclusions in the new version of the discussion paper on the AEGIS quality system. The SC requested this document to be redrafted before the end of 2008 and circulated for approval by the SC according to the established procedure (listserver).
- 5. Concerns were expressed that in the absence of a quality management system the AEGIS establishment process could get delayed and, consequently, the SC decided that the process for the individual countries to conclude the MoU should not wait for the final decisions on the quality management system.

Introductory comments

In the Strategic Framework Policy Guide 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 ECPGR 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 minimum 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, i.e. AEGIS, 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 and continuity of the conservation operations at the collaborating genebanks. If one asks the question what one needs to know of a given genebank before entrusting important tasks to it, apart from the operational procedures that need to meet 'my standards', it will be the issue of continuity. Detailed measures will have to be developed and adopted by the Steering Committee in case continuity of operation by the collaborating institutions should be put at risk.

In view of the above this revised discussion paper has been prepared with the intention of continuing a wide and "participatory" discussion within ECPGR and its various bodies that are actively participating in the shaping and establishment of AEGIS and, where relevant, also at the national level among the collaborating institutes in AEGIS, in order to provide a scientifically strong, technically solid, clear and transparent basis for the effective and efficient management of the European Collection.

Definition of a Quality Management System

The AEGIS Quality Management System is the set of policies, processes and procedures that are to be followed by all members of AEGIS to assure an appropriate quality of the activities in AEGIS, the virtual European genebank system.

During the discussion in the model crop groups, it was pointed out that it was misleading to use the expression "Quality Management System", since people would associate this to the, to some perceived as, daunting and bureaucratic process of ISO 9000 certification. Since this type of certification would not be the target of AEGIS, it was preferred to simply talk about the "AEGIS Quality System" and the acronym "AQUAS" was created.

Principles of the AEGIS Quality System (AQUAS)

In order to develop the AQUAS 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. AQUAS is based on the principle of consensus.
- 3. With respect to the technical standards, agreement has to be reached through a well-defined process on what the "lowest" acceptable standards are, i.e. standards that will ensure long-term and secure conservation, genetic integrity, identity and availability of the accessions. Such standards have been coined by the Steering Committee as the "**agreed minimum standards**". In order to ensure adequate "buy in" from all the partners it will be critically important to involve all of them in the development process of these minimum standards.
- 4. Capacity building is a central activity in building and operating the virtual European genebank system at an appropriate level of quality management and thus establishing and operating AQUAS. Capacity building efforts, in particular with regard to training, 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. They need to be continuing efforts in which all members of the Network have to participate and should be based on the principle "learning by doing" as far as training is concerned. With respect to infrastructural capacity the onus will be in the first place on the respective country. Collaborating European partners are expected to assist with their advice on upgrading to the extent possible. The Steering Committee sees capacity building as a "central requirement" in the establishment and operation of AQUAS, especially as the SC sees "guiding and advising" the partners in such a system as the principal approach rather then policing and monitoring. The involvement of collaborators from the broader PGR community in capacity building measures is essential in order to ensure a wider participation in AEGIS related activities. Consequently, targeted efforts should be made to allow this involvement to happen.
- 5. The AQUAS should be **as little bureaucratic as possible**, pragmatic rather than doctrinaire, and it should be recognized that different participating collections can achieve agreed minimum standards in different ways. Furthermore, the general principles are more important than over-prescriptive protocols.
- 6. A **monitoring system** should allow the participants to be encouraged to improve the performance, and thus to strengthen the capacity, rather then to feel being policed. Therefore, an "effective guiding and advisory approach at the AEGIS level" will need to be developed to facilitate compliance of the partners with the collectively agreed management and minimum standards. Whereas some kind of monitoring the performance of partners will be essential in order to operate the AQUAS effectively, it is proposed that the emphasis should be on reporting and that the "minimum" monitoring activities will be integrated in this approach. To this effect, a system of "record keeping" of the performance monitoring itself should be conducted by an ECPGR or a completely independent body.

AQUAS system components

AQUAS will consist of four complementary components, i.e. the a) operational framework, b) technical elements, c) capacity building, and d) oversight mechanism.

1. Operational framework

The operational framework is schematically presented in Table 1, where responsibilities of the various ECPGR bodies are defined against the elements of the AQUAS. The framework outlined in Table 1 proposes how to establish, manage, administer, encourage and monitor the implementation of the agreed policies, processes and procedures. The "implementation steps of AQUAS" (see below) describe how this operational framework should enter into effect according to a suggested time frame.

Table 1. Responsibilities of the ECPGR bodies involved in the implementation of
AQUAS

	Secretariat	Working Groups*	AEGIS Advisory Committee	ECPGR Steering Committee (SC)	Associate member
Comoria	Droft	Commont on	(AC)	A pproves the	A dont the
operational standards	standards	draft	draft	generic standards	standards
Operational genebank manual	Provide template, in collaboration with genebanks	Comment on the template, provided by the Secretariat	Approves the template	-	Fill in and publish the manual
Agreed minimum standards (by crops or crop groups)	Comment on standards; Publish on- line and archive	 Draft and agree on the list of standards Keep under ongoing revision 	Comment the standards, especially from a "between crops" perspective	Approves the standards	Adopt the standards
System of record keeping	Give advice on the system	Give advice on the system	Give advice on the minimum requirements of the record keeping system	-	Implement the system
Reporting	Receives reports, archives and distributes, as appropriate	Organize reporting system; send reports to Secretariat for SC approval	Give advice on the system; Comment on reports and inform SC as appropriate	Approve reports	Adopt reporting system and provide reports to WG
Monitoring	1) Receives reports, archives and distributes as appropriate 2) Facilitates implementati on of recommendat ions	Organize and implement the monitoring system; report to AC through Secretariat	Give advice on issues, makes proposal for capacity building and send recommendatio ns to SC	Takes decisions on issues and considers capacity building recommendations	Adopt monitoring system

* In the case that for a given crop no ECPGR WG exists (like for maize, rice or rye) the Network Coordinating Group (NCG) concerned should assume the responsibilities as listed for the WG, identify and prioritize such crops that would require minimum standards and advise on the best way forward to draft these standards. The Secretariat should play a supporting and coordinating role in this process.

2. Technical elements

The second component deals with the technical operations of conserving and facilitating the use of the selected accessions. The elements to be developed, according to the operational framework, are the "generic operational standards", the "operational genebank manual" and the "agreed minimum standards (by crop or crop group)". On the basis of these elements, the Working Groups will be expected to plan and implement the activities that are assigned to them.

3. Capacity building

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. In cases a genebank is accepted by its country National Coordinator as an Associate Member of AEGIS, but it is not (yet) able to meet (all) the standards, assistance will need to be arranged, in close consultation with the National Coordinator, to reach such standards. Support in this direction is expected to primarily be provided by the national programme or, according to the advice of the AEGIS Advisory Committee, through donor support or project financing. Where relevant and possible topical training sessions, either generic ones such as seed storage or documentation, or crop-group specific training activities, e.g. on regeneration protocols and collecting strategies) could be planned at the Network or even Programme level. Additionally, training activities will be done "on the job", through arrangements between the partners in a Network, including those that are outside the "formal sector".

4. Oversight mechanism

The first level of monitoring the implementation of the AQUAS is delegated to the Working Groups through internally established mechanisms. A second level oversight mechanism will ensure the use of comparable quality of the technical standards, as well as comparable effectiveness of monitoring mechanisms across Working Groups. The AEGIS Advisory Committee will assume this role by providing independent scientific oversight to the entire establishment process of the AQUAS. The AEGIS Advisory Committee will therefore advise on the establishment of the standards and on the systems of record keeping, monitoring and reporting and in general it will oversee the implementation of the AQUAS.

Implementation steps of AQUAS

The proposed specific elements that make up the AQUAS system and the corresponding action points are:

- The Secretariat, in consultation with Working Groups and the AEGIS Advisory Committee, will draft generic operational standards, to be approved by the Steering Committee at its 12th meeting in 2011.Target areas for generic genebank management standards are the following:
 - a) Germplasm distribution practices
 - b) Safety duplication
 - c) Information management

- 2) Based on a template of an operational genebank manual, provided by the Secretariat in collaboration with the genebanks, commented by the NCGs and approved by the AEGIS Advisory Committee, each associate member of AEGIS will prepare a manual that contains descriptions of the routine genebank management procedures and practices and will make it available on-line (within one year from signing the Associate Membership Agreement).
- 3) Technical minimum standards for the crop-specific operations will be developed, discussed and agreed upon by the Working Groups, in order to compile a list of agreed minimum standards. The agreement should be reached within two years from the establishment of an AEGIS list of accessions for the respective crop; the Working Group agreement will need to be endorsed by the Steering Committee. Target areas for crop specific technical standards are the following:
 - a) Collecting methodology
 - b) Regeneration methodology
 - c) Preparation for storage (e.g. drying regime)
 - d) Storage conditions (for various collection types) and field genebank operations
 - e) Seed quality and viability monitoring
- 4) Some suggestions on the process to follow to establish operational/technical minimum standards:

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 and others 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)

It is suggested to assess minimum standards on their scientific merits with respect to longevity and genetic integrity (especially regarding storage, viability testing and regeneration) and then to agree on a set of minimum standards for the individual crops or group of crops.

- 5) An effective **system of record keeping** of verifiable facts of collection management Activities will be put in place by each associate member of AEGIS (within one year from the decision on "agreed minimum standards"), based on recommendations regarding minimum record keeping requirements from the AEGIS Advisory Committee, the WGs and the Secretariat.
- 6) Working Groups will assume the responsibility for **monitoring the application** of these standards (based on self-auditing and reporting as well as external audits, when necessary), for providing feedback to the National Coordinators with concrete suggestions for improvements, capacity building suggestions etc., and for **reporting** to the Steering Committee through the Secretariat. It is left to the Working Groups whether or not to consider a special focal point or a sub-committee for these duties. Working Groups will report to the AEGIS Advisory

Committee, through the Secretariat, about the implementation of the monitoring system. Reporting and monitoring systems should be agreed at the Working Group (or Network) level within four years from the establishment of an AEGIS list of accessions for the respective crop.

- 7) Working Groups will take the following additional responsibilities:
 - a) Prepare/coordinate the implementation of Crop Conservation Work Plans.
 - b) Oversee and encourage the improvement of data quality and coverage of AEGIS accessions
 - c) Survey institutes and other existing organizations (i.e. ability to provide capacities)
 - d) Implement crop conservation work plans, e.g.:
 - i) manage central crop database
 - ii) coordinate collecting activities
 - iii) coordinate characterization/ evaluation
 - e) Crop WGs can propose to the Steering Committee to delegate the responsibilities listed under this point 7 to a European Coordinating Lead Institution (for each crop genepool). Such a Coordinating Lead Institution operates under the supervision of the respective Crop WG.

NB. It has been suggested that the Steering Committee (at its 12th meeting in 2011) revisit the TORs and composition of the WGs in the context of these increased responsibilities.

- 8) The AEGIS Advisory Committee has the role of providing **technical oversight** over the implementation of AQUAS, to guide and advise the WGs regarding the actual implementation of AQUAS. The Advisory Committee, based on information received from the WGs and the Secretariat, will make recommendations regarding the status of implementation of AQUAS, including provision of feedback on proposed standards and oversight of the monitoring process to the Steering Committee.
- 9) The Secretariat will ensure that all the ECPGR bodies are prompted to follow up with agreed responsibilities in due time and it will keep track of all the adopted standards and reporting and monitoring systems. A publicly available Web repository will be set up of all the official documents.